



सीमाशुल्क आयुक्त का कार्यालय, एनएस-II
OFFICE OF THE COMMISSIONER OF CUSTOMS, NS-II
केंद्रीकृत निर्यात आकलन कक्ष, जवाहरलाल नेहरू सीमाशुल्क भवन
CENTRALIZED EXPORT ASSESSMENT CELL, JAWAHARLAL NEHRU
CUSTOM HOUSE,
न्हावा शेवा, तालुका -उरण, जिला -रायगढ़, महाराष्ट्र- 400 707
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Show cause notice issued under section 124 of Customs Act 1962

Brief Facts of the Case

An intelligence was gathered by NSPU that M/s Coral Laboratories Ltd. (IEC-0394033353) was trying to export MOXBRO FORTE SYRUP without having manufacturing drug licence and without having mandatory NOC for manufacturing of the said goods from Central Drugs Standard Control Organisation (CDSCO) vide Shipping Bill No. 3766710 dated 22.07.2025.

1.1 It was found that M/s. Coral Laboratories Ltd. (IEC- 0394033353), a manufacturer Exporter (hereinafter also referred to as the Exporter), having registered address at Plot No. 27/28, Pharma City, Selaqui, Dehradun, Uttarakhand- 248001 have filed Shipping Bill No. 3766710 dated 22.07.2025 through their authorised Customs Broker M/s. Star India Container Line Pvt. Ltd for the export of Medicaments i.e. "Moxbro Forte Syrup" having Manufacturing date 03/2025 and expiry date 08/2027, under ITC(HS) 30041030 and the shipment was destined to M/s Asal Pharma Co. (APHCO), Bakaro Medicine Market, Mogadishu, Somalia. The declared FOB value of the consignment was Rs. 25,53,000/- under Scheme Code- 19 (Drawback) with RoDTEP (Remission of Duties, Taxes on Exported Products). A summary of the shipping bill is as below-

S/bill no. and date	Goods description & HS Code	FOB Value (INR)	Quantity	Batch No.	Drawback Claimed (Rs.)	RoDTEP Claimed (Rs.)	IGST Paid/LUT
3766710 22.07.2025	Moxbro Forte Syrup (30041030)	25,53,000	50,000 Units	UFM2501 to UFM2510	30,636	17,871	LUT

The said consignment was put on hold vide mail dated 24.07.2025 and letter bearing Hold No. 09/2025-26 dated 24.07.2025.

2. The consignment was examined vide Panchanama dated 25.07.2025 in presence of Shri. Mayank Chetan Katira Authorised Representative of M/s. Coral Laboratories Ltd. (IEC- 0394033353) and Shri. Sanjay Yashwant Jadav representative of the Customs Broker. The consignment was found packed in cartons of same size. The said cartons

were having marks of product name, batch No., manufacturing date, expiry date, gross weight, net weight and quantity. Each carton was containing 120 boxes having glass bottles of product with labelling "Amoxicillin and Bromhexine Hydrochloride Dry Suspension Moxbro Forte Syrup for oral suspension 250". Each bottle had mark of 100 ml content. Manufacturing date and expiry date were found as declared in shipping bill as 03/2025 and 08/2027 respectively. The term "NOT FOR MEDICINAL USE" was not found marked on bottles as well as on packing boxes. Representative samples of each batch were also drawn under Panchanama. It was observed that the goods attempted to export contained a drug composition of Amoxicillin and Bromhexine Hydrochloride as per the marking on the label. The Certificates of Analysis submitted by the exporter also confirmed its composition that it contains Amoxicillin and Bromhexine Hydrochloride.

3. One representative sample was forwarded to the Chief Chemical Examiner, DYCC lab, JNCH vide letter dated 29.07.2025 to find about the nature and composition of the subject sample and whether sample is same as declared and if the sample does not match the description of the goods then what is the nature of the goods and its composition. The DyCC JNCH vide Test Memo dated 11.08.2025 has confirmed the positive tests for Amoxicillin and Bromhexine hydrochloride. However, the presence of psychotropic or narcotic substance was not clarified by DyCC, JNCH. Therefore, DyCC, JNCH vide letter dated 11.08.2025 was again requested to confirm whether any psychotropic or narcotic substance in the sample is available. To which, DyCC, JNCH has replied vide letter dated 12.08.2025 that New Customs House Laboratory is the one to test and give report for Psychotropic or narcotic substance. Therefore, representative sample was forwarded to DyCC New Custom House vide letter dated 13.08.2025. DYCC lab NCH, Mumbai vide report dated 25.08.2025 stated that the sample **does not answer positive test** for Heroin, Morphine, Ganja, Charas, THC, MDMA, Amphetamine and Diazepam.

4. Later, the exporter vide email dated 29.07.2025 submitted the NOC dated 23.04.2025 for Manufacture of Unapproved/Banned/New Drugs for export purpose issued by CDSCO-North Zone. However, Exporter was supposed to get the Manufacturing License from State Licensing Authority for Manufacture of Unapproved/Banned/New Drugs for export purpose, after issuance of CDSCO NOC and before manufacturing of the goods as per the central government letter dated 30.04.2024 issued vide file no. IMP-12/1/2024. As the NOC was issued on 23.04.2025 and the goods manufactured in the month of March, 2025. To ascertain if the said NOC is valid for this consignment, a letter dated 29.07.2025 was forwarded to CDSCO-North Zone to clarify the same. In reply vide email dated 05.08.2025, CDSCO has informed that the NOC has been issued from their office for export purpose. However, manufacturing licence/ product permissions are being issued by concerned state Licensing Authority. Hence, for further clarification in the matter, letter dated 22.08.2025 regarding manufacture license/product permission for manufacture of unapproved/approved new drug (bulk) for R&D/ Formulation Development/ Manufacture of exhibit batches for export purpose was forwarded through mailed to

Drug Controller and State Licensing Authority, Uttarakhand. But reply is not received till date.

5. Statement of Shri Mayank Katira, Export Executive in Logistics department from M/s Coral Industries Pvt. Ltd. (IEC-0394033353) was recorded on 05.08.2025 under section 108 of Customs Act, 1962 wherein he interalia stated that:

- I. M/s Coral Laboratories (IEC-0394033353) is in the business of exports of Pharmaceutical formulations (Tablets, Capsules, Injection, Syrup). They have exported to around 44 countries. Currently, they supply 25 countries, mainly African countries and Common Wealth countries. They mainly purchase raw materials from Domestic Market itself. They supply for Government Tenders in India (Pharmaceuticals & Medical Devices Bureau of India(PMBI), Bihar Medical Supplies, Haryana Medical Supplies) and Shri Mayank Katira was employed as an Executive for Export and supply chain Management from 2021. He takes all the decisions regarding Customs export clearance and logistics. He handled the export and logistics for the consignment under shipping bill no. 3766710 dated 22.07.2025 which is a consignment of MOXBRO Forte Syrup containing Amoxicillin and Bromhexine Hydrochloride.
- II. On being asked about powers conferred under section 26A of the Drugs and Cosmetics Act, 1940 and prohibition on the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Amoxicillin + Brohexine with immediate effect in India, vide Notification No. S.O. 777(E) published in the Gazette of India, Extraordinary, Part-II, Section 3(ii), dated 10.03.2016, he interalia stated that he was aware that the combination of Amoxicillin + Brohexine is prohibited for manufacture for sale, sale and distribution for human use of drug fixed dose in India.
- III. On being asked about the procedure for export of such combination of Amoxicillin + Brohexine. He interalia stated that their License No. 42/UA/SC/P-2006 was renewed for another five years from 7th June 2021 to 6th June 2026 for the factory at Dehradun for the product list having items for export purpose only. The list at serial no. 27 has item MOXBRO Forte Syrup containing Amoxicillin & Brohexine Hydrochloride, got approval from 13.06.2016 for export only. They were then supposed to get the CDSCO NOC for each lot i.e. quantity specific as this product was notified as prohibited for manufacture for sale, sale and distribution for human use in India, by the notification date 02.06.2023 referring the gazette notification of 2016. So, they were supposed to get the product permission again from state licensing authority i.e. state drug controller, then they were supposed to manufacture the product. After that they were supposed to export the product. They were also supposed to submit the Certificate of Good Manufacturing Practices which they already have valid till 27.07.2025 and further also renewed till 26.02.2026.
- IV. On being asked about the consignments of item containing Amoxicillin + Brohexine being exported by you during the period 2023-2024 & 2025 till date. He interalia stated that they have only exported MOXBRO Forte Syrup dry

containing Amoxicillin + Brohexine. No other product of same composition has been exported by them. From 20.07.2023, they have exported 06 consignments of the same product i.e. MOXBRO Forte Syrup dry suspension and also to the same buyer. The details of export of 06 consignments are as follows.

Sr. No.	Shipping Bill No.	Date	Quantity
01	2588618	20.07.2023	50000
02	4254270	28.09.2023	40000
03	5706761	30.11.2023	40000
04	8911107	05.04.2024	50000
05	1341448	31.05.2024	50000
06	5045353	23.10.2024	50000

- V. On being asked about submitting/ e-sanchit of all the requisite documents related to export of this particular item i.e. "MOXBRO Forte Syrup dry suspension" in the System while filing Shipping Bill for all the previous shipping bills of this particular item. He interalia stated that they have submitted GMP certificate, Product permission issued by state drug controller in 2021, Certificate of analysis, Customs Invoice, packing list, No hazardous certificate.
- VI. On being asked if they specifically have the NOC for export for those previous consignments exported vide shipping bill mentioned above, NOC conditions or requirements were compiled in those previous consignment. He interalia stated that they did not have CDSCO NOC & fresh product permission from State licensing authority for those particular consignments as mentioned above. Hence, these were not uploaded in E-sanchit.
- VII. On being asked about the consignment of item MOXBRO Forte Syrup dry suspension containing Amoxicillin + Brohexine previously exported by you in previous shipments were valid export. He interalia stated that they were not aware about the guidelines and hence they had not taken the CDSCO NOC & fresh product permission from State licensing authority. Hence he accepted that these were not valid export.
- VIII. On being asked about the requirement and conditions imposed by CDSCO NOC for export of item MOXBRO Forte Syrup. He interalia stated that they manufactured the goods at the Dehradun factory itself. The said product is manufactured only for export purpose. One condition of the CDSCO NOC says to bear on its label "not for medicinal use" invariably. However, the said goods are for human consumption only, so the condition should not be valid for our product. However, they would have a discussion with CDSCO regarding the same. So they have not affixed any such label on their stock.
- IX. On being asked about Labelling requirement on packaging for pharmaceutical items and if they have compiled them. He interalia stated that it is mandatory to have manufacturing license, expiry date, Batch detail, manufacturing date, company name, manufacturer & buyer name, composition, bar code detail. Some other details like dosage direction, indications, directions for reconstitution are

supposed to be printed on the literature leaflet kept in every Mono-cartons. As per his knowledge the same has been complied with their product.

- X. On being asked about the filed SB No. 9644578 dated 03.04.2025 at JNCH and the status of the export of said consignment. He interalia stated that the particular consignment was not exported. As they came to know first time about the whole procedure for export of this particular product, at the time of clearing the said shipping bill No. 9644578 dated 03.04.2025. So they did not have any NOC from CDSCO while filing the said shipping bill. This was informed by the Docks Customs Officer at CFS, GDL Logistics about the whole procedure. Then they applied the CDSCO NOC which was issued on 23.04.2025. However, because the NOC was issued on later date, Order in Original No. 309(L)/2025-26/ADC/CEAC/NS-II/CAC/JNCH dated 16.06.2025 was issued to us for back to town of the goods with fine and penalty of Rs. 1,00,000 each. This fine and penalty amount has already been paid by them on 21.06.2025. The said consignment was lying at GDL CFS till June, 2025. After O-I-O they shifted the goods from GDL, CFS to their godown at Swiddhinath Complex, Dapode, Bhiwandi-421302. The said goods were brought to Conex, CFS on 22.07.2025 for export purpose to the same supplier at Somalia.
- XI. On being asked if they have provided all the requisite documents to Customs, then why did they agree for back to town and also comply with the Order conditions, why did they not appeal against Order. He interalia stated that they did not have CDSCO NOC at the time of filing the shipping bill and presenting the shipping bill for clearance before the Customs. However, CDSCO NOC was issued on 23.04.2025. They also did not have Manufacturing license/fresh product permission as the same could only be issued for future manufacturing. But the said lot was already manufactured. These were the reasons, they accepted the Back to Town (BTT). They did not want to lose on the shelf life of the product, and they were not aware of the process of the appeal, so they did not appeal against it.
- XII. On being asked about the changes made in terms of product or documents, to make it export-worthy now and again trying to export the said goods vide shipping bill no. 3766710 dated 22.07.2025. He interalia stated that there is no major change. However, now at the time of filing the shipping bill or presenting the shipping bill for clearance they had CDSCO NOC beforehand. They could not dispose these goods into India as per the Law, so they thought of exporting the same. However, he accepted that these goods were manufactured before issuance of CDSCO NOC but as they had already paid the fine and penalty therefore they tried to export and thought that Customs can support the trade.
- XIII. On being asked that the same lot of consignment was brought back to attempt to export the goods and if they presented CDSCO NOC in e-sanchit for SB No. 3766710 dated 22.07.2025, it appears that they have deliberately attempted to export the same consignment again without any updation of documents or product. He interalia stated that they have uploaded the CDSCO NOC dated 23.04.2025 while filing the shipping bill no. 3766710 dated 22.07.2025. Their

product was not psychotropic or narcotic substance and they had already paid the fine and penalty therefore they tried to export and thought that Customs can support the trade.

XIV. On being asked he interalia stated that their product 'MoxBro Fortis Syrup' is an antibiotic product used to treat respiratory tract infection and does not contain any psychotropic or narcotic substance. As per the current export trade situation, many African countries are facing the crisis of foreign exchange which has impacted export trade in Pharma Industry. They have already faced a shelf-life loss of 5 months with Rs. 1,00,000 fine and penalty each along with storage and shipping line cancellation charges and it has impacted a huge financial loss. They as an exporter requested Customs authorities to allow the export for this shipment and they ensure that they will complete all the guidelines issued for this product for their future exports.

6. As per the Gazette of India Notification S.O 777(E) dated 10.03.2016 , The Central Government has prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose of compound Amoxicillin and Bromhexine in India. As per CDSCO Letter no. 7-5/2018/Misc./034(NOC) dated 02.08.2018, the activity of issuance of NOCs for manufacture of unapproved/banned/new drugs solely for export purpose was delegated to the CDSCO Zonal offices vide File No. DCG (1)/Misc/2011 dated 01.06.2011 with effect from 20.06.2011. This process of grant of such NOCs by the CDSCO was discontinued from 20.08.2018 and after that such NOCs were granted by state licensing authority till 15.05.2024 after satisfying that the following conditions are complied with in the process of grant of permission for manufacture of unapproved/banned/new drugs:

- (i) The applicant shall provide copy of valid export order.
- (ii) The applicant shall provide copy of manufacturing license issued under Drugs & Cosmetics Act, 1940 and Rules, 1945.
- (iii) The applicant should mention whether the batch to be exported has undergone Quality control testing or shall be tested at the destined site.
- (iv) The applicant shall ensure that the drug(s) manufactured on the basis of the permission granted is exported and that no part of it is diverted for domestic sale in India through a declaration in the form of an affidavit on non-judicial paper.
- (v) The applicant shall maintain a stock register for quantities of API purchased for manufacturing drug formulations manufactured, consignments exported and remaining stocks of drugs and bulk drugs which will be open for a periodic inspection by the State Licensing Authority.
- (vi) The applicant shall make available for inspection of the appropriate authorities, on completion of the export orders, information regarding each consignment dispatched, remaining stock of drug and related raw materials and intermediates in hand.

(vii) The applicant shall ensure physical destruction of all un-exported quantity of drugs. This should be included as a condition of manufacturing license issued to the applicant by the State licensing authority.

(viii) In the event of cancellation of the export order, the manufacturer shall ensure the physical destruction of all unexported quantity of the drug and shall submit a declaration to State Licensing Authorities in the form of affidavit on non-judicial stamp paper.

(ix) The applicant shall ensure that the drug for which permission has been given shall cease to be manufactured or exported if the drug is prohibited in future in the country or in the importing country.

(x) In the case of drugs covered under the Narcotic Drugs and Psychotropic Substances Act, 1985 (NDPS), the applicant shall obtain NOC from the Narcotic Commissioner of India, Central Bureau of Narcotics, Gwalior. The batches to be exported shall undergo quality control testing under the control of CBN Gwalior or at destination site.

7. Vide letter dated 30.04.2024 issued vide file no. IMP-12/1/2024, Central Government through the Directorate General of Health Services, Drugs Standard Control Organization has stated that NOC's for Manufacture of Unapproved/Banned/New Drugs for export purpose from 15.05.2024 can be obtained from respective Zonal Offices of CDSCO before issuing Manufacturing License from State Licensing Authority for Manufacture of Unapproved/Banned/New Drugs for export purpose.

"... it has been decided with the approval of Hon'ble HFM vide Ministry F.no. X. 11035/210/2018-DR(Pt) dated 21st June, 2023 that industry must be facilitated to file fresh applications- for NOC manufacture of unapproved/ approved new drug/banned drugs solely for export, purpose from 15th May, 2024 on online mode CDSCO Zonal Offices. Accordingly, power delegated to State/UT licencing authority stands withdrawn w.e.f. 15th May, 2024 and such NOC's shall be granted by the head of respective CDSCO zonal office w.e.f. 15th May, 2024, Further, All State/UT drugs controllers are required to handover all NOC's issued from 20th August, 2018 to 14th May, 2024 to respective Zonal offices of CDSCO."

8. In view of the above, it appears that said exporter was supposed to get the NOC either from State Licencing Authority (from 20.08.2018 to 15.05.2024) or from CDSCO (after 15.05.2024) for export purpose before manufacturing of the said goods. In this instance, the Exporter M/s Coral Laboratories ltd had Licence No. 42/UA/SC/P-2006 issued by Drug Controlling & Licensing Authority, Uttarakhand to manufacture the drug Amoxicillin and Bromhexine Hydrochloride suspension (Moxbro Dry Syrup).

9. Exporter had also attempted to export the same live consignment previously from GDL Logistics, CFS. However due to absence of CDSCO NOC the consignment was not allowed to export. Order in Original No. 309(L)/2025-26/ADC/CEAC/NS-II/CAC/JNCH dated 16.06.2025 was issued to the exporter for back to town of the goods with redemption fine and penalty of Rs. 1,00,000 each.

10. In this matter, it is evident that the exporter M/s. Coral Laboratories Ltd. has neither obtained fresh NOC from concerned CDSCO Zonal Office nor manufacturing license/product permission from state licensing Authority before the manufacturing of said goods attempted to be exported vide Shipping Bill No. 3766710 dt 22.07.2025. The condition that marking as “not for medicinal use” was also not found mentioned on the bottle/packing. It appeared that the manufacturer exporter has not only manufactured an unapproved/banned/new drug without following procedures laid down in Central Government letter dated 30.04.2024 issued vide IMP-12/1/2024 and letter no. 7-5/2018/Misc./034(NOC) dated 02.08.2018, also the labels are not having basic instructions printed as mandated in the NOC granted by the CDSCO. The representative of the said exporter in his statement recorded under Section 108 of the Customs Act, 1962 has also admitted that he has not taken NOC from the CDSCO for the said consignment prior to manufacture of the same. It was also ascertained that the said exporter tried to export said goods vide Shipping Bill No. 9644578 dt 03.04.2025 and Customs detained said consignment and finally case was adjudicated vide Order-In-Original No. 309(L)/2025-26/ADC/CEAC/NS-II/CAC/JNCH dated 16.06.2025 denying for export, allowing the goods for back to town on payment of redemption fine and penalty of Rs. 1,00,000 each which has not been appealed by the said exporter. The said exporter accepted the said Order and also paid fine and penalty. The representative of the exporter has also admitted said facts in his statement. The said exporter, again attempted to export same goods from a different CFS. These facts clearly indicates that exporter was aware that there is no change in facts or consignment or relevant documents, still exporter re-attempted to export the same goods in same conditions, under which the consignment cannot be allowed to export. It is also re-iterated that the consignment containing amoxicillin and bromhexine was prohibited for manufacture for sale, sale and distribution in Indian domestic market. Hence, the consignment can neither be sold in India nor can be exported to abroad. Therefore, it appears that the said exporter has rendered the said goods liable to absolute confiscation under Section 113(d), (ia) & (ja) of the Customs Act, 1962. Hence, the above said goods namely Moxbro Forte Syrup covered under Shipping Bill 3766710 dated 22.07.2025 were Seized vide seizure memo dated 25.08.2025 under the Section 110(1) of the Customs Act, 1962.

11. It has been gathered that during last five years, the said exporter had previously exported item namely MOXBRO Forte Syrup dry suspension containing Amoxicillin + Bromhexine vide shipping bill as detailed in the table below:

Sr No	Shipping Bill No	Dated	Description	Manufacturing date/ Expiry date	FOB Value (Rs.)	Drawback (Rs.)	RoDTEP (Rs.)	IGST (Rs.)
1	8693333	16.02.2021	Moxbro Forte Syrup	10/2020& 09/2022	83636	1087	0	10036

2	32494 73	20.07.20 21	Moxb ro Forte Syrup	06/20 21 & 05/20 23	2351030	30563	0	282123
3	35243 51	31.07.20 21	Moxb ro Forte Syrup	06/20 21 & 05/ 2023 07/20 21 & 06/20 23	2513170	32671	0	301580
4	86056 80	01.03.20 22	Moxb ro Forte Syrup	02/20 22 & 01/20 24	1427520	18558	0	171302
5	11688 25	04.05.20 22	Moxb ro Forte Syrup	03/20 22 & 02/20 24	1448640	18832	0	173836
6	26004 23	04.07.20 22	Moxb ro Forte Syrup	03/20 22 & 02/20 24	1483200	19282	0	177984
7	26054 95	05.07.20 22	Moxb ro Forte Syrup	03/20 22 & 02/20 24	1483200	19282	0	177984
8	51683 52	01.11.20 22	Moxb ro Forte Syrup	09/20 22 & 02/20 25	2038560	26501	0	244627
9	54169 04	12.11.20 22	Moxb ro Forte Syrup	09/20 22 & 08/20 24	246300	3202	0	29556
10	54172 93	12.11.20 22	Moxb ro Forte Syrup	09/20 22 & 08/20 24	246300	3202	0	29556
11	65224 25	29.12.20 22	Moxb ro Forte Syrup	12/20 22 & 05/20 25	2028640	26372	16229	243436
12	25886 18	20.07.20 23	Moxb ro	06/20 23 &	1794100	23323	14353	215292

			Forte Syrup	11/2025				
13	4254270	28.09.2023	Moxbro Forte Syrup	09/2023 & 02/2026	2008120	26106	16065	240974.4
14	5706761	30.11.2023	Moxbro Forte Syrup	11/2023 & 04/2026	2012634	24152	16101	243492.48
15	8911107	05.04.2024	Moxbro Forte Syrup	03/2024 & 08/2026	2344601	28135	18757	280308
16	1341448	31.05.2024	Moxbro Forte Syrup	05/2024 & 10/2026	2560910.25	30731	20487	307458
17	5045353	23.10.2024	Moxbro Forte Syrup	09/2024 & 02/2027	2496000	29952	17472	305510.4
		Total			2,85,66,561	3,61,951	1,19,464	34,35,055

Scrutiny of documents submitted by exporter along with said shipping bill in E-Sanchit, it is found that they had not submitted copy of NOC from State licencing Authority for Shipping Bills 8693333 dated 16.02.2021, 3249473 dated 20.07.2021, 3524351 dated 31.07.2021, 8605680 dated 01.03.2022, 1168825 dated 04.05.2022, 2600423 dated 05.07.2022, 2605495 dated 05.07.2022, 5168352 dated 01.11.2022, 5416904 dated 12.11.2022, 5417293 dated 12.11.2022, 6522425 dated 29.12.2022, 2588618 dated 20.07.2023, 4254270 dated 28.09.2023, 5706761 dated 30.11.2023, 8911107 dated 05.04.2024 and NOC from CDSCO for Shipping Bills 1341448 dated 31.05.2024 & 5045353 dated 23.10.2024. It appears that the said exporter was not having mandatory NOC from CDSCO or State licencing Authority as well as permission from State Licencing authority to manufacture said goods for export purpose. Exporter neither obtained fresh NOC from concerned state licencing authority nor manufacturing license/product permission from state licencing Authority before the manufacturing of said goods for the past exports. Here, it appeared that the manufacturer exporter has not only manufactured an unapproved/banned/new drug without following procedures laid down in Central Government letter dated 30.04.2024 issued vide IMP-12/1/2024 and letter no. 7-5/2018/Misc./034(NOC) dated 02.08.2018. The representative of the said exporter in his statement recorded under Section 108 of the Customs Act, 1962 has also admitted that he has not taken NOC from the concerned authority even for

the best of his knowledge and belief and certify that the quality and specifications of the goods as stated in those documents, are in accordance with the terms of the export contract entered into with the buyer or consignee in pursuance of which the goods are being exported and shall subscribe a truthful declaration of such statement at the foot of such Shipping bill or any other documents.

C. Customs Act, 1962:-

- (i) Section 2(22):** *"goods" includes (a) vessels, aircrafts and vehicles; (b) stores; (c) baggage; (d) currency and negotiable instruments; and (e) any other kind of movable property;*
- (ii) Section 2(33):** *"prohibited goods" means any goods the import or export of which is subject to any prohibition under this Act or any other law for the time being in force but does not include any such goods in respect of which the conditions subject to which the goods are permitted to be imported or exported have been complied with;*
- (iii) Section 11H(a)** *'illegal export' means the export of any goods in contravention of the provisions of this Act or any other law for the time being in force;*
- (iv) Section 17: Assessment of duty. — (1)** *An importer entering any imported goods under section 46, or an exporter entering any export goods under section 50, shall, save as otherwise provided in section 85, self-assess the duty, if any, leviable on such goods.*

(2) The proper officer may verify the entries made under section 46 or section 50 and the self-assessment of goods referred to in sub-section (1) and for this purpose, examine or test any imported goods or export goods or such part thereof as may be necessary:

Provided that the selection of cases for verification shall primarily be on the basis of risk evaluation through appropriate selection criteria.

(3) For the purposes of verification under sub-section (2), the proper officer may require the importer, exporter or any other person to produce any document or information, whereby the duty leviable on the imported goods or export goods, as the case may be, can be ascertained and thereupon, the importer, exporter or such other person shall produce such document or furnish such information.]

(4) Where it is found on verification, examination or testing of the goods or otherwise that the self-assessment is not done correctly, the proper officer may, without prejudice to any other action which may be taken under this Act, re-assess the duty leviable on such goods.

(5) Where any re-assessment done under sub-section (4) is contrary to the self-assessment done by the importer or exporter and in cases other than those where the importer or exporter, as the case may be, confirms his acceptance of the said re-assessment in writing, the proper officer shall pass a speaking order on the re-

past consignment of the said goods. Therefore, it appears that the said exporter has rendered the said goods exported vide said 17 Shipping Bills as discussed at table above having total FOB Rs 2,85,66,561 appears liable for absolute confiscation under Section 113(d), (ia) & (ja) of the Customs Act, 1962, though goods are not available for confiscation.

11.1 As per Rule 14 (1) of the Customs and Central Excise duty drawback Rules, 2017, claim of drawback depends upon permitting clearance for exportation under section 51 of the Customs Act, 1962. However, export clearance of prohibited goods is not allowed under section 51 of the Act. Hence, claim of drawback can be rejected as per Rule 14(1) of the Customs and Central Excise duty drawback Rules, 2017 read with section 51 of the Customs Act, 1962. In the instant case, the said exporter has claimed drawback amount of Rs 3,61,951/- for the goods exported vide said 17 Shipping Bills as per table above in the past, they had already received said amount which was not due to them. The said amount is recoverable from them under Rule 17 of the Customs and Central Excise duty Drawback Rules, 2017, read with section 75 & 75A of the Customs Act, 1962 alongwith applicable interest under Section 28AA of the Customs Act, 1962.

11.2 The said exporter has availed IGST refund wrongly as said goods exported vide said 17 Shipping Bills as per table above were prohibited for exports and exporter has exported prohibited goods wilfully and knowingly. Section 73 of CGST Act, 2017, "*Determination of tax not paid or short paid or erroneously refunded or input tax credit wrongly availed or utilised for any reason other than fraud or any wilful-misstatement or suppression of facts.* Section 74 of CGST Act, 2017 reads as "*Determination of tax not paid or short paid or erroneously refunded or input tax credit wrongly availed or utilised by reason of fraud or any wilful misstatement or suppression of fact*". The said exporter has wrongly availed IGST refund in violation of Section 73 & 74 of the CGST Act which is recoverable and jurisdictional CGST Commissionerate is being requested to recover the same alongwith applicable interest charges.

11.3 The said exporter has availed RODTEP for the previous 17 export consignments as per table above. Since, export of said goods was prohibited, the exporter is not eligible to claim RoDTEP. Therefore, the regional DGFT authorities may be informed to recover the undue RODTEP benefits availed by the exporter.

12. RELEVANT LEGAL PROVISIONS: The following provisions of law are applicable in the instant case: -

A. Foreign Trade (Development and Regulation) Act, 1992

(i) **Section 11:** (1) *No export or import shall be made by any person except in accordance with the provisions of this Act, the rules and orders made there under and the foreign trade policy for the time being in force.*

B. Rule 11 of the Foreign Trade (Regulations), 1993- *Stipulates that on exportation out of any customs port of any goods, whether liable to duty or not, the owner of the such goods shall in the S/bill or any other documents prescribed under the Customs Act, 1962, state the value, quantity and description of such goods to*

assessment, within fifteen days from the date of re-assessment of the bill of entry or the shipping bill, as the case may be

(v) Section 50: Entry of goods for exportation. -

(1) The Exporter of any goods shall make entry thereof by presenting (electronically)[on the customs automated system] to the proper officer in the case of goods to be exported in a vessel or aircraft, a shipping bill, and in the case of goods to be exported by land, a bill of export (in such form and manner as may be prescribed):

Provided the (Principal Commissioner of Customs or Commissioner of Customs) may, in cases where it is not feasible to make entry by presenting electronically on the customs automated system, allow an entry to be presented in any other manner.)

(2) The Exporter of any goods, while presenting a shipping bill or bill of export, shall make and subscribe to a declaration as to the truth of its contents.

(3) The Exporter who presents a shipping bill or bill of export under this section shall ensure the following, namely: -

(a) the accuracy and completeness of the information given therein;

(b) the authenticity and validity of any document supporting it; and

(c) compliance with the restriction or prohibition, if any, relating to the goods under this Act or under any other law for the time being in force.

(vi) Section 51. Clearance of goods for exportation.—

“(1) Where the proper officer is satisfied that any goods entered for export are not prohibited goods and the exporter has paid the duty, if any, assessed thereon and any charges payable under this Act in respect of the same, the proper officer may make an order permitting clearance and loading of the goods for exportation:

Provided that such order may also be made electronically through the customs automated system system on the basis of risk evaluation through appropriate selection criteria:

Provided further that the Central Government may, by notification in the Official Gazette, permit certain class of exporters to make deferred payment of said duty or any charges in such manner as may be provided by rules.]

(2) Where the exporter fails to pay the export duty, either in full or in part, under the proviso to sub-section (1) by such due date as may be specified by rules, he shall pay interest on said duty not paid or short-paid till the date of its payment at such rate, not below five per cent and not exceeding thirty-six per cent per annum, as may be fixed by the Central Government, by notification in the Official Gazette.”

(vii) Section 75: “(1) Where it appears to the Central Government that in respect of goods of any class or description manufactured, processed or on which any operation has been carried out in India, being goods which have been entered for

export and in respect of which an order permitting the clearance and loading thereof for exportation has been made under section 51 by the proper officer, or being goods entered for export by post under clause (a) of section 84) and in respect of which an order permitting clearance for exportation has been made by the proper officer, a drawback should be allowed of duties of customs chargeable under this Act on any imported materials of a class or description used in the manufacture or processing of such goods or carrying out any operation on such goods, the Central Government may, by notification in the Official Gazette, direct that drawback shall be allowed in respect of such goods in accordance with, and subject to, the rules made under sub-section (2).

Provided that no drawback shall be allowed under this sub-section in respect of any of the aforesaid goods which the Central Government may, by rules made under sub-section (2), specify, if the export value of such goods or class of goods is less than the value of the imported materials used in the manufacture or processing of such goods or carrying out any operation on such goods or class of goods, or is not more than such percentage of the value of the imported materials used in the manufacture or i processing of such goods or carrying out any operation on such goods or class of goods as the Central Government may, by notification in the Official Gazette, specify in this behalf:

Provided further that where any drawback has been allowed on any goods under this sub-section and the sale proceeds in respect of such goods are not received by or on behalf of the exporter in India within the time allowed under the Foreign Exchange Management Act, 1999 (42 of 1999), such drawback shall, 4(except under such circumstances or such conditions as the Central Government may, by rules, specify, be deemed never to have been allowed and the Central Government may, by rules made under sub-section (2), specify the procedure for the recovery or adjustment of the amount of such drawback.

(1A) Where it appears to the Central Government that the quantity of a particular material imported into India is more than the total quantity of like material that has been used in the goods manufactured, processed or on which any operation has been carried out in India and exported outside India, then, the Central Government may, by notification in the Official Gazette, declare that so much of the material as is contained in the goods exported shall, for the purpose of subsection (1), be deemed to be imported material.

(2) The Central Government may make rules for the purpose of carrying out the provisions of sub-section (1) and, in particular, such rules may provide -

(a) for the payment of drawback equal to the amount of duty actually paid on the imported materials used in the manufacture or processing of the goods or carrying out any operation on the goods or as is specified in the rules as the average amount of duty paid on the materials of that class or description used in the manufacture or processing of export goods or carrying out any operation on export goods of that class or description either by manufacturers generally or by persons processing or

carrying on any operation generally or by any particular manufacturer or particular person carrying on any process or other operation, and interest if any payable thereon;

(aa) for specifying the goods in respect of which no drawback shall be allowed;

(ab) for specifying the procedure for recovery or adjustment of the amount of any drawback which had been allowed under sub-section (1) or interest chargeable thereon;

(b) for the production of such certificates, documents and other evidence in support of each claim of drawback as may be necessary;

(c) for requiring the manufacturer or the person carrying on any process or other operation to give access to every part of his manufactory to any officer of customs specially authorised in this behalf by the Assistant Commissioner of Customs or Deputy Commissioner of Customs to enable such authorised officer to inspect the processes of manufacture, process or any other operation carried out and to verify by actual check or otherwise the statements made in support of the claim for drawback.

(d) for the manner and the time within which the claim for payment of drawback may be filed;

(3) The power to make rules conferred by sub-section (2) shall include the power to give drawback with retrospective effect from a date not earlier than the date of changes in the rates of duty on inputs used in the export goods."

(viii) Section 75A: "(1) Where any drawback payable to a claimant under section 74 or section 75 is not paid within a period of one month from the date of filing a claim for payment of such drawback, there shall be paid to that claimant in addition to the amount of drawback, interest at the rate fixed under section 27A from the date after the expiry of the said period of one month till the date of payment of such drawback:

(2) Where any drawback has been paid to the claimant erroneously or it becomes otherwise recoverable under this Act or the rules made thereunder, the claimant shall, within a period of two months from the date of demand, pay in addition to the said amount of drawback, interest at the rate fixed under section 28AA and the amount of interest shall be calculated for the period beginning from the date of payment of such drawback to the claimant till the date of recovery of such drawback."

(ix) Section 113: Confiscation of goods attempted to be improperly exported, etc.

"The following goods shall be liable to confiscation:

(d): any goods attempted to be exported or brought within the limits of any customs area for the purpose of being exported, contrary to any prohibition imposed

by or under this Act or any other law for the time being in force, shall be liable to confiscation;

(ia): any goods entered for exportation under claim for drawback which do not correspond in any material particular with any information furnished by the exporter or manufacturer under this Act in relation to the fixation of rate of drawback under section 75;]

(ja): any goods entered for exportation under claim of remission or refund of any duty or tax or levy to make a wrongful claim in contravention of the provisions of this Act or any other law for the time being in force

(x) Section 114(i): Any person who, in relation to any goods, does or omits to do any act which act or omission would render such goods liable to confiscation under section 113, or abets the doing or omission of such an act, shall be liable, in the case of goods in respect of which any prohibition is in force under this Act or any other law for the time being in force, to a penalty not exceeding three times the value of the goods as declared by the Exporter or the value as determined under this Act, whichever is the greater.

(xi) Section 114AA: Penalty for use of false and incorrect material.—If a person knowingly or intentionally makes, signs or uses, or causes to be made, signed or used, any declaration, statement or document which is false or incorrect in any material particular, in the transaction of any business for the purposes of this Act, shall be liable to a penalty not exceeding five times the value of goods.

(xii) Section 117: Any person who contravenes any provision of this Act or abets any such contravention or who fails to comply with any provision of this Act with which it was his duty to comply, where no express penalty is elsewhere provided for such contravention or failure, shall be liable to a penalty not exceeding [one lakh rupees] [Substituted by Act 18 of 2008, Section 70, for " ten thousand rupees".]

(xiii) Section 124: Issue of show cause notice before confiscation of goods, etc.

- No order confiscating any goods or imposing any penalty on any person shall be made under this Chapter unless the owner of the goods or such person-

(a) is given a notice in [writing with the prior approval of the officer of Customs not below the rank of a Deputy Commissioner of Customs, informing] [Substituted by Act 29 of 2006, Section 28, for " writing informing" (w.e.f. 13.7.2006).] him of the grounds on which it is proposed to confiscate the goods or to impose a penalty;

(b) is given an opportunity of making a representation in writing within such reasonable time as may be specified in the notice against the grounds of confiscation or imposition of penalty mentioned therein; and

(c) is given a reasonable opportunity of being heard in the matter:

Provided that the notice referred to in clause (a) and the representation referred to in clause (b) may, at the request of the person concerned, be oral. [Provided further that notwithstanding issue of notice under this section, the proper officer may issue

a supplementary notice under such circumstances and in such manner as may be prescribed.] [Inserted by Finance Act, 2018 (Act No. 13 of 2018), dated 29.3.2018.]

D. Violations under Drugs and Cosmetics Act, 1940

- (i) **Section 26A:** Powers of Central Government to regulate, restrict or prohibit manufacture, etc., of drug and cosmetic in public interest.—Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic.

E. GST/IGST refund & export incentive violation

- (i) **Section 73:** Determination of tax not paid or short paid or erroneously refunded or input tax credit wrongly availed or utilised for any reason other than fraud or any wilful-misstatement or suppression of facts.
- (ii) **Section 74:** Determination of tax not paid or short paid or erroneously refunded or input tax credit wrongly availed or utilised by reason of fraud or any wilful misstatement or suppression of facts.

F. Drawback rules, 2017

- (i) **Rule 2(a) of the Customs and Central Excise Duty Drawback Rules, 2017**

- "drawback in relation to any goods manufactured in India and exported, means the rebate of duty excluding integrated tax leviable under sub-section (7) and compensation cess leviable under sub-section (9) respectively of section 3 of the Customs Tariff Act, 1975(51 of 1975) chargeable on any imported materials or excisable materials used in the manufacture of such goods."

- (ii) **Rule 14(1) of the Customs and Central Excise Duty Drawback Rules, 2017**

Manner and time for claiming drawback on goods exported other than by post.

"14(1). Electronic shipping bill in Electronic Data Interchange (EDI) under the claim of drawback or triplicate copy of the shipping bill for export of goods under a claim of drawback shall be deemed to be a claim for drawback filed on the date on which the proper officer of Customs makes an order permitting clearance and loading of goods for exportation under section 51 and said claim for drawback shall be retained by the proper officer making such order."

- (iii) **Rule 17 of the Customs and Central Excise Duty Drawback Rules, 2017**

- "Where an amount of drawback and interest, if any, has been paid erroneously or the amount so paid is in excess of what the claimant is entitled to, the claimant

shall, on demand by a proper officer of Customs repay the amount so paid erroneously or in excess, as the case may be, and where the claimant fails to repay the amount it shall be recovered in the manner laid down in sub-section (1) of section 142 of the Customs Act, 1962 (52 of 1962)."

(iv) Rule 18 the Customs and Central Excise Duty Drawback Rules, 2017 -

"(1) Where an amount of drawback has been paid to an exporter or a person authorised by him (hereinafter referred to as the claimant) but the sale proceeds in respect of such export goods have not been realised by or on behalf of the exporter in India within the period allowed under the Foreign Exchange Management Act, 1999 (42 of 1999), including any extension of such period, such drawback shall, except under circumstances or conditions specified in sub-rule (5), be recovered in the manner specified below:

Provided that the time-limit referred to in this sub-rule shall not be applicable to the goods exported from the Domestic Tariff Area to a special economic zone.

(2) If the exporter fails to produce evidence in respect of realisation of export proceeds within the period allowed under the Foreign Exchange Management Act, 1999, or any extension of the said period by the Reserve Bank of India, the Assistant Commissioner of Customs or the Deputy Commissioner of Customs, as the case may be, shall cause notice to be issued to the exporter for production of evidence of realisation of export proceeds within a period of thirty days from the date of receipt of such notice and where the exporter does not produce such evidence within the said period of thirty days, the Assistant Commissioner of Customs or Deputy Commissioner of Customs, as the case may be, shall pass an order to recover the amount of drawback paid to the claimant and the exporter shall repay the amount so demanded within thirty days of the receipt of the said order:

Provided that where a part of the sale proceeds has been realised, the amount of drawback to be recovered shall be the amount equal to that portion of the amount of drawback paid which bears the same proportion as the portion of the sale proceeds not realised bears to the total amount of sale proceeds.

(3) Where the exporter fails to repay the amount under sub-rule (2) within said period of thirty days referred to in sub-rule (2), it shall be recovered in the manner laid down in rule 17.

(4) Where the sale proceeds are realised by the exporter after the amount of drawback has been recovered from him under sub-rule (2) or sub-rule (3) and the exporter produces evidence about such realisation within a period of three months from the date of realisation of sale proceeds, the amount of drawback so recovered shall be repaid by the Assistant Commissioner of Customs or Deputy Commissioner of Customs, as the case may be, to the claimant provided the sale proceeds have been realised within the period permitted by the Reserve Bank of India:

Provided that-

(i) the Principal Commissioner of Customs or Commissioner of Customs, as the case may be, may extend the aforesaid period of three months by a period of nine months provided the sale proceeds have been realised within the period permitted by the Reserve Bank of India;

(ii) an application fee equivalent to 1% of the FOB value of exports or one thousand rupees whichever is less, shall be payable for applying for grant of extension by the Principal Commissioner of Customs or Commissioner of Customs, as the case may be.

(5) Where sale proceeds are not realised by an exporter within the period allowed under the Foreign Exchange Management Act, 1999 (42 of 1999), but such non-realisation of sale proceeds is compensated by the Export Credit Guarantee Corporation of India Ltd. under an insurance cover and the Reserve Bank of India writes off the requirement of realisation of sale proceeds on merits and the exporter produces a certificate from the concerned Foreign Mission of India about the fact of non-recovery of sale proceeds from the buyer, the amount of drawback paid to the exporter or the claimant shall not be recovered."

13. In view of the above, it appears that, the goods covered under the Shipping Bill No. 3766710 dated 22.07.2025, declared as "Moxbro Forte Syrup", having declared FOB value of Rs. 25,53,000/- were attempted to be improperly exported by the Exporter even when the goods are unapproved/banned in nature vide Gazette notification no. CG-DL-E-02062023-246249 dated 02.06.2023 and vide notification no. S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016. Further, the No objection certificate issued by the CDSCO for export, also does not seem to be applicable for already manufactured goods as per the laid down procedure. No licence from State Licencing authority after issuance of CDSCO NOC has been issued before manufacturing of the goods and the conditions stipulated in the NOC regarding labelling and packaging are not complied with, during the manufacturing of the goods. Packages were supposed to be labelled "Not for medicinal use" as per CDSCO NOC. However, these packages did not have any such markings. Further, it is also evident that the Central Government have prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of amoxicillin and bromhexine in India. Hence, the said consignment can neither be sold in India nor can be exported to abroad.

13.1 Further, the scope of definition of "prohibited goods" as specified under Section 2 (33) of the Customs Act, 1962 is no more res-integra in light of Judgement dated 17.06.2021 of Hon'ble Supreme Court in the case of Union of India & Ors Vs Raj Grow Impex LLP & Ors [CIVIL APPEAL NO(s). 2217-2218 of 2021 (Arising out of SLP(C) Nos. 14633-14634 of 2020)].

It is settled that "prohibition" under the aforesaid provision would include every type of "prohibition" and would include the "restrictions".

Further, in self-assessment era, it is the responsibility of the Exporter to ensure compliance with the restriction or prohibition, if any, relating to the goods under this

Act or under any other law for the time being in force, thus by attempting to export the unapproved/banned drugs without the requisite No Objection Certificate issued by the CDSCO, the exporter has also violated the provisions of section 50 (3) of the Customs Act, 1962 and provisions of section 11 of Foreign Trade (Development and Regulation) Act, 1992. The representative of the said exporter in his statement recorded under Section 108 of the Customs Act, 1962 has also admitted that they do not have mandatory NOC from CDSCO as well as manufacturing permission. The exporter knowingly and deliberately attempted to export said goods even they were aware that these goods cannot be exported and in earlier attempts, they were caught and case was adjudicated. Thus, by these acts of omission and commission, the exporter has rendered the said goods covered under the Shipping Bill No. 3766710 dated 22.07.2025, declared as "Moxbro Forte Syrup", having declared FOB value of Rs. 25,53,000/- liable for confiscation under Section 113(d) of Customs Act, 1962, and the exporter has also claimed drawback and RoDTEP benefits on the improper export of unapproved/banned goods which also makes the goods liable for confiscation under section 113(ia) and 113(ja) respectively of the Customs Act, 1962 and therefore, for attempting to improperly export the goods without the requisite and applicable No Objection Certificate issued by CDSCO and manufacturing license issued by State licensing authority, the exporter appears liable for penal actions under the Customs Act, 1962.

13.2 The said exporter had exported said goods in the past vide Shipping Bills 8693333 dated 16.02.2021, 3249473 dated 20.07.2021, 3524351 dated 31.07.2021, 8605680 dated 01.03.2022, 1168825 dated 04.05.2022, 2600423 dated 05.07.2022, 2605495 dated 05.07.2022, 5168352 dated 01.11.2022, 5416904 dated 12.11.2022, 5417293 dated 12.11.2022, 6522425 dated 29.12.2022, 2588618 dated 20.07.2023, 4254270 dated 28.09.2023, 5706761 dated 30.11.2023, 8911107 dated 05.04.2024, 1341448 dated 31.05.2024 & 5045353 dated 23.10.2024 having total FOB Rs 2,85,66,561/- without having mandatory NOC from CDSCO or State licencing Authority as well as permission from State Licensing authority to manufacture said goods for export purpose. The representative of the said exporter in his statement recorded under Section 108 of the Customs Act, 1962 has also admitted that he has not taken NOC from the concerned authority even for past consignment of the said goods. Therefore, it appears that the said exporter has rendered the said goods exported vide said 17 Shipping Bills as discussed at table above having total FOB Rs 2,85,66,561 appears liable for absolute confiscation under Section 113(d), (ia) & (ja) of the Customs Act, 1962, though goods are not available for confiscation. Further, the exporter has also claimed drawback, IGST and RoDTEP benefits on the improper export of unapproved/banned goods which also makes the goods liable for confiscation under section 113(ia) and 113(ja) respectively of the Customs Act, 1962 and therefore, for attempting to improperly export the goods without the requisite and applicable No Objection Certificate issued by CDSCO or from State Authority and manufacturing license issued by State licensing authority, the exporter appears liable for penal actions under the Customs Act, 1962.

13.3 Thus by attempting to export the unapproved/banned drugs without the requisite No Objection Certificate issued by the CDSCO, the exporter has also violated the provisions of section 50 (3) of the Customs Act, 1962 and provisions of section 11 of

Foreign Trade (Development and Regulation) Act, 1992. The representative of the said exporter in his statement recorded under Section 108 of the Customs Act, 1962 has also admitted that they do not have mandatory NOC from CDSCO as well as manufacturing permission. The exporter knowingly and deliberately attempted to export said goods even they were aware that these goods cannot be exported and in earlier attempts, they were caught and case was adjudicated. The exporter, M/s. Coral Laboratories Ltd. (IEC-0394033353) for their acts of omission and commission in respect of the subject goods to improperly export the unapproved/banned drugs without requisite and applicable NOC from CDSCO appears to be liable for imposition of penalty under Section 114(i) of the Customs Act, 1962.

13.4 The said exporter while filing said Shipping Bills make a wrong statement and as per sub section 2 of Section 50 of Customs Act, 1962, they, while presenting said Shipping Bills were required to make and subscribe to a declaration as to the truth of its contents. As per Sub Section 3 of Section 50 of Customs Act, 1962, the exporter who presents a shipping bill under this section shall ensure the accuracy and completeness of the information given; the authenticity & validity of any document supporting it and compliance with restriction or prohibition, if any, relating to the goods under this Act or under any other law for the time being in force. In case of live export shipment, the exporter was required to produce a valid NOC from prescribed agency however, the said exporter intentionally has submitted a invalid NOC to which they were aware of the fact that based on said NOC earlier they were not allowed to export. The said exporter also intentionally exported said goods without having valid mandatory NOC in case of 17 exports made in the past. The said exporter, at the same time, made declaration to the truthiness of declaration made in said Shipping Bills. Therefore, said exporter appears liable for penalty under Section 114AA of the Customs Act, 1962.

14. Now M/s. Coral Laboratories Ltd. (IEC- 0394033353) having registered address at Plot No. 27/28, Pharma City, Selaqui, Dehradun, Uttarakhand- 248001 is hereby called upon to show cause to the Additional Commissioner of Customs, CEAC NS-II JNCH having office at Jawaharlal Nehru Custom House, Nhava Sheva, Tal- Uran, Dist- Raigad, Maharashtra within 30 days of receipt of this notice as to why:

- i.** the goods namely Moxbro Forte Syrup attempted to export vide Shipping Bill No 3766710 dated 22.07.2025 having FOB value as Rs 25,53,000/- (Rupees Twenty Five Lakhs Fifty Three Thousands only) should not be held liable to absolute confiscation under Section 113 (d), (ia) & (ja) of the Customs Act, 1962.
- ii.** the goods namely Moxbro Forte Syrup exported vide Shipping Bill No. 8693333 dated 16.02.2021, 3249473 dated 20.07.2021, 3524351 dated 31.07.2021, 8605680 dated 01.03.2022, 1168825 dated 04.05.2022, 2600423 dated 05.07.2022, 2605495 dated 05.07.2022, 5168352 dated 01.11.2022, 5416904 dated 12.11.2022, 5417293 dated 12.11.2022, 6522425 dated 29.12.2022, 2588618 dated 20.07.2023, 4254270 dated 28.09.2023, 5706761 dated 30.11.2023, 8911107 dated 05.04.2024 1341448 dated 31.05.2024 & 5045353 dated 23.10.2024 having total FOB Rs 2,85,66,561/- (Rupees Two Crores Eighty

Five Lakhs Sixty Six Thousands Five Hundred Sixty One Only) should not be held liable to confiscation under Section 113 (d), (ia) & (ja) of the Customs Act, 1962 (though goods are not available).

- iii. the claim of duty drawback benefit claimed for the goods namely Moxbro Forte Syrup attempted to export vide Shipping Bill No 3766710 dated 22.07.2025 should not be denied under Rule 14 (1) of the Customs and Central Excise duty drawback Rules, 2017, read with section 51 of the Customs Act, 1962.
- iv. Since, goods namely Moxbro Forte Syrup attempted to export vide Shipping Bill No 3766710 dated 22.07.2025 are being held prohibited for exports, IGST and RoDTEP should not be denied.
- v. drawback amount Rs. 3,61,951/- (Rs. Three Lakhs Sixty-One Thousand Nine Hundred Fifty-One only) paid towards Shipping Bill No. 8693333 dated 16.02.2021, 3249473 dated 20.07.2021, 3524351 dated 31.07.2021, 8605680 dated 01.03.2022, 1168825 dated 04.05.2022, 2600423 dated 05.07.2022, 2605495 dated 05.07.2022, 5168352 dated 01.11.2022, 5416904 dated 12.11.2022, 5417293 dated 12.11.2022, 6522425 dated 29.12.2022, 2588618 dated 20.07.2023, 4254270 dated 28.09.2023, 5706761 dated 30.11.2023, 8911107 dated 05.04.2024 1341448 dated 31.05.2024 & 5045353 dated 23.10.2024 should not be recovered from them under Rule 17 of the Customs and Central Excise duty Drawback Rules, 2017, read with section 75 & 75A of the Customs Act, 1962 along with interest as per section 28AA of the Customs Act, 1962.
- vi. the IGST refund amount Rs. 34,35,055/- (Rs. Thirty-Four Lakhs Thirty-Five thousand Fifty-Five only) disbursed to them against Shipping Bill No. 8693333 dated 16.02.2021, 3249473 dated 20.07.2021, 3524351 dated 31.07.2021, 8605680 dated 01.03.2022, 1168825 dated 04.05.2022, 2600423 dated 05.07.2022, 2605495 dated 05.07.2022, 5168352 dated 01.11.2022, 5416904 dated 12.11.2022, 5417293 dated 12.11.2022, 6522425 dated 29.12.2022, 2588618 dated 20.07.2023, 4254270 dated 28.09.2023, 5706761 dated 30.11.2023, 8911107 dated 05.04.2024 1341448 dated 31.05.2024 & 5045353 dated 23.10.2024 should not be recovered from them through the jurisdictional CGST authorities along with applicable interest.
- vii. the RODTEP Rs. 1,19,464/- (Rs. One Lakh Nineteen Thousand Four Hundred Sixty-Four Only) availed against Shipping Bill No. 8693333 dated 16.02.2021, 3249473 dated 20.07.2021, 3524351 dated 31.07.2021, 8605680 dated 01.03.2022, 1168825 dated 04.05.2022, 2600423 dated 05.07.2022, 2605495 dated 05.07.2022, 5168352 dated 01.11.2022, 5416904 dated 12.11.2022, 5417293 dated 12.11.2022, 6522425 dated 29.12.2022, 2588618 dated 20.07.2023, 4254270 dated 28.09.2023, 5706761 dated 30.11.2023, 8911107 dated 05.04.2024 1341448 dated 31.05.2024 & 5045353 dated 23.10.2024 should not be recovered along with applicable interest from M/s. Coral

Laboratories Ltd. (IEC - 0394033353) in terms of Notification 76/2021- Customs (N.T) dated 23.09.2021 and section 28AAA read along with Section 28AA of Customs Act 1962.

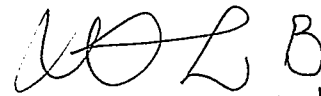
viii. penalty should not be imposed on M/s. Coral Laboratories Ltd. (IEC - 0394033353) under section 114 (i) & 114 AA of the Customs Act, 1962.

15. The noticee is required to specifically mention in their written reply as to whether they wish to be heard in person before the case is decided. In case the noticee do not submit a written reply within the aforesaid period or if they fail to attend the personal hearing, whenever it is fixed by the adjudicating authority, the case will be decided on the basis of material evidence available on record, ex parte, without any further reference to them.

16. The Department reserves its right to add, amend, modify, etc. this notice based on any fresh facts or evidence which may come to the notice of the Department after issue of this notice but prior to adjudication thereof.

17. This showcause notice is issued without prejudice to any other action that may be taken against the persons/firms mentioned herein or any other person under the Customs Act, 1962 or any other law for the time being in force.

18. List of the documents relied upon in this notice (RUDs) are as per Annexure-1 attached with this notice.


(Raghu Kiran B.) 11/12/25

Additional Commissioner of Customs
CEAC,NS-II, JNCH

To

1. M/s. Coral Laboratories Ltd. (IEC- 0394033353)
Plot No. 27/28, Pharma City, Selaqui
Dehradun, Uttarakhand- 248001

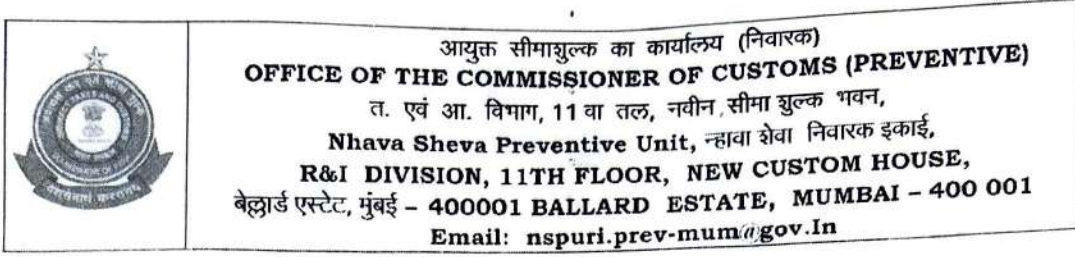
Copy to:

1. The Deputy. Commissioner of Customs, NSPU, R&I, NCH
2. The Deputy. Commissioner of Customs,CRAC, JNCH
3. The Deputy Commissioner of Customs,CAC,JNCH
4. The Deputy Commissioner, Zone: Meerut, Commissionerate: Dehradun
Division: Division Dehradun, Range:II Vikas Nagar
4. Supdt/CHS, JNCH for display on Notice Board.

5. Office Copy

Annexure 1 (RUDs)

Sr. No.	Documents	Page No.
1	Hold letter dated 25.07.2025	1
2	Panchanama dated 25.07.2025 along with supporting documents	2-34
3	NOC mail from Exporter	35-36
4	CDSCO NOC dated 23.04.2025	37-38
5	Letter of DGHSC dated 30.04.2024	39-40
6	Gazette Notification dated 10.03.2016	41-43
7	Letter to CDSCO 29.07.2025	44
8	Summons dated 05.08.2025	45
9	Statement dated 07.08.2025 along with documents	46-63
10	Letter to DYCC JNCH dated 29.07.2025	64
11	Letter to DYCC JNCH 11.08.2025	65-66
12	Test memo from DYCC JNCH 11.08.2025	67
13	Letter from DYCC JNCH 12.08.2025	68
14	Mail from CDSCO 13.08.2025	69-70
15	Letter to DYCC NCH 13.08.2025	71
16	Letter to SLA 22.08.2025	72-73
17	Seizure Memo 25.08.2025	74-75
18	Test memo DYCC NCH 25.08.2025	76
19	Statement of Bank realisation	77-84
20	Certificate of GMP	85
21	End use certificate by M/s Coral Laboratories	86
22	Extension of validity of GMP	87
23	GLP Certificate	88
24	License Product List	89
25	Gazette Notification dated 02.06.2023	90-92
26	O-in-O dated 16.06.2025	93-103



DIN: 202507790C0000222834 Date: 25-07-2025

Hold No. 09/2025-26 NSPU(R&I)

To,
 The Shed Manager (Operations),
 M/s Conex Terminal Pvt. Ltd.
 Nhava Sheva, Raigarh

Gentleman,

Sub:- Hold of consignment exported by M/s Coral Laboratories Limited (IEC-0394033353) lying at M/s Conex Terminal Pvt. Ltd., CFS - reg.

This office is investigating a case of export in respect of the consignment bearing shipping number 3766710 dated 22.07.2025.

2. The above said consignment is to be put on hold immediately until further orders. The consignment should also be placed under CCTV surveillance.
3. It is also directed that opening, examining, dispensing and clearing of the goods contained in above said consignment should not be allowed without prior permission of this office in writing.
4. This issues with the approval of Commissioner of Customs (Preventive).

Digitally signed by
 Naresh Kumar Tiwari
 Date: 25-07-2025
 13:03:59

(Naresh Kr. Tiwari)
 Deputy Commissioner of Customs
 NSPU/R&I

Copy to:

1. The DC/AC Export Docks, M/s. Conex Terminal Pvt. Ltd.

Panchnama dated 25.07.2025 drawn at the premises of M/s Conex Terminal Pvt. Ltd. CFS, Uran Road, Jawarharlal Nehru Port Trust, Raigarh- 400707 for the examination of goods to export by M/s Coral Industries Pvt. Ltd (IEC-0394033353) vide Shipping Bill No. 3766710 dated 22.07.2025 filed by CB M/s Star India Container Line Pvt. Ltd.

Pancha No.1

Name: Prabhakar Naga Patil
Age: 55
Occupation: Service
Address : House No. 181, Bander Ali, At-kalve, Johe, Raigarh, Mah-402107
Aadhar No: 8888 3073 1299
Mobile No: 9270000441

Pancha No. 2

Name: Sanjay kashinath Bhagat
Age: 34
Occupation: Service
Address : VTC: Aware, PO:Awre, Uran, Raigarh, Mah-410206
Aadhar No: 2770 8839 5756
Mobile No : 9082586715

We, the above mentioned Panchas, on being called upon by Shri Umesh Chander, Preventive Officer of Customs (P), Nhava Sheva Preventive Unit, R&I, Mumbai, presented ourselves at 1500 hrs on 25.07.2025 in front of the Admin Building at M/s Conex Terminal Pvt. Ltd. (hereon referred to as "Conex CFS"), Raigarh. Here, he introduced us to Shri Bhuwnesh Dixit, Superintendent of Customs (P), Shri Rajat Aggarwal, Preventive Officer of Customs (P). The officers (hereon referred to as "the said officers") identified themselves by showing their official identity cards. The said officers informed us that the consignment to be exported vide Shipping Bill No. 3766710 dated 22.07.2025 filed by CB M/s. Star India Container Line Pvt. Ltd on behalf of Exporter M/s Coral Industries Pvt. Ltd (IEC-0394033353) was put on hold on 24.07.2025 for examination. The officer then showed us the hold letter dated 25.07.2025. We had put our dated signature as a token of having it seen.

Thereafter, we the above mentioned Panchas were introduced to Shri Mayank Chetan Katira authorised representative of M/s Coral Industries Pvt. Ltd (IEC-0394033353) & Shri Sanjay Yashwant Jadhav, G card holder (herein referred Customs Broker) who was also duly authorized by the Exporter M/s Coral Industries Pvt. Ltd (IEC-0394033353). The said officers informed us that the Shipping Bill No. 3766710 dated 22.07.2025 has been filed by above mentioned Customs Broker on behalf of the exporter and entire examination will be carried out in the presence of us, the above mentioned Panchas and the Customs Broker. The said officers requested us to bear witness to the said proceedings to which we the above mentioned Panchas voluntarily agreed upon. We, the Panchas and the Customs Broker have put our dated signatures on the copies of Export documents i.e. Shipping Bill, Invoice List, Certificate of Analysis provided by Exporter as a token of seeing the same and details as per above mentioned documents were as below :

P₁
25/7/25

P₂
Sanjay
25/7/25

CHA
@Kalyan
25/7/25

Exporter.
@Katira

TABLE-I

Shipping Bill and date	Invoice & Packing list No. (No. of Packages)	Product Name
3766710 dated 22.07.2025	M-28/25-26 dated 22.07.2025 (420)	Moxbro Forte Syrup

Further, the above consignment was located in the shed 2, Thereafter, the said officers began the examination in our presence. The consignment was found packed in cartons of same size. The cartons carried description of the product name, batch no. Mfg. date, Exp. Date. Gross weight, Tare weight, Net weight and Quantity. A carton box was then opened in which there were 120 Boxes having glass bottle of product with the labelling "Amoxicilin and Bomhexine Hydrochloride Dry Suspension "Moxbro Forte Syrup" for oral suspension 250" on each of them. Each of these boxes had a brown translucent glass bottle (100 ML as described) of the same inscription and bearing Manufacturing licence No., batch No., Manufacturing date and expiry date. Each bottle seemed to have a powdered substance in it filled almost to the bottle's half level. Subsequently each Carton Boxes were opened and was found with same product as described above. The total number of the carton boxes were found to be 420 which matched with the invoice list and the number of glass bottles were also found as per invoice and packing list.


10 glass bottles were drawn and then packed in 05 envelopes as representative samples in the presence of us, the exporter and the Customs Broker, which were then sealed in 5 green envelopes in our presence by the officers with Customs PO seal 57. Each envelope were signed by us, the exporter, Customs Broker and the officer.

The Panchnama commenced at 1500 hrs on 25.07.2025 and ended at 1930 hrs on the same day. The whole procedure was carried out in a peaceful and systematic manner and no untoward incident occurred and no socio-cultural-religious feelings of anybody were hurt. No damage was caused. We, both the above mentioned Panchas, the said officers and the Customs Broker were present throughout the course of the Panchnama. The Panchnama running in 01 to 02 pages was typed by the Customs officer as per our say on the desktop of Manager of M/s Conex Terminal Pvt Ltd.

Drawn by me:


25/7/25

(Umesh Chander)
IO/NSPU, R&I

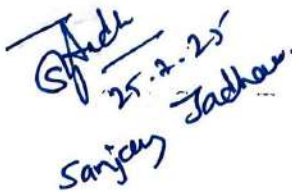

25/7/25
PRABHAKAR NAGA PATIL


Pancha No. 1


25/7/25

Sanjay Kashinath Bhagwat

Pancha No. 2


25.7.25
Sanjay Jadhav


25/07/25
Meharaj Kahira

STAR INDIA CONTAINER LINE PVT. LTD.

DATE TO BE ENTERED BY EXAMINING OFFICERS WHEN EXPORT GOODS ARE BROUGHT FOR EXAMINATION

- 1. SB No. 3766710 Date : 22/07/2025
- 2. (a) Nature of Cargo Containerised Cargo
- (b) Marks & Nos. AS PER INV, WE INTEND TO CLAIM BENEFIT UNDER RODTEP FOR ALL EXPORT PRODUCTS (REMISSION OF DUTIES AND TAXES ON EXPORTED PRODUCTS) UNDER IGST
- (c) Rotation No. & Date
- 3. Freight & Insurance Charges FOB : 2553000.00
 (i) Freight Value 500.00 Currency : USD
 (i) Insurance Value Currency : USD
- 4. Total Number of Packages 420
- 5. Type of Packages (Boxes, Cartons, Bags etc.): CTN
- 6. Number marked on the packages (1-25) etc 1 to 420
- 7. Gross Weight (in kgs) 9395.800
- 8. Net Weight (in kgs) 8400.400
- 9. Unit of weight KGS
- 10. Container Particulars

Container No	Size	Place of sealing	Seal No	Date of Sealing

- 10. Container Particulars
Separate sheet attached
- 11. Name of the sealing agency
- 12. Whether factory stuffed (Y/N) NO
 (i) if Yes, whether sample accompanies : (Y/N) NO
 (i) Factory Name & Address

CVR
TAX INV
GMP
COA

13. Details of AR - 4 (Details of AR-4 (or any other document containing examination details by Central Excise Officer))

Sl No	AR4 Number of any other Document Number	Date	Commissionerate	Division	Range

I / We declare that the particulars given above are true and correct
 Name of the Exporter / CHA
 I D No. of the authorised signatory of CHA
 Date :

Goods arrived, Verified the number of packages and marks and numbers there on and found to be declared.
 Name of the Examining Officer :
 Signature of the Examining Officer :

- Notes :**
- 1. For factory/CFS stuffed containers, gross weight given in Sl. No.7 should be exclusive of the weight of the Container
 - 2. Extra sheets may be attached, if necessary

25/7/25
 25/7/25

STAR INDIA CONTAINER LINE PVT. LTD.
Shipping Bill Checklist

Job No	: 651	Date	: 21/07/2025
Reference No	: CL/E/S/000651/25-2	EDI No	: 651
CHA	: AAKCS2074FCH001	Name	: STAR INDIA CONTAINER LINE PVT. LTD.
SB No & Date	: 3766710 22/07/2025	State	: MAHARASHTRA
Printed on	: 22/07/2025	Time	: 13:11:37

Exporter Details
0394033353(5) PAN :AAACC4421G
CORAL LABORATORIES LIMITED
SHED NO. 3B, PATANWALA COMPOUND
OPP SHREYAS,, LBS MARG, GHATKOPAR W
MUMBAI - 400086
MAHARASHTRA

Consignee Details
ASAL PHARMA CO (APHCO)
BAKARO MEDICINE MARKET,
MOGADISHU SOMALIA
.
.
SOMAALIA

AD Code	: 0510002	A/C No	:
IFSC Code	:		
Exporter type	: MANUFACTURER		
GSTIN Type	: GSN	GSTIN	: 27AAACC4421G1Z3
NFEI Category	:	RBI Waiver No	:
Port of Loading	: NHAVA SHEVA SEA (INNSA1)		
Discharge Port	: MOGADISHU (SOMGQ)	Date	:
Port of Destination	: MOGADISHU (SOMGQ)		
Destination Country	: SOMAALIA (SO)		
Discharge Country	: SOMAALIA (SO)		
Gross weight	: 9395.800 KGS	Net Weight	: 8400.400 KGS
Total Packages	: 420 CTN	Loose Packets	:
Nature of Cargo	: C	No. of Containers	:
Factory Stuffed	: NO	Sample	: NO
MAWB Number	:	HAWB Number	:
Rotation Number	:	Rotation Date	:
Gateway Port	:	Transhipper Code	:
Custodian	:	Received	: <u>420</u> Packages
Forex Bank A/c	:	Warehouse Code	: <u>III</u> As per
FOB Value	: 2553000.00	Drawback A/c No	:
		Shipping Bill No.	: <u>3766710</u>
			: <u>22/07/25</u>

CWC DISTRI PARK

Received 420 Packages

Warehouse Code III As per

Shipping Bill No. 3766710

Date 22/07/25

INCHARGE

HITEN BHOIR
Conex Terminal Pvt Ltd

Marks & Nos

AS PER INV, WE INTEND TO CLAIM BENEFIT UNDER: RODTEP FOR ALL EXPORTED PRODUCTS (REMISSION OF DUTIES AND TAXES ON EXPORTED PRODUCTS) Said to Container Basis

25/7/25

25/7/25

24/7

Conex Terminal Pvt. Ltd.
Ramesh Thakur - Surva

Invoice Serial Number : 1
 Invoice Number : M-28/25-26
 Nature of Contract : CF
 Nature of Payment : AP
 Period :
 LC No :
 Date :
 Currency : USD (85.1000)
 AEO Country :
 AEO Role :
 AEO Code :
 Invoice Value : 30500.00000
 Invoice Value in INR : 2595550.00
 DBK in INR : 30636.00
 Contract Number : NA

Date : 22/07/2025

Buyer Detail

ASAL PHARMA CO (APHCO)
 BAKARO MEDICINE MARKET, MOGADISHU
 SOMALIA . .

Invoice Third Party Details :

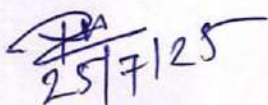
	Rate	Currency	Amount
Insurance	:	USD	0.00
Freight	:	USD	500.00
Commission	:	USD	0.00
Discount	:	USD	0.00
Other Deductions	:	USD	0.00
Packing Charges	:	USD	

Item No	RITC	Otv Units	Rate	Unit	PMV	FC	FOB
	Alls per Tariff:	Otv Units			RoDTEP		Total PMV
	Description						Reward
	Scheme Code						
	State of Origin	District of Origin				PTA/FTA Details	
1	30041030	50000.000 NOS				30500.000000	2553000.00
	As per Tariff:	8400.400 KGS			Y		
		0.610000 PER 1 NOS				57.10	2855000.00
MOXBRO FORTE SYRUP BATCH NO:UFM2501 TO UFM2510 MFG DT:03/2025 EXP DT:08/2027							
	19-DRAWBACK						Y
	MAHARASHTRA (27)	MUMBAI (482)				No PTA/FTA (NCPTI)	
						30500.000000	2553000.00

FOB Value in INR : 2553000.00 FOB Value in USD : 30000.00

Manufacturer Details

Inv No	Item No	Mfr.Type	Src State	Trns. Cntry	Enduse	HAWB No	Tot Pkg
IGST Status	Accessory	Taxable Value	IGST Per	IGST Amount	IGST Cess Amount		
Manufacturer Details		Cess Rs/Unit	Cess %				
1	1				DCH400		306359.99
P		2552999.95	12.00 %				0.00
		2552999.95	IGST Total				306359.99
			IGST Cess Total				0.00


 25/7/25

Ganig
 25/7/25

DRAWBACK DETAILS

Inv. No	Item No	Sch.No	Customs Rate Excise Rate	Adv. Rate	Qty	Amount
1	1	3004B	0.000 1.200	1.200	50000.000	30636.00
Total						30636.00

PACKING LIST DETAILS

Serial No	From	To	Package Code
1	1	420	CTN

RoDTEP Rate/Amount Details

Inv No	Item No	RITC	FOB	Qty/Unit	Rate	Qty/Unit
1	1	3004103C	2553000.00	8400.400000	0.7%	17871.00
Total						17871.00

Info Type Details for RoDTEP Scheme

Inv No	Item No	Info Type	Info Qfr	Info Code	Info Text	Qty/Unit
1	1	DTY	RDT	RODTEPY	Claimed	8400.400000/KGS

Statement Details

Inv No	Item No	Statement Type	Statement Code
1	1	DEC	RD001

eSANCHIT (Supporting Documents) Details

Inv. No - Item No	: 0 - 0	Issuing Party Details	
Dec. No & Date	:	CORAL LABORATORIES LIMITED	
Dec. Type	: B	.	
CHA License No	: AAKCS2074FCH001	.	
IEC	: 0394033353	.	
IRN No	: 2025072200043479	.	
Document Type	: 022C01	Beneficiary Details	
Document No.	: NON HAZ DECLERATI	.	
Place of Issue	: JNPT	.	
Issued Date	: 22/07/2025	.	
Expiry Date	:	.	
File Type	: PDF	.	
ICEGATE ID	: SICLMUMBAI	.	

Handwritten:
25/7/25

Handwritten:
25/7/25

Inv. No - Item No : 0 - 0
Dec. No & Date :
Dec. Type : B
CHA License No : AAKCS2074FCH001
IEC : 0394033353
IRN No : 2025072200044197
Document Type : 022CO1
Document No. : PRODUCT LIST
Place of Issue : JNPT
Issued Date : 22/07/2025
Expiry Date :
File Type : PDF
ICEGATE ID : SICLMUMBAI

Issuing Party Details
CORAL LABORATORIES LIMITED

Beneficiary Details

Inv. No - Item No : 1 - 0
Dec. No & Date :
Dec. Type : B
CHA License No : AAKCS2074FCH001
IEC : 0394033353
IRN No : 2025072200043476
Document Type : 001000
Document No. : M-28/25-26
Place of Issue : MUMBAI
Issued Date : 22/07/2025
Expiry Date :
File Type : PDF
ICEGATE ID : SICLMUMBAI

Issuing Party Details
CORAL LABORATORIES LIMITED
SHED NO. 3B, PATANWALA COMPOUND
OPP SHREYAS,, LBS MARG, GHATKOPAR
W
MUMBAI - 400086

Beneficiary Details
ASAL PHARMA CO (APHCO)
BAKARO MEDICINE MARKET,
MOGADISHU SOMALIA

Inv. No - Item No : 1 - 0
Dec. No & Date :
Dec. Type : B
CHA License No : AAKCS2074FCH001
IEC : 0394033353
IRN No : 2025072200043477
Document Type : 934000
Document No. : M-28/25-26
Place of Issue : MUMBAI
Issued Date : 22/07/2025
Expiry Date :
File Type : PDF
ICEGATE ID : SICLMUMBAI

Issuing Party Details
CORAL LABORATORIES LIMITED
SHED NO. 3B, PATANWALA COMPOUND
OPP SHREYAS,, LBS MARG, GHATKOPAR
W
MUMBAI - 400086

Beneficiary Details
ASAL PHARMA CO (APHCO)
BAKARO MEDICINE MARKET,
MOGADISHU SOMALIA

Inv. No - Item No : 1 - 0
Dec. No & Date :
Dec. Type : B
CHA License No : AAKCS2074FCH001
IEC : 0394033353
IRN No : 2025072200043478
Document Type : 331000
Document No. : M-28/25-26
Place of Issue : MUMBAI
Issued Date : 22/07/2025
Expiry Date :
File Type : PDF
ICEGATE ID : SICLMUMBAI

Issuing Party Details
CORAL LABORATORIES LIMITED
SHED NO. 3B, PATANWALA COMPOUND
OPP SHREYAS,, LBS MARG, GHATKOPAR
W
MUMBAI - 400086

Beneficiary Details
ASAL PHARMA CO (APHCO)
BAKARO MEDICINE MARKET,
MOGADISHU SOMALIA

Handwritten signature
25/7/25

Handwritten signature
25/7/25

Inv. No - Item No	: 1 - 0	Issuing Party Details
Dec. No & Date	:	CORAL LABORATORIES LIMITED
Dec. Type	: B	SHED NO. 3B, PATANWALA COMPOUND
CHA License No	: AAKCS2074FCH001	OPP SHREYAS,, LBS MARG, GHATKOPAR
IEC	: 0394033353	W
IRN No	: 2025072200043480	MUMBAI - 400086
Document Type	: 271000	
Document No.	: M-28/25-26	Beneficiary Details
Place of Issue	: MUMBAI	ASAL PHARMA CO (APHCO)
Issued Date	: 22/07/2025	BAKARO MEDICINE MARKET,
Expiry Date	:	MOGADISHU SOMALIA
File Type	: PDF	
ICEGATE ID	: SICLMUMBAI	

Declaration for RoDTEP Scheme (RD001)

I/We, in regard to my/our claim under RoDTEP scheme made in this Shipping Bill or Bill of Export, hereby declare that:

1. I/ We undertake to abide by the provisions, including conditions, restrictions, exclusions and time-limits as provided under RoDTEP scheme, and relevant notifications, regulations, etc., as amended from time to time.
2. Any claim made in this shipping bill or bill of export is not with respect to any duties or taxes or levies which are exempted or remitted or credited under any other mechanism outside RoDTEP.
3. I/We undertake to preserve and make available relevant documents relating to the exported goods for the purposes of audit in the manner and for the time period prescribed in the Customs Audit Regulations,

I/We undertake to abide by the provisions of Foreign Exchange Management Act, 1999, as amended from time to time, including realisation or repatriation of foreign exchange to or from India from time to time.

I/We have declare that the particulars given herein are true and are correct

Signature of
Exporter / CHA with date

CORAL LABORATORIES LIMITED

AP
25/7/25

Sanjay
25/7/25

INVOICE

Exporter CORAL LABORATORIES LTD #3B PATANWALA INDL. ESTATE, OPP. SHREYAS CINEMA, NEXT TO FITNESS WORLD, GHATKOPAR(W), MUMBAI 400086 INDIA Ph-0091 22 25005245 Fax-0091 22 25004893		GST Invoice No. & Date M-28/25-26 22/07/2025	
Consignee ASAL PHARMA CO (APHCO) BAKARO MEDICINE MARKET, MOGADISHU SOMALIA		Buyer's Order No. & Date PROF. INV. NO. CLL/EXPROF/310/23-24 DTD. 26.02.2024	
		Other Reference(s) CLL/EXP/069/25-26 DATE: 21.07.2025	
Pre-carriage by MULTI MODEL TRANSPORT BY SEA		Buyer (if other than Consignee) ASAL PHARMA CO (APHCO) BAKARO MEDICINE MARKET MOGADISHU SOMALIA	
		Country of Origin of Goods INDIA	
Vessel/Flight No.		Country of Final Destination SOMALIA	
Port of Discharge MOGADISHU		Terms of Delivery and Payment CFR SEA MOGADISHU, SOMALIA 30% ADVANCE AND BALANCE BEFORE DISPATCH OF THE GOODS	
Place of Receipt by Pre-carrier		Final Destination SOMALIA	
Port of Loading NHAVA SHEVA, INDIA			
Marks & Nos./ Container No.			

Marks & Nos./ Container No.	No. & Kind of Pkgs.	S.No. Description of Goods	Unit Pack	Taxable Amt	IGST Rate	IGST AMT	Quantity	CFR Rate	FOB Rate	Amount	
								USD	USD		
ASAL PHARMA CO (APHCO) BAKARO MEDICINE MARKET, MOGADISHU SOMALIA.	1	MOXBRO FORTE SYRUP	1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20	
			Amoxicillin and Bromhexine Hydrochloride	1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
			Dry Suspension	1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20
			Composition:	1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
			Each 5 ml reconstituted suspension Contains:	1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20
			Amoxicillin Trihydrate BP equivalent to	1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
			Amoxicillin.....250 mg	1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20
			Bromhexine Hydrochloride BP.....8 mg	1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
			Excipients.....q.s.	1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20
			Colour : Sunset Yellow	1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
			H.S.Code :	1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20
				1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
				1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20
				1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
				1X100M	251215.20	12	30,145.82	4920	0.61	0.6000	3001.20
				1X100M	4084.80	12	490.18	80	0.61	0.6000	48.80
	30500.00										


Amount Chargeable (In words)

TOTAL NO. OF 420 CARTONS.
 01 - 41, 42, 43 - 83, 84, 85 - 125, 126, 127 - 167, 168,
 169 - 209, 210, 211 - 251, 252, 253 - 293, 294, 295 - 335,
 336, 337 - 377, 378, 379 - 419, 420.

FREIGHT: \$ 500.00
 27AAACC4421G1Z3 THIS EXPORT IS UNDER IGST TAX

Declaration:
 We declare that this Invoice shows actual price of the goods described and that all particulars are true and correct.

Sanjay
25/7/25


 Signature and Date
 For CORAL LABORATORIES LTD

INVOICE

Continuation Sheet

Exporter CORAL LABORATORIES LTD #3B PATANWALA INDL. ESTATE, OPP. SHREYAS CINEMA, NEXT TO FITNESS WORLD, GHATKOPAR (W), MUMBAI 400086 INDIA Ph-0091 22 25005245 Fax-0091 22 25004893	GST Invoice No. & Date M-28/25-26 22/07/2025 Buyer's Order No. & Date PROF. INV. NO. CLL/EXPROF/310/23-24 DTD. 26.02.2024 Other Reference(s)
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Marks & Nos./ Container No.	No. & Kind of Pkgs.	S.No.	Description of Goods	Unit Pack	Taxable Amt	IGST Rate	IGST AMT	Quantity	CFR Rate	FOB Rate	Amount
			Balance B/f....						USD		USD 30500.00
			RODTEP SCHEME We intend to avail the benefit of RODTEP scheme (Remission of Duties and Taxes on Exported Products)								
			DRAWBACK SCHEME We intend to claim Duty Drawback Scheme								
US DOLLARS THIRTY THOUSAND FIVE HUNDRED ONLY					Total	2553000.00	306360.00	CFR SEA MOGADISHU			30500.00

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Total IGST Amt : 306360.00

Declaration :

We declare that this Invoice shows actual price of the goods described and that all particulars are true and correct.

Signature and Date  For CORAL LABORATORIES LTD

PACKING LIST

Exporter CORAL LABORATORIES LTD #3B PATANWALA INDL. ESTATE, OPP. SHREYAS CINEMA, NEXT TO FITNESS WORLD, GHATKOPAR(W), MUMBAI 400086 INDIA Ph-0091 22 25005245 Fax-0091 22 25004893		GST Invoice No. & Date M-28/25-26 22/07/2025		I.E.C. Code : 0394033353	
		Buyer's Order No. & Date PROF. INV. NO. CLL/EXPROF/310/23-24 DTD.26.02.2024			
		Other Reference(s) CLL/EXP/069/25-26 DATE: 21.07.2025			
Consignee ASAL PHARMA CO(APHCO) BAKARO MEDICINE MARKET, MOGADISHU SOMALIA		Buyer(if other than Consignee) ASAL PHARMA CO(APHCO) BAKARO MEDICINE MARKET MOGADISHU SOMALIA			
		Country of Origin of Goods INDIA		Country of Final Destination SOMALIA	
		Terms of Delivery and Payment CFR SEA MOGADISHU, SOMALIA 30% ADVANCE AND BALANCE BEFORE DISPATCH OF THE GOODS			
		Pre-carriage by MULTI MODEL TRANSPORT BY SE.		Place of Receipt by Pre-carrier NHAVA SHEVA, INDIA	
Vessel/Flight No.		Port of Loading NHAVA SHEVA, INDIA			
Port of Discharge MOGADISHU		Final Destination SOMALIA			

Marks & Nos./ Container No.	No. & Kind of Pkgs.				Description of Goods				Quantity	
	PRODUCT NAME	CASE NOS.	TOTAL CASE	NO.OF CARTONS PER CASE	TOT.NW (KGS.)	TOT.GW (KGS.)	BATCH NO.	MFD DATE	EXPIRY DATE	TOTAL QTY (NOS.)
	MOXBRO FORTE SYRUP	01-41	41	120	826.15	923.32	UFM2501	03/2025	08/2027	4920
	Amoxicillin and Bromhexine Hydrochloride	42	01	80	13.89	16.26	UFM2501	03/2025	08/2027	80
	Dry Suspension	43-83	41	120	826.15	923.32	UFM2502	03/2025	08/2027	4920
	Composition:	84	01	80	13.89	16.26	UFM2502	03/2025	08/2027	80
	Each 5 ml reconstituted suspension Contains:	85-125	41	120	826.15	923.32	UFM2503	03/2025	08/2027	4920
	Amoxicillin Trihydrate BP equivalent to	126	01	80	13.89	16.26	UFM2503	03/2025	08/2027	80
	Amoxicillin.....250 mg	127-167	41	120	826.15	923.32	UFM2504	03/2025	08/2027	4920
	Bromhexine Hydrochloride BP.....8 mg	168	01	80	13.89	16.26	UFM2504	03/2025	08/2027	80
	Excipients.....q.s.	169-209	41	120	826.15	923.32	UFM2505	03/2025	08/2027	4920
	Colour : Sunset Yellow	210	01	80	13.89	16.26	UFM2505	03/2025	08/2027	80
	H.S.Code :	211-251	41	120	826.15	923.32	UFM2506	03/2025	08/2027	4920
		252	01	80	13.89	16.26	UFM2506	03/2025	08/2027	80
		253-293	41	120	826.15	923.32	UFM2507	03/2025	08/2027	4920
		294	01	80	13.89	16.26	UFM2507	03/2025	08/2027	80
		295-335	41	120	826.15	923.32	UFM2508	03/2025	08/2027	4920
		336	01	80	13.89	16.26	UFM2508	03/2025	08/2027	80
		337-377	41	120	826.15	923.32	UFM2509	03/2025	08/2027	4920
		378	01	80	13.89	16.26	UFM2509	03/2025	08/2027	80

TOTAL NO. OF 420 CARTONS.
 01 - 41, 42, 43 - 83, 84, 85 - 125, 126, 127 - 167, 168,
 169 - 209, 210, 211 - 251, 252, 253 - 293, 294, 295 - 335,
 336, 337 - 377, 378, 379 - 419, 420.

Signature
 25/7/25



For CORAL LABORATORIES LTD

PACKING LIST

Continuation Sheet

Exporter CORAL LABORATORIES LTD	GST Invoice No. & Date M-28/25-26 22/07/2025
Consignee ASAL PHARMA CO(APHCO) SOMALIA	Buyer's Order No. & Date PROF. INV. NO. CLL/EXPROF/310/23-24 DTD.26.02.2024
Other Reference(s) CLL/EXP/069/25-26 DATE: 21.07.2025	

Marks & Nos./ Container No.	No. & Kind of Pkgs.				Description of Goods				Quantity
	CASE NOS.	TOTAL CASE	NO.OF CARTONS PER CASE	TOT.NW (KGS.)	TOT.GW (KGS.)	BATCH NO.	MFD DATE	EXPIRY DATE	
PRODUCT NAME	379-419	41	120	826.15	923.32	UFM2510	03/2025	08/2027	TOTAL QTY (NOS.) 4920
	420	01	80	13.89	16.26	UFM2510 ✓	03/2025	08/2027	80

TOTAL GW 9395.80
TOTAL NW 8400.40

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Handwritten Signature: Sanjay
25/7/25



For CORAL LABORATORIES LTD

List of the product specified in Schedule C & C1 and excluding Schedule X to be manufactured at
M/S Coral Laboratories Ltd, Plot No- 27 & 28 , Pharmacy Dehradun Uttarakhand under
License No. 42/UA/SC/P-2006 on Form No. 28

S.NO	Generic Name	Composition	Date of Approval
20	Cefixime For Oral Suspension USP 100 MG/5ML	Composition: Each 5 ml of reconstituted suspension contains: Cefixime Trihydrate USP equivalent to anhydrous Cefixime : 100 mg Excipients: q.s.	13.06.2016 For Export
21	Cefixime Capsules 200 mg	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 200 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
22	Cefixime Capsules 200 mg CORXIME 200 CAPSULES	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 200 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
23	Cefixime Capsules 200 mg DORXIME 200 CAPSULES	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 200 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
24	Cefixime Capsules 400 mg	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 400 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
25	Cefixime Capsules 400 mg DORXIME 400 CAPSULES	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 400 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
26	Amoxicillin And Bromhexine Hydrochloride Suspension MOXBRO DRY SYRUP	Composition: Each 5 ml of reconstituted syrup contains Amoxicillin Trihydrate BP equivalent to Amoxicillin :125 mg Bromhexine Hydrochloride BP:4 mg Excipients: q.s. Colour: Erythrosine & Tartrazine	13.06.2016 For Export
27	Amoxicillin And Bromhexine Hydrochloride Dry Suspension MOXBRO FORTE SYRUP	Composition: Each 5 ml of reconstituted syrup contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin :250 mg Bromhexine Hydrochloride BP:8 mg Excipients: q.s. Colour: Sunset Yellow	13.06.2016 For Export
28	Cloxacillin Sodium For Oral Solution USP 125 mg/5 ml CLODAX DRY SYRUP	Composition: Each 5 ml of reconstituted syrup contains: Cloxacillin Sodium USP equivalent to Cloxacillin : 125 mg Colour: Sunset Yellow	13.06.2016 For Export

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28/7/25

Samay
28/7/25

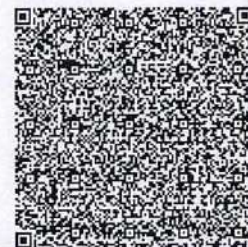


(Tajber Singh)
28/6/2021
Drug Controlling & Licensing Authority
Uttarakhand

Tax Invoice

e-Invoice

(SUPPLY MEANT FOR EXPORT/SUPPLY TO SEZ UNIT OR SEZ DEVELOPER FOR AUTHORISED OPERATIONS ON PAYMENT OF IGST)



IRN : 0106c655b22621804bf9a64cb021f5d8676d50a-c5482aca8b0088d9042c11654
 Ack No. : 122527736179150
 Ack Date : 22-Jul-25

CORAL LABS LTD MUMBAI (23-24)
 UDYAM : UDYAM-MH-19-0087134 (Medium)
 Company's GSTIN/UIN : 27AAACC4421G1Z3
 CIN: L24231MH1997PLC422233

Consignee (Ship to)
Asal Pharma CO (APHCO)
 Bakaro Medicine Market,
 Mogadishu

Buyer (Bill to)
Asal Pharma CO (APHCO)
 Bakaro Medicine Market,
 Mogadishu

Invoice No. M-28/25-26	Dated 22-Jul-25
Delivery Note	Mode/Terms of Payment 30% Adv and Balance Before Dispatch
Reference No. & Date. CLL/EXP/069/25-26 dt. 21-Jul-25	Other References CLL/EXP/069/25-26
Buyer's Order No.	Dated
Dispatch Doc No.	Delivery Note Date
Dispatched through	Destination Somalia
Country: Somalia	
Terms of Delivery CFR	

Sl No.	Description of Goods	HSN/SAC	Quantity	Rate	per	Disc. %	Amount
1	Moxbro Forte Syrup Hsn 30041030 UFM 2501 Batch : UFM 2501 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
2	Moxbro Forte Syrup Hsn 30041030 UFM 2502 Batch : UFM 2502 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
3	Moxbro Forte Syrup Hsn 30041030 UFM 2503 Batch : UFM 2503 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
4	Moxbro Forte Syrup Hsn 30041030 UFM 2504 Batch : UFM 2504 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
5	Moxbro Forte Syrup Hsn 30041030 UFM 2505 Batch : UFM 2505 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
6	Moxbro Forte Syrup Hsn 30041030 UFM 2506 Batch : UFM 2506 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00

continued ...

This is a Computer Generated Invoice

Handwritten signature and date: 25/7/25

Handwritten signature and date: 25/7/25

Tax Invoice(Page 2)

(SUPPLY MEANT FOR EXPORT/SUPPLY TO SEZ UNIT OR SEZ DEVELOPER FOR AUTHORISED OPERATIONS ON PAYMENT OF IGST)

CORAL LABS LTD MUMBAI (23-24)
 UDYAM : UDYAM-MH-19-0087134 (Medium)
 Company's GSTIN/UIN : **27AAACC4421G1Z3**
 CIN: L24231MH1997PLC422233

Invoice No. M-28/25-26	Dated 22-Jul-25
Delivery Note	Mode/Terms of Payment 30% Adv and Balance Before Dispatch
Reference No. & Date. CLL/EXP/069/25-26 dt. 21-Jul-25	Other References CLL/EXP/069/25-26
Buyer's Order No.	Dated
Dispatch Doc No.	Delivery Note Date
Dispatched through	Destination Somalia
Country: Somalia	
Terms of Delivery CFR	

Consignee (Ship to)
Asal Pharma CO (APHCO)
 Bakaro Medicine Market,
 Mogadishu

Buyer (Bill to)
Asal Pharma CO (APHCO)
 Bakaro Medicine Market,
 Mogadishu

SI No.	Description of Goods	HSN/SAC	Quantity	Rate	per	Disc. %	Amount
7	Moxbro Forte Syrup Hsn 30041030 UFM 2507 Batch : UFM 2507 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
8	Moxbro Forte Syrup Hsn 30041030 UFM 2508 Batch : UFM 2508 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
9	Moxbro Forte Syrup Hsn 30041030 UFM 2509 Batch : UFM 2509 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
10	Moxbro Forte Syrup Hsn 30041030 UFM 2510 Batch : UFM 2510 Mfg Dt.: Mar-2025 Expiry: 31-Aug-27	30041030	5,000 Nos 5,000 Nos	51.06	Nos		2,55,300.00
11	Freight -30041030	30041030					42,550.00
							25,95,550.00
	<i>Sales Output IGST @ 12%</i>						3,11,466.00
	Total		50,000 Nos				₹ 29,07,016.00

Amount Chargeable (in words) **INR Twenty Nine Lakh Seven Thousand Sixteen Only** E. & O.E

HSN/SAC	Taxable Value	IGST		Total
		Rate	Amount	Tax Amount
30041030	25,95,550.00	12%	3,11,466.00	3,11,466.00
Total	25,95,550.00		3,11,466.00	3,11,466.00

Tax Amount (in words) : **INR Three Lakh Eleven Thousand Four Hundred Sixty Six Only**

Remarks:
 Bill No. M-28/25-26 dt. 22.07.2025 CLL/EXP/069/25-26 for USD 30500 @ 85.10
 Company's GSTIN/UIN : **27AAACC4421G1Z3**
 Company's PAN/ IEC Code : **AAACC4421G**

Declaration
 We declare that this invoice shows the actual price of the goods described and that all particulars are true and correct.

for CORAL LABS LTD MUMBAI (23-24)

Authorised Signatory

This is a Computer Generated Invoice

Handwritten signature and date: 25/7/25

Handwritten signature and date: 25/7/25



CORAL LABORATORIES LTD.

PLOT NO27-28, SELAQUI-248011

REG.OFF.: 3B, PATANWALA COMPOUND, SHREYAS CINEMA, BESIDE FITNESS WORLD LBS MARG GHATKOPAR, MUMBAI-400086

Phone : 022-25005245, 25005246

Email : purchase@corallab.com Website : WWW.CORALLAB.COM

QUALITY CONTROL DEPARTMENT

Page 1 of 2

THE DRUG & COSMETIC ACT, 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP	A.R. No. : BLFP/319/24-25
Packing : 100ML	Rel. Dt. : 29-03-2025
Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	T.R. Slip No. : CLBPT24320
Product Code : MOXB11	T.R. Slip Dt. : 21-03-2025
Batch No. : UFM2501	Analysis Date : 29-03-2025
Actual Batch Size : 247.35 KG (5100 BOT)	
Packing Batch Size : 247.35 KG	
Sample Size : 12.000 BOT	
Released Qty : 247.350 KG (5100 BOT)	
Mfg. Dt. : 03/2025	
Exp. Dt. : 08/2027	
Test Packing : 12 BOT	
Mfg. Lic No. : 42/UA/SC/P-2006	
Country : SOMALIYA	
Test As Per : IHS	
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
	Location : DEHRADUN-UNIT1
	Make : CORAL

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5678 g Max = 48.7569 g	Not less than 48.5 g / 100 ml
5	pH	5.85	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.18 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	258.289 mg 103.32 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit: 225 mg to 300 mg Limit: 90 % to 120 %
8	ASSAY 2	8.159 mg 101.99 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	251.7mg 100.70%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit: NLT 200 mg

Conclusion : The above sample complies as per IHS
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By RAHUL KUMAR YADAV OFFICER	Checked By KHILAP SINGH ASST. MANAGER	Approved By UMESH CHANDRA ASST. MANAGER
---	---	---

FGANLCERTQA

28/7/25

25/7/25

CORAL LABORATORIES LTD.

PLOT NO27-28, SELAQUI-248011

REG.OFF.: 3B, PATANWALA COMPOUND, SHREYAS CINEMA, BESIDE FITNESS WORLD LBS MARG GHATKOPAR, MUMBAI-400086

Phone : 022-25005245, 25005246

Email : purchase@corallab.com Website : WWW.CORALLAB.COM

QUALITY CONTROL DEPARTMENT

Page 1 of 2

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

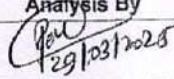
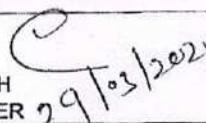
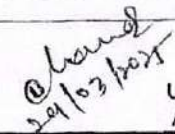
FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP Packing : 100ML Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	A.R. No. : BLFP/321/24-25 Rel. Dt. : 29-03-2025 T.R. Slip No. : CLBPT24322 T.R. Slip Dt. : 21-03-2025 Analysis Date : 29-03-2025
Product Code : MOXB11 Batch No. : UFM2503 Actual Batch Size : 247.35 KG (5100 BOT) Packing Batch Size : 247.35 KG Sample Size : 12.000 BOT Released Qty : 247.350 KG (5100 BOT)	Mfg. Dt. : 03/2025 Exp. Dt. : 08/2027 Test Packing : 12 BOT Mfg. Lic No. : 42/UA/SC/P-2006 Country : SOMALIYA Test As Per : IHS
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
Location : DEHRADUN-UNIT1 Make : CORAL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5687 g Max = 48.6368 g	Not less than 48.5 g / 100 ml
5	pH	5.86	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.18 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	258.594 mg 103.44 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : 225 mg to 300 mg Limit : 90 % to 120 %
8	ASSAY 2	8.030 mg 100.38 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	252.76mg 101.10%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : NLT 200 mg

Conclusion : The above sample complies as per IHS

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By  RAHUL KUMAR YADAV OFFICER	Checked By  KHILAP SINGH ASST. MANAGER	Approved By  UMESH CHANDRA ASST. MANAGER
---	--	---

FGANLCERTQA

Handwritten: 25/7/25

Handwritten: Sanjay 25/7/25

CORAL LABORATORIES LTD.

PLOT NO27-28, SELAQUI-248011

REG.OFF.: 3B, PATANWALA COMPOUND, SHREYAS CINEMA, BESIDE FITNESS WORLD LBS MARG GHATKOPAR, MUMBAI-400086

Phone : 022-25005245, 25005246

Email : purchase@corallab.com Website : WWW.CORALLAB.COM

QUALITY CONTROL DEPARTMENT

Page 1 of 2

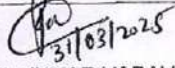
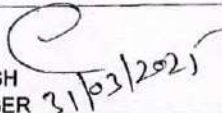
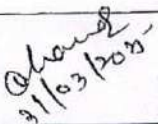
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP Packing : 100ML Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION Product Code : MOXB11 Batch No. : UFM2504 Actual Batch Size : 247.35 KG (5100 BOT) Packing Batch Size : 247.35 KG Sample Size : 12.000 BOT Released Qty : 247.350 KG (5100 BOT)	A.R. No. : BLFP/322/24-25 Rel. Dt. : 31-03-2025 T.R. Slip No. : CLBPT24323 T.R. Slip Dt. : 22-03-2025 Analysis Date : 31-03-2025
Mfg. Dt. : 03/2025 Exp. Dt. : 08/2027 Test Packing : 12 BOT Mfg. Lic No. : 42/JA/SC/P-2006 Country : SOMALIYA Test As Per : IHS	
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
Location : DEHRADUN-UNIT1 Make : CORAL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5579 g Max = 48.6678 g	Not less than 48.5 g / 100 ml
5	pH	5.89	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.18 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	253.069 mg 101.23 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : 225 mg to 300 mg Limit : 90 % to 120 %
8	ASSAY 2	8.0 mg 100.0 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	249.49mg 99.80%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : NLT 200 mg

Conclusion : The above sample complies as per IHS
 In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By  RAHUL KUMAR YADAV OFFICER	Checked By  KHILAP SINGH ASST. MANAGER	Approved By  UMESH CHANDRA ASST. MANAGER
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CORAL LABORATORIES LTD.

PLOT NO27-28, SELAQUI-248011

REG.OFF.: 3B, PATANWALA COMPOUND, SHREYAS CINEMA, BESIDE FITNESS WORLD LBS MARG GHATKOPAR, MUMBAI-400086

Phone : 022-25005245, 25005246

Email : purchase@corallab.com Website : WWW.CORALLAB.COM

QUALITY CONTROL DEPARTMENT

Page 1 of 2

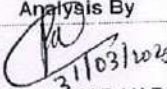
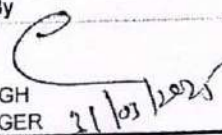
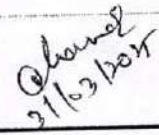
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP Packing : 100ML Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	A.R. No. : BLFP/323/24-25 Rel. Dt. : 31-03-2025 T.R. Slip No. : CLBPT24324 T.R. Slip Dt. : 22-03-2025 Analysis Date : 31-03-2025
Product Code : MOXB11 Batch No. : UFM2505 Actual Batch Size : 247.35 KG (5100 BOT) Packing Batch Size : 247.35 KG Sample Size : 12.000 BOT Released Qty : 247.350 KG (5100 BOT)	Mfg. Dt. : 03/2025 Exp. Dt. : 08/2027 Test Packing : 12 BOT Mfg. Lic No. : 42/UA/SC/P-2006 Country : SOMALIYA Test As Per : IHS
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
Location : DEHRADUN-UNIT1 Make : CORAL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5873 g Max = 48.6763 g	Not less than 48.5 g / 100 ml
5	pH	5.90	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.17 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	250.957 g 100.38 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : 225 mg to 300 mg Limit : 90 % to 120 %
8	ASSAY 2	7.982 mg 99.78 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	244.92mg 97.97%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : NLT 200 mg

Conclusion : The above sample complies as per IHS
 In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By  RAHUL KUMAR YADAV OFFICER	Checked By  KHILAP SINGH ASST. MANAGER	Approved By  UMESH CHANDRA ASST. MANAGER
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Page 1 of 2

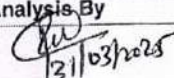
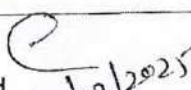
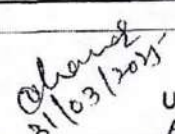
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP Packing : 100ML Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	A.R. No. : BLFP/324/24-25 Rel. Dt. : 31-03-2025 T.R. Slip No. : CLBPT24325 T.R. Slip Dt. : 22-03-2025 Analysis Date : 31-03-2025
Product Code : MOXB11 Batch No. : UFM2506 Actual Batch Size : 247.35 KG (5100 BOT) Packing Batch Size : 247.35 KG Sample Size : 12.000 BOT Released Qty : 247.350 KG (5100 BOT)	Mfg. Dt. : 03/2025 Exp. Dt. : 08/2027 Test Packing : 12 BOT Mfg. Lic No. : 42/UA/SC/P-2006 Country : SOMALIYA Test As Per : IHS
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
Location : DEHRADUN-UNIT1 Make : CORAL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5589 g Max = 48.6673 g	Not less than 48.5 g / 100 ml
5	pH	5.80	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.18 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	255.573 mg 102.23 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit: 225 mg to 300 mg Limit: 90 % to 120 %
8	ASSAY 2	8.079 mg 100.99 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	250.61mg 100.24%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit: NLT 200 mg

Conclusion : The above sample complies as per IHS
 In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By  RAHUL KUMAR YADAV OFFICER	Checked By  KHILAP SINGH ASST. MANAGER	Approved By  UMESH CHANDRA ASST. MANAGER
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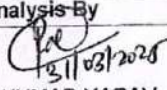
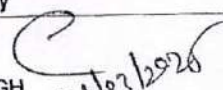
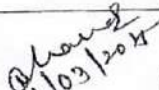
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP Packing : 100ML Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	A.R. No. : BLFP/325/24-25 Rel. Dt. : 31-03-2025 T.R. Slip No. : CLBPT24326 T.R. Slip Dt. : 22-03-2025 Analysis Date : 31-03-2025
Product Code : MOXB11 Batch No. : UFM2507 Actual Batch Size : 247.35 KG (5100 BOT) Packing Batch Size : 247.35 KG Sample Size : 12.000 BOT Released Qty : 247.350 KG (5100 BOT)	Mfg. Dt. : 03/2025 Exp. Dt. : 08/2027 Test Packing : 12 BOT Mfg. Lic No. : 42/UA/SC/P-2006 Country : SOMALIYA Test As Per : IHS
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
Location : DEHRADUN-UNIT1 Make : CORAL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5562 g Max = 48.6573 g	Not less than 48.5 g / 100 ml
5	pH	5.92	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.17 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	248.832 mg 99.53 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : 225 mg to 300 mg Limit : 90 % to 120 %
8	ASSAY 2	8.067 mg 100.84 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	245.62mg 98.25%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : NLT 200 mg

Conclusion : The above sample complies as per IHS
 In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By  RAHUL KUMAR YADAV OFFICER	Checked By  KHILAP SINGH ASST. MANAGER	Approved By  UMESH CHANDRA ASST. MANAGER
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REG.OFF.: 3B , PATANWALA COMPOUND, SHREYAS CINEMA, BESIDE FITNESS WORLD LBS MARG GHATKOPAR, MUMBAI-400086

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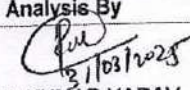
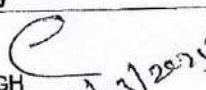
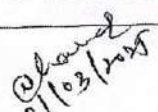
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP Packing : 100ML Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION Product Code : MOXB11 Batch No. : UFM2508 Actual Batch Size : 247.35 KG (5100 BOT) Packing Batch Size : 247.35 KG Sample Size : 12.000 BOT Released Qty : 247.350 KG (5100 BOT)	A.R. No. : BLFP/326/24-25 Rel. Dt. : 31-03-2025 T.R. Slip No. : CLBPT24327 T.R. Slip Dt. : 24-03-2025 Analysis Date : 31-03-2025
Mfg. Dt. : 03/2025 Exp. Dt. : 08/2027 Test Packing : 12 BOT Mfg. Lic No. : 42/UA/SC/P-2006 Country : SOMALIYA Test As Per : IHS	
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
Location : DEHRADUN-UNIT1 Make : CORAL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochlorido (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5648 g Max = 48.6670 g	Not less than 48.5 g / 100 ml
5	pH	5.90	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.18 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	249.994 mg 100.0 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : 225 mg to 300 mg Limit : 90 % to 120 %
8	ASSAY 2	8.019 mg 100.24 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	244.94mg 97.98%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : NLT 200 mg

Conclusion : The above sample complies as per IHS
 In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By  RAHUL KUMAR YADAV OFFICER	Checked By  KHILAP SINGH ASST. MANAGER	Approved By  UMESH CHANDRA ASST. MANAGER
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Handwritten: 25/7/25

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CORAL LABORATORIES LTD.

PLOT NO27-28, SELAQUI-248011

REG.OFF.: 3B, PATANWALA COMPOUND, SHREYAS CINEMA, BESIDE FITNESS WORLD LBS MARG GHATKOPAR, MUMBAI-400086

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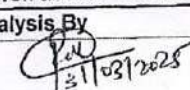
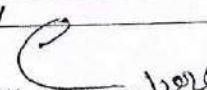
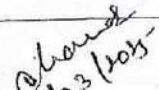
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP Packing : 100ML Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	A.R. No. : BLFP/327/24-25 Rel. Dt. : 31-03-2025 T.R. Slip No. : CLBPT24328 T.R. Slip Dt. : 24-03-2025 Analysis Date : 31-03-2025
Product Code : MOXB11 Batch No. : UFM2509 Actual Batch Size : 247.35 KG (5100 BOT) Packing Batch Size : 247.35 KG Sample Size : 12.000 BOT Released Qty : 247.350 KG (5100 BOT)	Mfg. Dt. : 03/2025 Exp. Dt. : 08/2027 Test Packing : 12 BOT Mfg. Lic No. : 42/UA/SC/P-2006 Country : SOMALIYA Test As Per : IHS
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
Location : DEHRADUN-UNIT1 Make : CORAL	

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5673 g Max = 48.6578 g	Not less than 48.5 g / 100 ml
5	pH	5.94	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.17 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	256.367 mg 102.55 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit: 225 mg to 300 mg Limit: 90 % to 120 %
8	ASSAY 2	7.893 mg 98.66 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	252.85mg 101.14%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit: NLT 200 mg

Conclusion : The above sample complies as per IHS
 In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By  RAHUL KUMAR YADAV OFFICER	Checked By  KHILAP SINGH ASST. MANAGER	Approved By  UMESH CHANDRA ASST. MANAGER
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QUALITY CONTROL DEPARTMENT

Page 1 of 2

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP	A.R. No. : BLFP/328/24-25
Packing : 100ML	Rel. Dt. : 31-03-2025
Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	T.R. Slip No. : CLBPT24329
Product Code : MOXB11	T.R. Slip Dt. : 24-03-2025
Batch No. : UFM2510	Analysis Date : 31-03-2025
Actual Batch Size : 247.35 KG (5100 BOT)	Mfg. Dt. : 03/2025
Packing Batch Size : 247.35 KG	Exp. Dt. : 08/2027
Sample Size : 12.000 BOT	Test Packing : 12 BOT
Released Qty : 247.350 KG (5100 BOT)	Mfg. Lic No. : 42/UA/SC/P-2006
	Country : SOMALIYA
	Test As Per : IHS
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	
	Location : DEHRADUN-UNIT1
	Make : CORAL

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5609 g Max = 48.6673 g	Not less than 48.5 g / 100 ml
5	pH	5.89	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.17 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	253.942 mg 101.58 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : 225 mg to 300 mg Limit : 90 % to 120 %
8	ASSAY 2	7.893 mg 98.66 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	247.80mg 99.12%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : NLT 200 mg

Conclusion : The above sample complies as per IHS

In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By 31/03/2025 RAHUL KUMAR YADAV OFFICER	Checked By 31/03/2025 KHILAP SINGH ASST. MANAGER	Approved By 31/03/2025 UMESH CHANDRA ASST. MANAGER
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FGANLCERTQA

28/7/25

Sanidya 25/7/25



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THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : MOXBRO FORTE SYRUP	A.R. No. : BLFP/320/24-25
Packing : 100ML	Rel. Dt. : 29-03-2025
Generic Name : AMOXICILLIN AND BROMHEXINE HYDROCHLORIDE DRY SUSPENSION	T.R. Slip No. : CLBPT24321
Product Code : MOXB11	T.R. Slip Dt. : 21-03-2025
Batch No. : UFM2502	Analysis Date : 29-03-2025
Actual Batch Size : 247.35 KG (5100 BOT)	Mfg. Dt. : 03/2025
Packing Batch Size : 247.35 KG	Exp. Dt. : 08/2027
Sample Size : 12.000 BOT	Test Packing : 12 BOT
Released Qty : 247.350 KG (5100 BOT)	Mfg. Lic No. : 42/UA/SC/P-2006
	Country : SOMALIYA
	Test As Per : IHS
Remarks : 10 Bottles for QC Department + 02 Bottles for Micro Department	Location : DEHRADUN-UNIT1
	Make : CORAL

Sr.	Test	Result	Specification
1	DESCRIPTION	A light orange coloured powder after addition of water gives a orange coloured Suspension	A light orange coloured powder after addition of water gives a orange coloured Suspension
2	IDENTIFICATION	Complies	Amoxicillin Trihydrate:(ByTLC) The Rf value of the principal spot obtained from the test solution corresponds to that of the standard solution.
3	IDENTIFICATION B	Complies	Bromhexine Hydrochloride (Red Colour develops.)
4	UNIFORMITY OF WEIGHT	Min = 48.5848 g Max = 48.7562 g	Not less than 48.5 g / 100 ml
5	pH	5.87	Limit: 4.5 to 7.0
6	SPECIFIC GRAVITY	1.17 g/ml	Limit: 1.10 to 1.20 g/ml
7	ASSAY	267.177 mg 102.87 %	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : 225 mg to 300 mg Limit : 90 % to 120 %
8	ASSAY 2	8.211 mg 102.64 %	Each 5ml of reconstituted suspension contains Bromhexine Hydrochloride BP - 8 mg Limit: 7.2 mg to 9.6 mg Limit: 90 % to 120 %
9	STABILITY OF SUSPENSION (AFTER 7 DAYS)	250.91mg 100.36%	Each 5ml of reconstituted suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin - 250 mg Limit : NLT 200 mg

Conclusion : The above sample complies as per IHS
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

Analysis By RAHUL KUMAR YADAV OFFICER	Checked By KHILAP SINGH ASST. MANAGER	Approved By UMESH CHANDRA ASST. MANAGER
---	---	---

FGANLCERTQA

29/3/25

29/3/25




CORAL LABORATORIES LTD



CORP. OFFICE : #3B, Patanwala Compound, Opp. Shreyas Cinema, L.B.S. Marg, Ghatkopar (West), Mumbai - 400 086, India
 Tel. : +91-22-2500 5245, 2500 8208, 2500 5246 • Fax : +91-22-2500 4893 • E-mail : exports@corallab.com • Website : www.corallab.com

CIN NO. XXXXXXXXXXXXXXXXXXXXXXXX
 L24231MH1997PLC422233

NON-HAZARDOUS CERTIFICATE

BL No.:	Port of Departure: NHAVA SHEVA, INDIA	Port of Destination: MOGADISHU, SOMALIA
<p>This is to certify that the articles substances of this shipment are properly described by name, that they are not listed in the current edition of IMDG. Dangerous Goods Regulations (DGR). Alphabetical List of Dangerous Goods nor do they correspond to any of the hazardous classes appearing in the DGR. Section 3 Classification of Dangerous Goods and that <u>they are known to be not dangerous i.e. not restricted.</u></p>		
Marks and Number of Packages	Proper Description of Goods (Trade Names not Permitted) Specify each articles separately	Net Quantity
ASAL PHARMA CO (APHCO) BAKARO MEDICINE MARKET, MOGADISHU SOMALIA.	MEDICINES MOXBRO FORTE SYRUP	QTY- 50,000 (1X100ML)
TOTAL NO OF CARTONS: 420 CARTONS	GROSS WT: 9395.80 KGS NET WT: 8400.40 KGS	
	CORAL LABORATORIES LIMITED DESIGNATION: EXPORT ASSISTANT SIGNATURE: 	

Handwritten signature
25/7/25

Handwritten signature
25/7/25

STAR INDIA CONTAINER LINE PVT. LTD.
Shipping Bill Checklist

Job No : 651 Date : 21/07/2025
Reference No : CL/E/S/000651/25-2 EDI No : 651
CHA : AAKCS2074FCH001 Name : STAR INDIA CONTAINER LINE PVT. LTD.
SB No & Date : 3766710 22/07/2025 State : MAHARASHTRA
Printed on : 22/07/2025 Time : 13:11:37

Exporter Details

0394033353(5) PAN :AAACC4421G
CORAL LABORATORIES LIMITED
SHED NO. 3B, PATANWALA COMPOUND
OPP SHREYAS,, LBS MARG, GHATKOPAR W
MUMBAI - 400086
MAHARASHTRA

Consignee Details

ASAL PHARMA CO (APHCO)
BAKARO MEDICINE MARKET,
MOGADISHU SOMALIA
. .
SOMAALIA

AD Code : 0510002 A/C No :
IFSC Code :
Exporter type : MANUFACTURER
GSTIN Type : GSN GSTIN :27AAACC4421G1
NFEI Category : RBI Waiver No :
Port of Loading : NHAVA SHEVA SEA (INNSA1)
Discharge Port : MOGADISHU (SOMGQ) Date :
Port of Destination : MOGADISHU (SOMGQ)
Destination Country : SOMAALIA (SO)
Discharge Country : SOMAALIA (SO)
Gross weight : **9395.800 KGS** Net Weight : **8400.400 K**
Total Packages : **420 CTN** Loose Packets :
Nature of Cargo : C No. of Containers :
Factory Stuffed : NO Sample :NO
MAWB Number : HAWB Number :
Rotation Number : Rotation Date :
Gateway Port : Transhipper Code :
Custodian :
Forex Bank A/c : Warehouse Code :
FOB Value : 2553000.00 Drawback A/c No :

Marks & Nos

AS PER INV, WE INTEND TO CLAIM BENEFIT UNDER RODTEP FOR AI
PRODUCTS (REMISSION OF DUTIES AND TAXES ON EXPORTED PRODUCTS) UNDER IGST

Handwritten: 25/7/25

Handwritten: 25/7/25



कार्यालय प्रधान आयुक्त, सीमाशुल्क (सामान्य), नवीन सीमाशुल्क भवन, बलार्ड एस्टेट, मुंबई-400001
 OFFICE OF THE PRINCIPAL COMMISSIONER OF CUSTOMS (GENERAL), NEW CUSTOM HOUSE, BALLARD ESTATE,
 MUMBAI-400001

e-mail: cbsec.nch@gov.in

Phone no: 022-22757891



FORM-G

[see sub-regulation (5) of regulation 13]

Identity Card

CARD NO. 791/2020

Valid upto 30-09-2025

Shri/Ms. SANJAY YASHWANT JADHAV having been registered in the books of this office as an authorised an Employee of Shri/Sarvashri/Ms./ M/s STAR INDIA CONTAINER LINE PVT LTD having been authorized by him/them to transact business at the Mumbai Custom House on his/their behalf is hereby permitted to do so from 01.10.2020 until the cancellation/ expiry of the license issued to his principal, whichever is earlier.

He/She has passed the examination conducted under sub-regulation (5) of regulation 13 of the Customs Brokers Licensing Regulations 2018.

Specimen signature of employee:

Permanent Account No. (PAN) of employee:

AGBPJ6365Q

Name of the Customs Broker:

STAR INDIA CONTAINER LINE PVT LTD

Customs Broker Licence No.:

AAKCS2074FCH001 [11/2602]

Customs station:

MUMBAI

Dated:

01.10.2020



Signature of the Deputy/Assistant Commissioner of Customs

1. यह कार्ड अंतरणीय नहीं है और इसे मुंबई सीमा शुल्क के किसी भी कर्मचारी द्वारा मांगे जाने पर प्रस्तुत किया जाना चाहिए।
2. यह कार्ड सीबीएलआर 2018 के विनियमन 13(5) के तहत सीमाशुल्क ब्रोकर के मालिक/भागीदार/निदेशक/कर्मचारी को जारी किया गया है जिसका नाम कार्ड के मुखपृष्ठ पर उल्लिखित है।
3. यह कार्ड मुंबई सीमा शुल्क क्षेत्र में सीमा शुल्क निकासी कार्य करने के लिए मान्य है।
4. इस कार्ड का उपयोग किसी अन्य उद्देश्य के लिए नहीं किया जाना चाहिए।
5. इस कार्ड को सीमा शुल्क क्षेत्र के अंदर हर समय पहना और प्रदर्शित किया जाना चाहिए।
6. जब यह कार्ड किसी भी कारण से अमान्य हो जाता है, तो इसे जारी करने वाले प्राधिकारी को तत्काल वापस किया जाना चाहिए।
7. इस कार्ड के खो जाने/मिलने की सूचना नियंत्रण कक्ष, नवीन सीमाशुल्क भवन, बलार्ड एस्टेट, मुंबई (फोन: 022-22757575 (24 घंटे)) या निकटतम पुलिस स्टेशन में तुरंत दें।

1. This card is non-transferrable and should be produced on demand by any employee of Mumbai Customs.
2. This card has been issued under Regulation 13(5) of CBLR 2018 to the Proprietor/Partner/Director/Employee of Custom Broker whose name is mentioned on the face of the card.
3. This card is only valid for transacting Customs clearance work in Mumbai Customs Zones.
4. This card should not be used for any other purpose.
5. This card should be worn and displayed at all times inside Customs Area.
6. When this card ceases to be valid for any reason, it should be returned to the issuing authority.
7. If this card is lost/found by anyone, it should be immediately be informed/returned to the Control room, New Custom House, Ballard Estate, Mumbai. Phone - 022-22757575 (24 hrs.) or to the nearest Police Station.

9870345670



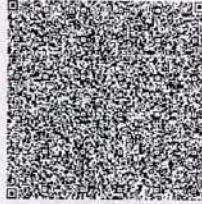
भारत सरकार
Government of India

भारतीय विशिष्ट ओळख प्राधिकरण
Unique Identification Authority of India

नोंदणी क्रमांक:/ Enrolment No.: 0658/00412/01096

To
संजय यशवंत जाधव
Sanjay Yashwant Jadhav
102, Namrata CHS
Opp Rayan International School
Plot No-73-C, Sector-11
Kharghar
Raigad Maharashtra - 410210
9870345670

Validity unknown
DIGITAL SIGNATURE
CERTIFICATE
AUTHORITY
Date: 2021/08/11 11:34:07
UTC



आपला आधार क्रमांक / Your Aadhaar No. :

3493 8006 9687

VID : 9126 6821 1947 7731

माझे आधार, माझी ओळख



भारत सरकार
Government of India



संजय यशवंत जाधव
Sanjay Yashwant Jadhav
जन्म तारीख/DOB: 03/08/1973
पुरुष/ MALE

Issue Date: 09/01/2012

3493 8006 9687

VID : 9126 6821 1947 7731

माझे आधार, माझी ओळख



Government of India



माहिती / INFORMATION

- आधार हा ओळखीचा पुरावा आहे, नागरिकत्वाचा नाही.
- आधार अद्वितीय आणि सुरक्षित आहे.
- सुरक्षित QR कोड/ ऑफलाइन XML/ ऑनलाइन प्रमाणीकरण वापरून ओळख सत्यापित करा.
- आधार कार्ड, पीव्हीसी कार्ड्स, ईआधार आणि mAadhaar सारखे आधारचे सर्व प्रकार तितकेच वैध आहेत. १२ अंकी आधार क्रमांकाच्या जागी क्वच्युअल आधार ओळख (VID) देखील वापरली जाऊ शकते.
- 10 वर्षांतून एकदा तरी आधार अपडेट करा.
- आधार तुम्हाला विविध सरकारी आणि गैर-सरकारी लाभ/सेवांचा लाभ घेण्यास मदत करते.
- आधारमध्ये तुमचा मोबाईल नंबर आणि ईमेल आयडी अपडेट ठेवा.
- आधार सेवांचा लाभ घेण्यासाठी स्मार्टफोनवर mAadhaar ॲप डाउनलोड करा.
- सुरक्षितता सुनिश्चित करण्यासाठी लॉक/अनलॉक बायोमेट्रिक्स/आधार या वैशिष्ट्यांचा वापर करा.
- आधारची मागणी करणाऱ्या योग्य संमती संस्थानी शोध घेणे बंधनकारक आहे.
- Aadhaar is a proof of identity, not of citizenship.
- Aadhaar is unique and secure.
- Verify identity using secure QR code/offline XML/online Authentication.
- All forms of Aadhaar like Aadhaar letter, PVC Cards, eAadhaar and mAadhaar are equally valid. Virtual Aadhaar Identity (VID) can also be used in place of 12 digit Aadhaar number.
- Update Aadhaar at least once in 10 years.
- Aadhaar helps you avail various Government and Non-Government benefits/services.
- Keep your mobile number and email id updated in Aadhaar.
- Download mAadhaar app on smart phones to avail Aadhaar Services.
- Use the feature of lock/unlock Aadhaar/biometrics to ensure security.
- Entities seeking Aadhaar are obligated to seek due consent.



भारतीय विशिष्ट ओळख प्राधिकरण
Unique Identification Authority of India

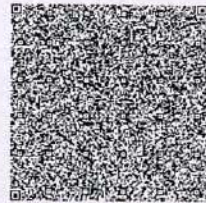


पत्ता:

१०२, नम्रता को.ओ.हो.सी, रायन इंटरनॅशनल स्कूल समोर,
प्लॉट नं-७३-सी, सेक्टर-११, खारघर, रायगड,
महाराष्ट्र - 410210

Address:

102, Namrata CHS, Opp Rayan International
School, Plot No-73-C, Sector-11, Kharghar,
Raigad,
Maharashtra - 410210



3493 8006 9687

VID : 9126 6821 1947 7731

1947

help@uidai.gov.in

www.uidai.gov.in

Handwritten signature and number:
3493 8006 9687
9870345670


 भारत सरकार
 Government of India




 मयंक चेतन कातिरा
Mayank Chetan Katira
 जन्म तारीख / DOB: 16/03/1995
 पुरुष / Male

9216 7557 8588

मेरा आधार, मेरी महत्ता

*Check
25/07/25*


 भारत सरकार
 Unique Identification Authority of India



मया: नारायण अपार्टमेंट ए विंग रूम नं. 506 / 5 फ्लोर,
 पाडवेल नगर फेकल्लकवा, प्राय परमेश्वर मंदिर जवळ, ठाणे
 पिन: ठाणे, ठाणे, महाराष्ट्र, 400604

Address: Nairaj Apartment A Wing Room
 No. 506 / 5th Floor, Padwal Nagar
 Checknaka, Near Panch Parmeshwar
 Temple, Thane - west, Thane, Thane
 Maharashtra, 400604

9216 7557 8588

1947 help@uidai.gov.in www.uidai.gov.in

भारत सरकार
Government of India

प्रभाकर नगा पाटील
Prabhakar Naga Patil

जन्म तारीख / DOB: 04/03/1970
पुरुष / Male

8888 3073 1299

आधार - सामान्य माणसाचा अधिकार

भारत सरकार
Unique Identification Authority of India

पत्ता: S/O: नगा पाटील घर क्र-181
बंदर भाडी, मु.कडवे पोस्ट, जिल्हा,
सा.पेण, जिल्हा-रायगड, कडवने, जिल्हा,
रायगड, महाराष्ट्र, 402107

Address: S/O: Naga Patil, house No-181,
Bander Av, A-Kadve, Post-Kadve-Tal-Phen,
Dist-Rayga, Karna, Jaha Raygarh,
Maharashtra 402107

8888 3073 1299

1947
1800 301 1947

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http://www.uidai.gov.in

UIDAI
www.uidai.gov.in

Prabhakar Naga Patil

no. 9270000441

भारत सरकार
Government of India

संजय काशिनार्थ भगत
Sanjay Kashinath Bhagat
जन्म तिथि/DOB: 22/12/1990
पुरुष/ MALE
Mobile No. 9082586715

2770 8839 5756
VID : 9151 2648 1058 8334

माझे आधार, माझी ओळख

भारतीय विशिष्ट ओळख प्राधिकरण
Unique Identification Authority of India


पत्ता:
S/O. काशिनार्थ भगत, आबरे, अहमरे, रायगड,
महाराष्ट्र - 410206

Address
S/O. Kashinath Bhagat, VTC, Aware, PO: Awre,
Sub District: Uran, District Raigam, State
Maharashtra, PIN Code: 410206.

2770 8839 5756

1947 | help@uidai.gov.in | www.uidai.gov.in

Sanjay
काशिनार्थ
9082586715

	आयुक्त सीमाशुल्क का कार्यालय (निवारक) OFFICE OF THE COMMISSIONER OF CUSTOMS (PREVENTIVE) त. एवं आ. विभाग, 11 वा तल, नवीन सीमा शुल्क भवन, Nhava Sheva Preventive Unit, न्हावा शेवा निवारक इकाई, R&I DIVISION, 11TH FLOOR, NEW CUSTOM HOUSE, बेल्लार्ड एस्टेट, मुंबई - 400001 BALLARD ESTATE, MUMBAI - 400 001 Email: nspuri.prev-mum@gov.in

DIN: 2025077900000222BB4 Date: 25-07-2025

Hold No. 09/2025-26 NSPU(R&I)

To,
 The Shed Manager (Operations),
 M/s Conex Terminal Pvt. Ltd.
 Nhava Sheva, Raigarh

Gentleman,

Sub: - Hold of consignment exported by M/s Coral Laboratories Limited (IEC-0394033353) lying at M/s Conex Terminal Pvt. Ltd., CFS - reg.

This office is investigating a case of export in respect of the consignment bearing shipping number 3766710 dated 22.07.2025.

- The above said consignment is to be put on hold immediately until further orders. The consignment should also be placed under CCTV surveillance.
- It is also directed that opening, examining, dispensing and clearing of the goods contained in above said consignment should not be allowed without prior permission of this office in writing.
- This issues with the approval of Commissioner of Customs (Preventive).

Digitally signed by
 Naresh Kumar Tiwari
 Date: 25-07-2025
 13:03:59

(Naresh Kr. Tiwari)
 Deputy Commissioner of Customs
 NSPU/R&I

Copy to:

- The DC/AC Export Docks, M/s. Conex Terminal Pvt. Ltd.

P1
 25/7/25

P2
 25/7/25

CHA
 25/7/25

Exporter
 25/7/25

RE: Examination letter dated 25.07.2025 for consignment bearing shipping no. 3766710 dated 22.07.2025.

2 emails

<log@corallab.com >

Tue, 29 Jul 2025 1:51:31 PM +0530

To ""NSPU R I Customs"<nspuri.prev-mum@gov.in>

Cc ""rp"<rp@conexterminal.com>,"tusharthakur"<tushar.thakur@conexterminal.com>,"bomcha"<bom.cha@staricl.com>,"anubhavjoshi"<anubhav.joshi@staricl.com>,"CLL-EXP1"<exports@corallab.com>

Dear Sir,

Please find attached herewith CDSCO Export NOC for your ready reference.

**Thanks & Regards,
Mayank Katira
(Export Executive)**

CORAL LABORATORIES LTD.

+91-22-25008208, 25005245/46

log@corallab.com



From: NSPU R I Customs <nspuri.prev-mum@gov.in>

Sent: 25 July 2025 12:26

To: rp <rp@conexterminal.com>; tusharthakur <tushar.thakur@conexterminal.com>; log <log@corallab.com>; bomcha <bom.cha@staricl.com>; anubhavjoshi <anubhav.joshi@staricl.com>

Subject: Examination letter dated 25.07.2025 for consignment bearing shipping no. 3766710 dated 22.07.2025.

Please find attached Examination letter for your information.

Regards

NSPU Section, R & I

R & I

O/o The Commissioner of Customs(P)

1 Attachment(s)

Export NOC.pdf

299.7 KB

NSPU R I Customs < nspuri.prev-mum@gov.in >

Fri, 25 Jul 2025 12:26:20 PM +0530

To "rp"<rp@conexterminal.com>,"tusharthakur"<tushar.thakur@conexterminal.com>,"log"<log@corallab.com>,"bomcha"<bom.cha@staricl.com>,"anubhavjoshi"<anubhav.joshi@staricl.com>

Please find attached Examination letter for your information.

Regards

NSPU Section, R & I

R & I

O/o The Commissioner of Customs(P)

1 Attachment(s)

Adobe Scan 25 Jul 2025 (2).pdf

398.1 KB



सत्यमेव जयते

File No. NOC/25/006551

GOVERNMENT OF INDIA
Central Drugs Standard Control Organisation
Ministry of Health & Family Welfare

CDSO -North Zone, Ghaziabad ,Office of Deputy Drugs
Controller(India), Central Govt. Office Building No.1, Kamla Nehru
Nagar Ghaziabad (India) - 201002

To ,

M/s. Coral Laboratories Ltd.
Plot No. 27-28, Pharmacy
Selaqui
Dehradun - 248197

Subject: NOC for manufacture of unapproved/ approved new drug (bulk) for R&D/Formulation
Development/manufacture of exhibit batches for export purpose- regarding.

Sir ,

Ref: Your application no. EXP/NOC/2025/46938 dated 17-APR-2025

No Objection Certificate (NOC) No. NA/NOC-T&A(Exhibit Batches)/2025/000037 is hereby granted to you on 23-
APR-2025 for the manufacture of following formulation for R&D/ Formulation Development/manufacture of exhibit
batches for export purpose only.

Sl. No	Details
1	Drug Name : Amoxicillin And Bromhexine Hydrochloride Dry Suspension 250 mg/5ml (In House Specification)-Each Bottle Contain Amoxicillin Trihydrate BP equivalent to Amoxicillin (B.P.) 250 - mg/5ml, Bromhexine Hydrochloride (B. P.) 8 - mg/5ml Brand Name : MOXBRO FORTE SYRUP Quantity : 50000 Bottle Package Size : 100 ML Name of importing country/ name of the consignee : Somalia

The above NOC is subject to the following conditions to be compiled with

1. The drug for development will be manufactured by M/s. Coral Laboratories Ltd. Plot No. 27-28, Pharmacy Selaqui Dehradun - 248197 and shall utilize API manufactured ad shown in the above table.
2. You are requested to ensure that entire quantity of the drug(s) manufactured on the basis of the above NOC is for the specified purpose and no part of it is diverted for domestic sale in India.
3. The stocks of the drugs manufactured shall invariably bear on its label "Not for medicinal use" on the labels affixed to their cartons/ packaging.
4. You shall submit a certificate in the below mentioned format after completion of the development to the State Licensing Authority.

Yours faithfully,

**AJAY
SACHAN**

Digitally signed by AJAY SACHAN
DN: c=IN, st=Uttar Pradesh,
2.5.4.20=491c1b4c6a744d73d42b655309961794d
d5e96297bd57b4e9beb7729223,
postalCode=201002, street=Room no 115-119 CGO
COMPLEX-4 HAPUR ROAD KAMLA NEHRU NAGAR,
serialNumber=9359a5a3ee7d4e112b0c51fbb4276
4916a23316127bcacbb068961f3efac, ou=CDSO,
o=CDSO, cn=AJAY SACHAN
Deputy Drugs Controller (India)
Address: Central Govt. Office Building No.1,
Kamla Nehru Nagar, Ghaziabad, Uttar Pradesh,
India - 201002

Application No: EXP/NOC/2025/46938

IMP-12/1/2024-eoffice
Government of India
Directorate General of Health Services Central
Drugs Standard Control Organization
(Import & Registration Division)

FDA Bhawan, Kotla Road,
New Delhi-110002

Dated:

20 APR 2024

To

All States/UT Drugs Controllers

Subject: NOC's for Manufacture of Unapproved/Banned/New Drugs Solely for Export Purpose -Reg

NOC's for manufacture of unapproved/banned/new drugs solely for export purpose are granted as per the Guidance Document issued by CDSCO.

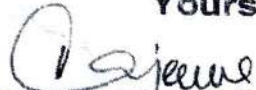
The above activity was delegated to State licensing Authorities w.e.f. 20th August, 2018 vide letter of F.No.7-5/2018/Misc./034(NOC) dated 2nd August, 2018

Now, it has been decided with the approval of Hon'ble HFM vide Ministry F. No. X.11035/210/2018-DR (Pt) dated 21st June, 2023 that Industry must be facilitated to file fresh applications for NOC for manufacture of unapproved/approved new drug/banned drugs solely for export purpose from 15th May, 2024 on online mode through CDSCO Zonal Offices. Accordingly, power delegated to State/UT Licensing Authority stands withdrawn w.e.f. 15th May, 2024 and such NOC's shall be granted by the Head of respective CDSCO Zonal office w.e.f. 15th May 2024. Further All State/UT Drugs Controllers are required to handover all NOC's issued from 20th August, 2018 to 14th May, 2024 to respective Zonal Offices of CDSCO.

All manufacturers may be informed that they are required to obtain NOC from respective Zonal Offices of CDSCO through online mode (SUGAM Portal) w.e.f. 15th May 2024 before issuing Manufacturing License from SLA for manufacture of Unapproved/Banned/New Drugs for export purpose.

Sh. Ranga Chandrashekar Rao Joint Drugs Controller (India) will be Nodal and designated person at CDSCO, HQ for said activity.

Yours faithfully


(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

Copy

1. All Zonal/Sub-Zonal/Port Offices of CDSCO for necessary action.
2. All stake holders through CDSCO website.

Copy for information to:

1. Deputy Secretary (Drug Regulation), MoH F & W, Govt. of India
2. Joint Secretary, (Drug Regulation), MoH F & W, Govt. of India



भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)

PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

सं. 608]

नई दिल्ली, बृहस्पतिवार, मार्च 10, 2016/फाल्गुन 20, 1937

No. 608]

NEW DELHI, THURSDAY, MARCH 10, 2016/ PHALGUNA 20, 1937

स्वास्थ्य और परिवार कल्याण मंत्रालय

(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 10 मार्च, 2016

का.आ. 705(अ).—केन्द्रीय सरकार का यह समाधान हो गया है कि एसिक्लोफेनक + पेरासिटामोल + रेबप्राजोल की नियत खुराक संयोजन औषधि के प्रयोग से मानव जीवन को खतरा होने की संभावना है जबकि उक्त औषधि के सुरक्षित अनुकल्प उपलब्ध हैं;

और इस विषय की केन्द्रीय सरकार द्वारा नियुक्त विशेषज्ञ समिति द्वारा जांच की गई है और उक्त विशेषज्ञ समिति ने केन्द्रीय सरकार को यह सिफारिश की है कि उक्त औषधि के बारे में यह पाया गया है कि इसका कोई चिकित्सीय औचित्य नहीं है;

और उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर केन्द्रीय सरकार का यह समाधान हो गया है कि देश में उक्त औषधि के मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण को प्रतिषिद्ध करके विनियमित करना लोकहित में आवश्यक और समीचीन है;

अतः, अब, केन्द्रीय सरकार, उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर और औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, एसिक्लोफेनक + पेरासिटामोल + रेबप्राजोल की नियत खुराक संयोजन औषधि का मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण तत्काल प्रभाव से प्रतिषिद्ध करती है।

[फा. सं. एक्स-11035/53/2014-डीएफक्यूसी]

कुंदन लाल शर्मा, संयुक्त सचिव

अधिसूचना

नई दिल्ली, 10 मार्च, 2016

का.आ. 776(अ).—केन्द्रीय सरकार का यह समाधान हो गया है कि मेट्रोनिडाजोल + नारफ्लोक्सासिन की नियत खुराक संयोजन औषधि के प्रयोग से मानव जीवन को खतरा होने की संभावना है, जबकि उक्त औषधि के सुरक्षित अनुकल्प उपलब्ध हैं;

और इस विषय की केन्द्रीय सरकार द्वारा नियुक्त विशेषज्ञ समिति द्वारा जांच की गई है और उक्त विशेषज्ञ समिति ने केन्द्रीय सरकार को यह सिफारिश की है कि उक्त औषधि के बारे में यह पाया गया है कि इसका कोई चिकित्सीय औचित्य नहीं है;

और उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर केन्द्रीय सरकार का यह समाधान हो गया है कि देश में उक्त औषधि के मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण को प्रतिषिद्ध करके विनियमित करना लोकहित में आवश्यक और समीचीन है;

अतः, अब, केन्द्रीय सरकार, उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर और औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, मेट्रोनिडाजोल + नारफ्लोक्सासिन की नियत खुराक संयोजन औषधि का मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण तत्काल प्रभाव से प्रतिषिद्ध करती है।

[फा. सं. एक्स-11035/53/2014-डीएफक्यूसी]

कुंदन लाल शर्मा, संयुक्त सचिव

NOTIFICATION

New Delhi, the 10th March, 2016

S.O. 776(E).—Whereas, the Central Government is satisfied that the use of the drug **fixed dose combination of Metronidazole + Norfloxacin** is likely to involve risk to human beings whereas safer alternatives to the said drug are available;

And Whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central Government that the said drug is found to have no therapeutic justification;

And Whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition of manufacture for sale, sale and distribution for human use of the said drug in the country;

Now, therefore, on the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of drug **fixed dose combination of Metronidazole + Norfloxacin** with immediate effect.

[F. No. X-11035/53/2014-DFQC]

K. L. SHARMA, Jt. Secy.

अधिसूचना

नई दिल्ली, 10 मार्च, 2016

का.आ. 777(अ).—केन्द्रीय सरकार का यह समाधान हो गया है कि एमोक्सिसिलिन + ब्रोमहेक्साइन की नियत खुराक संयोजन औषधि के प्रयोग से मानव जीवन को खतरा होने की संभावना है, जबकि उक्त औषधि के सुरक्षित अनुकल्प उपलब्ध हैं;

और इस विषय की केन्द्रीय सरकार द्वारा नियुक्त विशेषज्ञ समिति द्वारा जांच की गई है और उक्त विशेषज्ञ समिति ने केन्द्रीय सरकार को यह सिफारिश की है कि उक्त औषधि के बारे में यह पाया गया है कि इसका कोई चिकित्सीय औचित्य नहीं है;

और उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर केन्द्रीय सरकार का यह समाधान हो गया है कि देश में उक्त औषधि के मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण को प्रतिषिद्ध करके विनियमित करना लोकहित में आवश्यक और समीचीन है;

अतः, अब, केन्द्रीय सरकार, उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर और औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, एमोक्सिसिलिन + ब्रोमहेक्साइन की नियत खुराक संयोजन औषधि का मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण तत्काल प्रभाव से प्रतिषिद्ध करती है।

[फा. सं. एक्स-11035/53/2014-डीएफक्यूसी]

कुंदन लाल शर्मा, संयुक्त सचिव

NOTIFICATION

New Delhi, the 10th March, 2016

S.O. 777(E).—Whereas, the Central Government is satisfied that the use of the drug **fixed dose combination of Amoxicillin + Bromhexine** is likely to involve risk to human beings whereas safer alternatives to the said drug are available;

And Whereas, the matter has been examined by an Expert Committee appointed by the Central Government and the said Expert Committee recommended to the Central Government that the said drug is found to have no therapeutic justification;

And Whereas on the basis of the recommendations of the said Expert Committee, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition of manufacture for sale, sale and distribution for human use of the said drug in the country;

Now, therefore, on the basis of the recommendations of the said Expert Committee and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale and distribution for human use of drug **fixed dose combination of Amoxicillin + Bromhexine** with immediate effect.

[F. No. X-11035/53/2014-DFQC]

K. L. SHARMA, Jt. Secy.

अधिसूचना

नई दिल्ली, 10 मार्च, 2016

का.आ. 778(अ).—केन्द्रीय सरकार का यह समाधान हो गया है कि सिपरोफ्लोक्सासिन + फ्लुटिकासोन + क्लोट्रिमेजोल + नियोमाइसिन की नियत खुराक संयोजन औषधि के प्रयोग से मानव जीवन को खतरा होने की संभावना है, जबकि उक्त औषधि के सुरक्षित अनुकल्प उपलब्ध हैं;


और इस विषय की केन्द्रीय सरकार द्वारा नियुक्त विशेषज्ञ समिति द्वारा जांच की गई है और उक्त विशेषज्ञ समिति ने केन्द्रीय सरकार को यह सिफारिश की है कि उक्त औषधि के बारे में यह पाया गया है कि इसका कोई चिकित्सीय औचित्य नहीं है;

और उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर केन्द्रीय सरकार का यह समाधान हो गया है कि देश में उक्त औषधि के मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण को प्रतिषिद्ध करके विनियमित करना लोकहित में आवश्यक और समीचीन है;

अतः, अब, केन्द्रीय सरकार, उक्त विशेषज्ञ समिति की सिफारिशों के आधार पर और औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, सिपरोफ्लोक्सासिन + फ्लुटिकासोन + क्लोट्रिमेजोल + नियोमाइसिन की नियत खुराक संयोजन औषधि का मानव उपयोग के लिए विक्रयार्थ विनिर्माण, विक्रय और वितरण तत्काल प्रभाव से प्रतिषिद्ध करती है।

[फा. सं. एक्स-11035/53/2014-डीएफक्यूसी]

कुंदन लाल शर्मा, संयुक्त सचिव

	<p>आयुक्त सीमाशुल्क का कार्यालय (निवारक) OFFICE OF THE COMMISSIONER OF CUSTOMS (PREVENTIVE) त. एवं आ. विभाग, 11 वा तल, नवीन सीमा शुल्क भवन, NHAVA SHEVA PREVENTIVE UNIT, न्हावा शेवा निवारक इकाई, R&I DIVISION, 11TH FLOOR, NEW CUSTOM HOUSE, बेल्गार्ड एस्टेट, मुंबई - 400001 BALLARD ESTATE, MUMBAI - 400 001 Email: nspuri.prev-mum@gov.In</p>
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F.

No: GEN/INT/Misc/156/2025-NSPU-R&I Date:29-07-2025

DIN: 20250779OC000000A5EB

To,

The Licencing Authority,
Office of the Deputy Drugs Controller
Central Drugs Standard Control Organisation (North Zone),
Office Building No. 01, Kamla Nehru Nagar,
Ghaziabad-201002

Sir,

Subject: Noc for manufacture of unapproved/ approved new drug (bulk) for R&D/ Formulation Development/ manufacture of exhibit batches for export purpose-reg.

One Exporter M/s Coral Laboratories ltd. was issued NOC No. NA/NOC-T&A (Exhibit Batches)/2025/000037 dated 23.04.2025 vide file No. NOC/25/006551 by your office (copy enclosed).

2. The Exporter M/s Coral Laboratories ltd. vide shipping no. 3766710 dated 22.07.2025 has attempted to export the following item:

Sr. No.	Item	Brand Name	Manufacturing date	Batch No.	Mfg. Lic. No.:
1.	Amoxicillin and Bromhexine Hydrochloride Dry Suspension 250	Moxbro forte Syrup	03/2025	UFM2501-UFM2510 (10)	42/UA/SC/P-2006

3. In this regard, it is requested to kindly ascertain if the NOC No. NA/NOC-T&A (Exhibit Batches)/2025/000037 dated 23.04.2025 vide file no. NOC/25/006551 is valid for the above said consignment, which was manufactured in March, 2025 before the issuance of NOC.

4. An early response is highly solicited.

Digitally signed by
Naresh Kumar Tiwari
Date: 29-07-2025
13:49:16

Yours sincerely,

(Naresh Kumar Tiwari)
Deputy Commissioner of Customs
NSPU/R&I Mumbai Zone III

Enclosed: As above

File No- GEN/INT/MISC/156/2025-NSPU-R and I

CBIC-DIN-20250879OC0000914089

SUMMONS

[under Section 108 of the Customs Act, 1962 (52 of 1962)]

To,

M/s Coral Laboratories Ltd.

Plot No. 27-28, Pharmacy, Seaqui,
Dehradun-248011, Uttarakhand India
and #3B, Patanwala compound, Opp. to
Shreyas Cinema, LBS Marg,
Ghatkopar(West), Mumbai-400086 →

EM 8334031452N

EM 8334031542N

②
mc
66/08/25

WHEREAS I, BHUWNESH KUMAR DIXIT am making inquiry in connection with export of MOXBRO Forte Syrup containing Amoxicillin and Bromhexine under the Customs Act, 1962.

AND WHEREAS, I consider your attendance to

(a) give evidence and / or
(b) produce documents or things of the following description in your possession or under your control:

1. ID card and authorization letter on company letter head
2. Documents required for export of this particular item
3. Any other relevant document in support of your submission

NOW, THEREFORE, in exercise of powers vested in me under Section 108 of the Customs Act, 1962, I do hereby summon you to appear before me in person / or by an authorised agent on 2025-08-07 at 11:30:AM at the office of NSPU, 6th floor, R&I, New Custom House, Ballard Pier, Mumbai-400001

Inquiry as aforesaid is deemed to be a judicial proceeding within the meaning of section 229 and section 267 of Bharatiya Nyaya Sanhita, 2023 (45 of 2023) and non-compliance of this summons is an offence punishable under section 208 and section 210 of Bharatiya Nyaya Sanhita, 2023 (45 of 2023).

Given under my hand and seal of office to-day the 05 day of August, 2025 at Mumbai



Name : BHUWNESH KUMAR DIXIT

Signature : Bhwnesh

Designation :

Superintendent / Appraiser / Senior Intelligence Officer

Seal of Office.

o/c

Statement of Shri Mayank Katira, Export Executive in Logistics department from M/s Coral Industries Pvt. Ltd. (IEC-0394033353) having its Corporate Office address at #3B, Patanwala compound, Opp. Shreyas Cinema, LBS Marg, Ghatkopar (West), Mumbai - 400086 and factory office address at Plot No. 27/28, Pharma City, near Sealaqui World School, Dehradun in connection with the ongoing investigation of goods to be Exported by M/s Coral Industries Pvt. Ltd. (IEC-0394033353), recorded under Section 108 of the Customs Act, 1962 at NSPU, R&I Division, 6th Floor, Annex Building, New Custom House, Ballard Estate, Fort, Mumbai-400 001 on 07.08.2025.

I am in receipt of summons issued vide CBIC DIN No.-202508790C0000914089 dated 05.08.2025, to me to appear on 07.08.2025 by Shri Bhuwadesh Kumar Dixit, Superintendent of Customs (P). I am presenting myself before this office on 07.08.2025. I have been explained the provisions of Section 108 of the Customs Act, 1962 and have been warned that giving false evidence in this enquiry proceedings is an offence punishable under Sec. 229 of the Bhartiya Nyaya Sahita (BNS), 2023. Further, I have also been warned that my statement can be used against me in this enquiry proceeding or in any other proceedings which may be initiated against me. I present myself before Shri Bhuwadesh Kumar Dixit, Superintendent of Customs (P), for getting my statement recorded under Section 108 of Customs Act, 1962 having understood all the above provisions, I give my true and correct statement voluntarily as under:

I can read, write & understand Hindi and English languages well. I have requested the Customs Officer for typing my statement in the computer at NSPU office.

Q1. Please introduce yourself?

Ans. I am Mayank Katira S/o Chetan Katira, aged 30 years. I am providing copy of my Aadhar Card as proof of Identity and address. I am living at "Natraj Apartment, A Wing, Room No. 506/5th floor, Padwai Nagar Check naka, Near Panch Parmeshwar Temple, Thane-West-400604, Maharashtra". I am also submitting the Authorization letter issued by Director of M/s Coral Industries Pvt. Ltd. for recording this statement. My Phone number is 9820450005, Aadhar card No. is 9216 7557 8588 and my PAN No. is DJIPK8479K.

Q2. Do you know the purpose of being summoned?

Ans. Yes, I have been summoned in connection with the attempt to export of SB No. 3766710 dated 22.07.2025 by M/s Coral Industries Pvt. Ltd. (IEC-0394033353). I was also present at the time of examination of the said consignment at CFS M/s Conex Terminal Pvt. Ltd. I accept that representative samples of the product were drawn in my presence.

Q.3 What business does M/s Coral Laboratories (IEC-0394033353) do and what is your role in it?

M. Katira
07/08/25

Ans. M/s Coral Laboratories (IEC-0394033353) is in the business of exports of Pharmaceutical formulations (Tablets, Capsules, Injection, Syrup). We have exported to around 44 countries. Currently we supply 25 countries, mainly African countries and Common Wealth countries. We mainly purchase raw materials from Domestic Market itself. We supply for Government Tenders in India (Pharmaceuticals & Medical Devices Bureau of India(PMBI), Bihar Medical Supplies, Haryana Medical Supplies). I am employed as an Executive for Export and supply chain Management from 2021.

Q.4 Who takes the decision in your company related to Customs? Who specifically has taken decision for export the consignment under shipping bill 3766710 dated 22.07.2025?

Ans. I take all the decisions regarding Customs export clearance and logistics. I have handled the export and logistics for the consignment under shipping bill no. 3766710 dated 22.07.2025. This is a consignment of MOXBRO Forte Syrup containing Amoxicillin and Bromhexine Hydrochloride.

Q.5 Did you export the consignment of same item from any other port other than JNPT?

Ans. No, we only export through JNPT, Nhava seva. We have plant in Dehradun, Daman and Wada (Maharashtra). So, we export from JNCH only to combine the goods in same container for a particular country order.

Q.6 Central Govt. in exercise of the powers conferred under section 26A of the Drugs and Cosmetics Act, 1940 prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Amoxicillin + Brohexine with immediate effect in India, vide Notification No. S.O. 777(E) published in the Gazette of India, Extraordinary, Part-II, Section 3(ii), dated 10.03.2016. Are you aware about the fact?

Ans. Yes, I am aware that the combination of Amoxicillin + Brohexine is prohibited for manufacture for sale, sale and distribution for human use of drug fixed dose in India.

Q.7 What is the procedure for export of such combination of Amoxicillin + Brohexine?

Ans. Our License No. 42/UA/SC/P-2006 was renewed for another five years from 7th June 2021 to 6th June 2026 for the factory at Dehradun for the product list having items for export purpose only. This list at serial no. 27 has item MOXBRO Forte Syrup containing Amoxicillin & Brohexine Hydrochloride, got approval from 13.06.2016 for export only. We are then supposed to get the CDSCO NOC for each lot i.e quantity specific as this product was notified as prohibited for manufacture for sale, sale and distribution for human use in India, by the notification date 02.06.2023 referring the gazette notification of 2016. So we are supposed to get the product permission again from state licensing authority i.e. state drug controller, then we are supposed to manufacture the product. After that we are supposed to export the product. We are also supposed to submit the Certificate of Good Manufacturing Practices

Wekabir
07/08/25

which we already have valid till 27.07.2025 and further also renewed till 26.02.2026.

Q.8 How many consignments of item containing Amoxicillin + Brohexine is being exported by you during the period 2023-2024 & 2025 till date?

Ans. We have only exported MOXBRO Forte Syrup dry containing Amoxicillin + Brohexine. No any other product of same composition has been exported by us. From 20.07.2023 we have exported 06 consignment of same product i.e. MOXBRO Forte Syrup dry suspension and also to the same buyer. The details of export of 06 consignments are as follows.

Sr. No.	Shipping Bill	Date	Quantity
01	2588618	20.07.2023	50000
02	4254270	28.09.2023	40000
03	5706761	30.11.2023	40000
04	8911107	05.04.2024	50000
05	1341448	31.05.2024	50000
06	5045353	23.10.2024	50000

Q.9 Have you presented and done e-sanchit of all the requisite documents related to export of this particular item i.e. "MOXBRO Forte Syrup dry suspension" in the System while filing Shipping Bill for all the previous shipping bills of this particular item?

Ans. We have submitted GMP certificate, Product permission issued by sate drug controller in 2021, Certificate of analysis, Customs Invoice, packing list, No hazardous certificate.

Q.10 Did you specifically have the NOC for export for those previous consignments exported vide shipping bill mentioned in reply to question no. 08? NOC conditions or requirements were compiled in those previous consignment?

Ans. We did not have CDSCO NOC & fresh product permission from State licensing authority for those particular consignments as detailed in reply to question no. 08. Hence, these were not uploaded in E-sanchit.

Q.11 Do you think that the consignment of item MOXBRO Forte Syrup dry suspension containing Amoxicillin + Brohexine previously exported by you in previous shipments as detailed in reply to question no. 08, were valid export?

Ans. We were not aware about the guidelines and hence we had not taken the CDSCO NOC & fresh product permission from State licensing authority. Hence I accept that these were not valid export.

Q.12 What are the requirement and conditions imposed by CDSCO NOC for export of item MOXBRO Forte Syrup?

Ans. We have manufactured the goods at the Dehradun factory itself. This product is manufactured only for export purpose. One condition of the CDSCO NOC says to bear on its label "not for medicinal use" invariably. However, these goods are for human consumption only, so this condition should not be valid for

P. K. K. K.
07/08/25

our product. However, we will have a discussion with CDSCO regarding the same. So we have not affixed any such label on our stock.

Q.13 What about Labelling requirement on packaging for pharmaceutical items? Have you complied them?

Ans. It is mandatory to have manufacturing license, expiry date, Batch detail, manufacturing date, company name, manufacturer & buyer name, composition, bar code detail. Some other details like dosage direction, indications, directions for reconstitution are supposed to be printed on the literature leaflet kept in every Mono-cartons. As per our knowledge the same has been complied with our product.

Q.14 It has been found that you had filed SB 9644578 dated 03.04.2025 also at JNCH? what is the status of the export of said consignment?

Ans. This particular consignment was not exported. As we came to know first time about the whole procedure for export of this particular product, at the time of clearing the said shipping bill 9644578 dated 03.04.2025. So we did not have any NOC form CDSCO while filing the said shipping bill. This was informed by the Docks Customs Officer at CFS, GDL Logistics about the whole procedure. Then we applied the CDSCO NOC which was issued on 23.04.2025. However, because the NOC was issued on later date, Order in Original No. 309(L)/2025-26/ADC/CEAC/NS-II/CAC/JNCH dated 16.06.2025 was issued to us for back to town of the goods with fine and penalty of Rs. 1,00,000 each. This fine and penalty amount has already been paid by us on 21.06.2025. This consignment was lying at GDL CFS till June, 2025. After O-I-O we shifted the goods from GDL CFS to our godown at Swiddhinath Complex, Dapode, Bhiwandi-421302. These goods were brought to Conex, CFS on 22.07.2025 for export purpose to the same supplier at Somalia.

Q.15 If you think that you have provided all the requisite documents to Customs, then why did you agree for back to town. Did you comply with the Order conditions? Why did you not appeal against Order?

Ans. We did not have CDSCO NOC at the time of filing the shipping bill and presenting the shipping bill for clearance before the Customs. However, CDSCO NOC was issued on 23.04.2025. We also did not have Manufacturing license/fresh product permission as the same could only be issued for future manufacturing. But this lot was already manufactured. These were the reasons we accepted the Back to Town. We did not want to lose on the shelf life of the product and we were not aware of the process of the appeal, so we did not appeal against it.

Q.16 What changes have been made in terms of product or documents, to make it export worthy now? Then how did you try to export the said goods vide shipping bill no. 3766710 date 22.07.2025?

Ans. There is no major change. However, now at the time of filing the shipping bill or presenting the shipping bill for clearance we had CDSCO NOC beforehand. We could not dispose these goods into India as per the Law, so we thought of exporting the same. However, I accept that these goods were manufactured before issuance of CDSCO NOC but as we had already paid the

W.K. Kabir
07/08/25

fine and penalty therefore we tried to export and thought that Customs can support the trade.

Q.17 It appears that the same lot of consignment was brought back to attempt to export the goods. Did you present CDSCO NOC in e-sanchit for SB No. 3766710 dated 22.07.2025? It appears that you have deliberately attempted to export the same consignment again without any updation of documents or product.

Ans. We have uploaded the CDSCO NOC dated 23.04.2025 while filing the shipping bill no. 3766710 dated 22.07.2025. Our product is not psychotropic or narcotic substance and we had already paid the fine and penalty therefore we tried to export and thought that Customs can support the trade.

Q18. Do you have anything else to say or submit in your support in the subject matter?

Ans. Our product MoxBro Fortis Syrup which is manufactured is an antibiotic product used to treat respiratory tract infection and does not contain any psychotropic or narcotic substance. As per the current export trade situation, many African countries are facing the crisis of foreign exchange which has impacted export trade in Pharma Industry. We have already faced a shelf life loss of 5 months with Rs. 1,00,000 fine and penalty each along with storage and shipping line cancellation charges and it has impacted a huge financial loss. We as an exporter request Customs authorities to allow the export for this shipment and we ensure that we will complete all the guidelines issued for this product for our future exports.

The above statement running into five (v) pages is my true and correct statement typed as per my say which is given by me without any threat, force, inducement or coercion. During the record of the statement, no untoward incident was occurred and no socio-cultural-religious sentiments were hurt.

Date: 07.08.2025

W Katira
07/08/25

Mayank Chetan Katira

(Mr. Mayank Katira)

M/s Coral Industries Pvt. Ltd. (IEC-0394033353)

Recorded by

Bhwnesh

07/08/2025

(Bhwnesh Kumar Dixit)

Superintendent of Customs(P)

NOTIFICATION
New Delhi, the 2nd June 2023

S.O. 2395(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Amoxicillin+Bromhexine vide notification number S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(i), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. vs Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988, Central Government may, if it so chooses, de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or

distribution of this FDC under Section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended".

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 777 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of Amoxicillin+Bromhexine with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

Aradhana Patnaik, Jt. Secy.
Ministry of Health and Family Welfare
Department of Health and Family Welfare

IDMA Bulletin LIV (22) 08 to 14 June 2023

23

(16)
07/08/25


ICEGATE

INDIAN CUSTOMS NATIONAL TRADE PORTAL



We understand your world

E-RECEIPT Customs Duty Payment			
IG Reference No	008000SBINNSA11105276228947847	Transaction Expiry Date	21-06-2025 23:59:59
Total Challans	1	Bank Name	HDFC BANK
Document Type	SB	Bank Reference No	BHP2ZD9004CSLM
Id Number	03*****53	Date/ Time of Payment	21-06-2025 11:06:24
Id Name	CO*****EC	Transaction Status	SUCCESS
Payment Mode	Credit Card		

Sr No	Challan Date	Challan Number	Document Number	Challan Amount(INR)
1	21-06-2025	1462027378	9644578	1,00,000.00
Duty Paid	INR 1,00,000 (One Lakh Rupees Only)			

* This E-Receipt is issued by HDFC Bank with transaction details and status. Kindly download the final payment receipt from ICEGATE Portal.

Handwritten signature and date: 21/06/25



ICEGATE
INDIAN CUSTOMS NATIONAL TRADE PORTAL



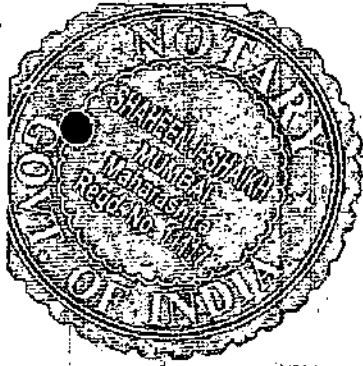
We understand your world

E-RECEIPT Customs Duty Payment			
IG Reference No	008000SBINNSA11056547410606360	Transaction Expiry Date	21-06-2025 23:59:59
Total Challans	1	Bank Name	HDFC BANK
Document Type	SB	Bank Reference No	BHP2QYT004C4W3
Id Number	03*****53	Date/ Time of Payment	21-06-2025 10:59:57
Id Name	CO*****EC	Transaction Status	SUCCESS
Payment Mode	Credit Card		

Sr No	Challan Date	Challan Number	Document Number	Challan Amount(INR)
1	21-06-2025	8787213228	9644578	1,00,000.00
Duty Paid	INR 1,00,000 (One Lakh Rupees Only)			

* This E-Receipt is issued by HDFC Bank with transaction details and status. Kindly download the final payment receipt from ICEGATE Portal.

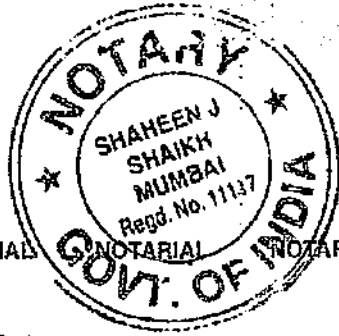
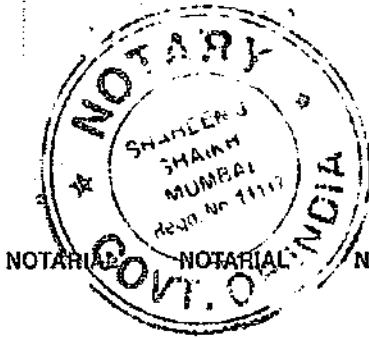
W
21/06/25



FIVE HUNDRED
RUPEES

RS. 500

JICIAL



महाराष्ट्र MAHARASHTRA

2025

EA 138344

Date: 03.07.2025

To,
Deputy Commissioner of Customs,
Export Documentation,
GDL CFS, Nhava Sheva

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.निक ८०००००६
26 JUN 2025
सहायक अधिकारी

श्रीमती एस. एस. चव्हाण

Reference: Shipping Bill No. 9644578 Date: 03.04.2025
Subject: Goods Undertaking w.r.t Goods Covered under Invoice No
UB0027 Dated: 28.03.2025

Respected Sir,

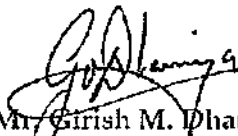
With reference to above mentioned shipping bill no, we hereby undertake that
"NO PART OF CONSIGNMENT WILL BE DIVERTED FOR DOMESTIC SALE
IN INDIA AND THAT ALL OTHER CONDITIONS STIPULATED IN THE NOC
WILL BE STRICTLY COMPLIED WITH".

Kindly allow us for Back to Town (BIT) as per the ORDER - IN - ORIGINAL.

Thanking You,

Yours Sincerely,

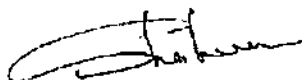
For Coral Laboratories LTD.,


Mr. Girish M. Dhameja.
(Director)



03 JUL 2025

ATTESTED BY ME


SHAHEEN J. SHAIKH
NOTARY GOVT. OF INDIA
Regd. No. 11117
3/14, Sai Prasad Shopping Centre Below
Vikhroil Court, Kannamwar Nagar No. 2
Vikhroil (East), Mumbai - 400 083.
Tel.. 9821816104

भारत सरकार
Government of India



मयंक चेतन कातिरा
Mayank Chetan Katira
जन्म तारीख / DOB: 16/03/1995
पुरुष / Male

9216 7557 8588

मेरा आधार मेरी पहचान

भारत सरकार
Government of India

भारतीय विभाजन प्राधिकरण
Bharatiya Bhaagan Authority of India

पता: पदरान अपार्टमेंट, बिल्डिंग नं. 505 / 5 फ्लोर
नारुल, पश्चिम, मुंबई, महाराष्ट्र 400004
पिन कोड: 400 004

Address: Narul Apartment A Wing Room
No. 505 / 5th Floor, Narul Nagar,
Chembur, Near Barchi, Parneshwar,
Thane West, Thane District,
Maharashtra 400004

9216 7557 8588

help@bda.gov.in www.bda.gov.in

W
07/08/25

**FOOD SAFETY & DRUGS ADMINISTRATION AUTHORITY,
DIRECTORATE GENERAL OF MEDICAL HEALTH AND FAMILY
WELFARE, SAHASTRADHARA ROAD, DEHRADUN**

F.No. 26/1/Drud/47/2019/ 1250

Dated: 11-05-2023

G.L.P. CERTIFICATE

This is to certify that M/s Coral Laboratories Ltd., Plot No. 27 & 28, Pharmacy, Selaqui, Dehradun, Uttarakhand (India) has been licensed under Drugs & Cosmetics Act 1940 & Rules there under. They are holding valid Drug manufacturing license 42/UA/2006 on form 25 & 42/UA/SC/P-2006 on Form-28 valid up to 06-06-2026 to manufacture for sale of Drugs.

In view of report dt. 09-05-2023 of Sr. Inspector of Drugs, Dehradun it is certified that M/s Coral Laboratories Ltd., Plot No. 27 & 28, Pharmacy, Selaqui, Dehradun, Uttarakhand (India) confirm to G.L.P. requirements of Rule 74,78 & 150E and Good Laboratory Practices as laid down under Schedule "L-1" (150-E) of the Drugs & Cosmetics Rule 1945.

This certificate is issued to the firm on their request for submission to Govt. departments / Institutions / Overseas Authority.

This certificate is valid for a period up to Three Year from the date of issue.



07/08/23

Tajber Singh
(Tajber Singh) 11/5/2023
Drug Controlling
Uttarakhand

From,

Add. Commissioner,
Food Safety & Drug Administration
Sahastradhara Road, Dehradun,
Uttarakhand.

To,

M/s Coral Laboratories Ltd.,
Plot No. 27 & 28, Pharmacy,
Selaqui, Dehradun,
Uttarakhand (India)

File No. 26/1/Drug/47/2019/ 114056 Dated 01/07/2025
Sub- Extension of Validity of COPP granted under WHO-GMP & COPP certification scheme
& WHO-GMP Certificate.

Sir,

In reference to your application dated 19-06-2025 regarding above noted subjects it is
to inform you that the validity of COPP granted under WHO-GMP certification scheme &
* WHO-GMP Certificate is further extended from 27-07-2025 to 26-02-2026 for Six months.



(Tajber Singh) 11/07/2025
Add. Commissioner
Food Safety & Drug Administration
Uttarakhand
ADD. COMMISSIONER
FOOD SAFETY &
DRUG ADMINISTRATION (U.K.)

F. No. 26/1/Drug/47/2019/

Of dated

Copy to- Dy. Drug Controller (North Zone) CDSCO, Govt. of India, Kamla Nehru Nagar,
Hapur Road, Gaziabad, UP.

02/08/25
(Signature)

(Tajber Singh)
Add. Commissioner
Food Safety & Drug Administration
Uttarakhand

msdps/2025



e-Challan

Bank Ref. No. - CPAFHMYIJO

Treasury Form-209(1)
Financial Handbook Vol. V, Part-II
Form No. 43A(1)
(See Paragraph 417 and 478)
Challan form for depositing amount



Name of the Treasury/Sub-Treasury/Bank/Bank Branch - State Bank Of India (Payment Gateway)

Status : (S) Completed successfully.


1	Name of the person (designation if necessary or Organization on whose behalf amount is being paid.	B H PATEL
2	Address	CORAL LABORATORIES LTD, PLOT NO 27 & 28 PHARMA CITY SELAQUI, DEHRADUN Uttarakhand 248011
3	Registration Number (if necessary)	
4	Full details of amount to be deposited (for which purpose and in favour of)	EXTENSION OF REVALIDATION OF WHO CERTIFICATE and COPP for 6 months
5	Gross value of Challan	3000
6	Net value of Challan	3000
7	Department	Food Safety and Drug Administration Uttarakhand
8	Related office for which challan is to be deposit	Commissioner Food Safety and Drug Administration, Uttarakhand, Dehradun
9	Full details of Head of Account	0210 - Medical and Public Health
10	13 Digit code of Head of A/c	As per details below

SL No.	Services	Detail Head	Amount
1	जमा	0210041040401	3000
Total Challan Amount-			3000

Amount (in words) - Rs. Three Thousand only

Signature of departmental officer with seal

B H PATEL

Challan No- 02100625E0076229	Amount in Figure(Rs.) - 3000
Date - 28-JUN-2025	Amount in words - Rs. Three Thousand only
 Received Through	
Bank Ref. No. - CPAFHMYIJO State Bank Of India (Payment Gateway)	



CORAL LABORATORIES LTD

AN ISO 9001: 2008 CERTIFIED ORGANIZATION



CORP. OFFICE : #3B, Palanwala Compound, Opp. Shreyas Cinema, L.B.S. Marg, Ghatkopar (West), Mumbai - 400 086. India
 Tel. : +91-22-2500 5245, 2500 8208, 2500 5246 • Fax : +91-22-2500 4893 • E-mail : exports@corallab.com • Website : www.corallab.com

CIN NO. U11109MH2011PTL0001659
 XXXXXXXXXXXXXXXXXXXXXXXX

L24231MH1997PLC422233

Date : 24.07.2025

To,
 Asstt. Commissioner of Customs,
 Export Department, Nhava Sheva,

Dear Sir,

Sub : End Use Clarification against Moxbro Forte Syrup

Ref : Shipping Bill No. 3766710 Dtd. 22.07.2025, our Invoice No. M-28/25-26 dtd 22.07.2025

Dear Sir,

We would like to inform you that Subject product is considered as a Dry Suspension and not a Syrup. A Syrup is defined as a solution of Sucrose in Purified Water as per USP and BP Monograph.

Moxbro Forte Syrup is a dry Suspension which needs to be reconstituted with water and forms a suspension and its usage is like an antibiotic used to treat respiratory tract infections. It is primarily used to treat infections and is administered only for a week. And not used as a "Cough Syrup".

Also we would like to inform you that we have not used any high-risk drug components like Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, and Sorbitol Solution in Moxbro Forte Syrup. So the risk of contamination with diethylene glycol (DEG) or ethylene glycol (EG) is ruled out for this product.

Hence Kindly give export allows on same to proceed for export shipment.

Your support is highly appreciated.

Thanking you,

Yours faithfully,
 For CORAL LABORATORIES LTD.



Authorised Signatory

**FOOD SAFETY & DRUGS ADMINISTRATION AUTHORITY,
DIRECTORATE GENERAL OF MEDICAL HEALTH AND FAMILY
WELFARE, SAHASTRADHARA ROAD, DEHRADUN**

File no. 26/1/Drug/47/2019/ 13341

Date: 28 July, 2022

Certificate of Good Manufacturing Practices

Certificate no.: 26/1/Drug/47/2019/

On the basis of the Joint Inspection carried out on 21-07-2022 and 22-07-2022, and further inspected by S.I.D HQ on Date 28-07-2022 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1- Name & Address of site:

2-

M/s Coral Laboratories Ltd,
Plot No-27,28,Pharmacy,
Selaqui, Dehradun-248011, Uttarakhand.

3- Manufacturer's license number:

Form 25- 42/UA/2006

Form 28- 42/UA/SC/P-2006

4- Table 1:

Dosage form(s)	Activity(ies)
Tablets (Non Beta Lactum & Beta Lactum)	Manufacturing
Capsule (Hard Gelatin) (Non Beta Lactum & Beta Lactum)	Manufacturing
Oral Liquid Dosage (Syrup & Suspensions) Non Beta Lactum)	Manufacturing
Dry Syrups (Non Beta Lactum & Beta Lactum)	Manufacturing
Preparation for External Application (Ointment, Cream, Ge, Ear Drops, Powder & Shampoo)	Manufacturing
Suppository (Non Beta Lactum)	Manufacturing
Effervescent Tablets (Non Beta Lactum)	Manufacturing

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 27-07-2025. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

The firm is following Good Manufacturing Practices as per World Health Organization (WHO) TRS Guide Lines, in the Manufacturing & testing of the said categories of Products and Items in respect of which the Certificates of Pharmaceuticals products have been issued.

Address of certifying Authority:

Directorate General of Medical Health & Family Welfare,
Sahastradhara Road, Dehradun (Uttarakhand) INDIA.

Name & function of responsible person:


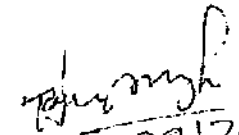
Shri Tajber Singh

Drugs Licensing & Controlling Authority
Uttarakhand.


Email: drugcontroluk@gmail.com

Tel.no. NA

Fax. no. 0135260874



 (Tajber Singh) 28/7/2022
 Drugs Licensing & Controlling Authority
 (Uttarakhand)

भारत सरकार
GOVERNMENT OF INDIA
 वाणिज्य और उद्योग मंत्रालय
MINISTRY OF COMMERCE & INDUSTRY
 विदेश व्यापार महानिदेशालय
DIRECTORATE GENERAL OF FOREIGN TRADE
 मान्यता प्रमाण पत्र
Certificate of Recognition



संख्या: **LD/INT/Misc/156/2025-NSPU-R** दिनांक: **05-10-2021**
 प्राप्त करने वाले का नाम: **श्री. राहुल कुमार** पता: **राहुल कुमार, 101/1, 101/2, 101/3, 101/4, 101/5, 101/6, 101/7, 101/8, 101/9, 101/10, 101/11, 101/12, 101/13, 101/14, 101/15, 101/16, 101/17, 101/18, 101/19, 101/20, 101/21, 101/22, 101/23, 101/24, 101/25, 101/26, 101/27, 101/28, 101/29, 101/30, 101/31, 101/32, 101/33, 101/34, 101/35, 101/36, 101/37, 101/38, 101/39, 101/40, 101/41, 101/42, 101/43, 101/44, 101/45, 101/46, 101/47, 101/48, 101/49, 101/50, 101/51, 101/52, 101/53, 101/54, 101/55, 101/56, 101/57, 101/58, 101/59, 101/60, 101/61, 101/62, 101/63, 101/64, 101/65, 101/66, 101/67, 101/68, 101/69, 101/70, 101/71, 101/72, 101/73, 101/74, 101/75, 101/76, 101/77, 101/78, 101/79, 101/80, 101/81, 101/82, 101/83, 101/84, 101/85, 101/86, 101/87, 101/88, 101/89, 101/90, 101/91, 101/92, 101/93, 101/94, 101/95, 101/96, 101/97, 101/98, 101/99, 101/100**
 को विदेश व्यापार नीति: 2015-2020 के प्रावधानों के अनुसार **एक** तारा निर्यात घर का स्तर
 प्रदान किया जाता है। यह प्रमाण पत्र, प्रक्रिया पुस्तिका(2015-2020) के पत्र 3.100(बी) में दी गयी
 शर्तों के अधिन **एक** वर्ष की अवधि के लिए प्रभाव **05-10-2021** से **04-10-2022** तक प्रयोग
 में आने के लिए प्रयोग किया जा सकता है।

MS. No. **LD/INT/Misc/156/2025-NSPU-R**
 and Income Tax PAN **XXXXXXXXXX**
 are hereby awarded the status of One Star Export House in accordance with the provisions
 of the Foreign Trade Policy, 2015-2020. This Certificate is valid for a period of **01** years
 effective from **05-10-2021** to **04-10-2022** subject to the conditions prescribed in
 Para 3.100 of the Hand Book of Procedures, 2015-2020.

जारी करने वाला: **श्री. राहुल कुमार**
 निदेशाधीन, विदेश व्यापार महानिदेशालय
**Additional Joint Deputy
 Director General of Foreign Trade
 Development Commissioner (S1 Z)**

स्थान: **PLA VADODARA**
RAHUL SINGH
 Date: **05-10-2021**

Handwritten signature of RAHUL SINGH

Signature Not Verified
 Digitally Signed
 Name: DR RAHUL SINGH (Deputy
 DSP)
 Date: 05-Oct-2021 16:30
 Reason: DR RAHUL SINGH@NIC IN
 Location: RA VADODARA

This document has been digitally signed by RAHUL SINGH, Deputy DGFT, RA VADODARA on 05-Oct-2021.

Certificate Of Registration

Geotek Global Certification Pvt. Ltd.

hereby certify that the organization

Coral Laboratories Ltd.

Head Office : #3B, Patanwala Compound, Opp. Shreyas Cinema, L.S.B. Marg, Ghatkopar (W), Mumbai 400086, Maharashtra, India
 Site 1 : Plot No. 57/1 (16), Bhenslore, Dunetha, Nani Daman 396210, U.T., India
 Site 2 : Plot No.27-28, Pharmacy, Selaqui, Dehradun 248011, Uttarakhand, India

has implemented and maintains a Quality Management System for

Scope :

Manufacture, Packing and Supply of Tablets, Capsules, Dry Syrup, Powder, Liquid Orals, Oral Drops, Suppositories and External Preparations (Ointments, Creams, Paste, Gels, Lotions, Shampoos, Sprays, Ear Drops & Sprinkling Powder)

An audit was performed and proof has been furnished that the management system fulfils the requirements of international standard detailed below ...

Standard : ISO 9001:2015
 Certificate No. : 15.GGCS.IN.09482
 Certification Date : 12th February 2011
 Re-certification Date : 28th June 2024
 Cert. Expiry Date : 27th June 2027



Geotek Global
 Certification Pvt. Ltd.

Reg. No. IN.QMS22.0511



imab

International Management
 Accreditation Board

Chief Executive Officer

Geotek Global Certification Pvt. Ltd.
 102, Raj Legacy, Near Bramhand Phase 5, Off. GB Road,
 Thane (West), Pin 400607, Maharashtra, India

Geotek Global Certification Pvt. Ltd. is accredited by International Management Accreditation Board (Singapore)
 51, Goldhill Plaza, #07-10/11, Singapore 308900

The continual validity of the certificate is conditional to compliance with the terms and the conditions of Geotek Global Certification Pvt. Ltd. - Certification Scheme Regulation. Validity of the certificate may be verified on following websites : www.geotek.co.in and accreditation body's website : www.imab.com

SUMMARY OF EXPORTS - MOXBRO FORTE SYRUP

Composition:

Amoxicillin and Bromhexine Hydrochloride Dry Suspension

Composition:

Each 5 ml reconstituted suspension Contains:

Amoxicillin Trihydrate BP equivalent to

Amoxicillin.....250 mg

Bromhexine Hydrochloride BP.....8 mg

Excipients.....q.s

Colour : Sunset Yellow

SR NO	INVOICE NO	GST INVOICE NO	DATE	QUANTITY	SB NO	SB DATE
1	CLL/EXP/080/23-24	UB0007	18.07.2023	50000	2588618	20.07.2023
2	CLL/EXP/149/23-24	UB0010	27.09.2023	40000	4254270	28.09.2023
3	CLL/EXP/196/23-24	UB0015	30.11.2023	40000	5706761	30.11.2023
4	CLL/EXP/313/23-24	UB0034	30.03.2024	50000	8911107	05.04.2024 ✓
5	CLL/EXP/078/24-25	UB0005	31.05.2024	50000	1341448	31.05.2024 ✓
6	CLL/EXP/228/24-25	UB0015	19.10.2024	50000	5045353	23.10.2024 ✓
TOTAL						

(Signature)
02/08/20

	<p>आयुक्त सीमाशुल्क का कार्यालय (निवारक) OFFICE OF THE COMMISSIONER OF CUSTOMS (PREVENTIVE) त. एवं आ. विभाग, 11 वा तल, नवीन सीमा शुल्क भवन, NHAVA SHEVA PREVENTIVE UNIT, न्हावा शेवा निवारक इकाई, R&I DIVISION, 11TH FLOOR, NEW CUSTOM HOUSE, बेल्गार्ड एस्टेट, मुंबई – 400001 BALLARD ESTATE, MUMBAI – 400 001 Email: nspuri.prev-mum@gov.in</p>
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F. No: GEN/INT/Misc/156/2025-NSPU-R&I

Date: 29-07-2025

To,

The Chief Chemical Examiner,
DYCC, JNCH,
Uran, Dist - Raigad,
Maharashtra

Sir,

Sub: Testing of samples for goods covered under the shipping bill no. 3766710 dated 22.07.2025-reg.

Please refer to the above mentioned subject. This office is investigating a case of goods meant for export under Shipping Bill no. 3766710 dated 22.07.2025. Representative Sample is hereby forwarded to you for testing of the goods.

The details of the goods meant for export under the said Shipping Bill:

Sr No.	Shipping Bill	Seal No.	Product
1	3766710 dated 22.07.2025	PO 57	Amoxicillin and Brohexine Hydrochloride Dry Suspension Moxbro Forte Syrup

Test Query:

- 1) What is the nature and composition of the subject sample?
- 2) Whether sample is same as declared i.e. Amoxicillin and Brohexine Hydrochloride Dry Suspension Moxbro Forte Syrup in the above shipping bill. If the sample does not match the description of the goods what is the nature of the goods and its composition.

If the above samples cannot be tested at DyCC, please suggest the NABL accredited lab where it can be tested.

Yours Sincerely,

Digitally signed by
Naresh Kumar Tiwari
Date: 29-07-2025
13:46:30

(Naresh Kumar Tiwari)
Deputy Commissioner of Customs
NSPU/R&I Mumbai Zone III

Enclosed: One Sealed Sample (Sealed with PO seal 57).

	<p>आयुक्त सीमाशुल्क का कार्यालय (निवारक) OFFICE OF THE COMMISSIONER OF CUSTOMS (PREVENTIVE) त. एवं आ. विभाग, 11 वा तल, नवीन सीमा शुल्क भवन, NHAVA SHEVA PREVENTIVE UNIT, न्हावा शेवा निवारक इकाई, R&I DIVISION, 11TH FLOOR, NEW CUSTOM HOUSE, बेल्गार्ड एस्टेट, मुंबई - 400001 BALLARD ESTATE, MUMBAI - 400 001 Email: nspuri.prev-mum@gov.In</p>
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No: GEN/INT/Misc/156/2025-NSPU-R and I

11-08-2025

To,

The Chief Chemical Examiner,
DYCC, JNCH,
Uran, Dist - Raigad,
Maharashtra

Sub: Testing of samples for goods covered under the shipping bill no. 3766710 dated 22.07.2025-reg.

Please refer to this office letter of even no. dated 28.07.2025 and Test Memo Lab no. 494/R&I dated 29.07.2025 on the above mentioned subject. This office is investigating a case of goods meant for export under Shipping Bill no. 3766710 dated 22.07.2025. Representative Sample was forwarded to you for testing of the goods.

The details of the goods meant for export under the said Shipping Bill:

Sr No.	Shipping Bill	Seal No.	Product
1	3766710 dated 22.07.2025	PO 57	Amoxicillin and Brohexine Hydrochloride Dry Suspension Moxbro Forte Syrup

Test Query:

- 1) What is the nature and composition of the subject sample?
- 2) Whether sample is same as declared i.e. Amoxicillin and Brohexine Hydrochloride Dry Suspension Moxbro Forte Syrup in the above shipping bill. If the sample does not match the description of the goods what is the nature of the goods and its composition.
- 3) In addition to above, you are also requested to ascertain psychotropic or narcotic substance in the sample, if any.

If the above samples cannot be tested at DyCC, please suggest the NABL accredited lab where it can be tested.

Digitally signed by
Naresh Kumar Tiwari
Date: 11-08-2025
17:14:15

(Naresh Kumar Tiwari)
Deputy Commissioner of Customs

NSPU/R&I Mumbai Zone III

Lab No. 494 / R & I dt. 29/07/25

S/B No-3766710

dt - 22-07-2025

Report:- The sample as received is in the form of off white powder, kept in side sealed amber glass bottle pasted with printed label described as "Amoxicillin and Bromhexine Hydrochloride Dry Suspension MOXBRO FORTE SYRUP", which further kept in a paper box having printed description reads as "MOXBRO FORTE SYRUP 100ML, Batch No- UFM 2504, Mfg Date - 03/2025, Exp Date - 08/2027".

On the basis of instrumental analysis, the sample v/a answers positive tests for Amoxicillin and Bromhexine hydrochloride.

Saled R/S returned

Abhayankar
11/08/2025

ABHAYANKAR MAURYA
Chemical Assistant

NB/M
11/08/25

जे. पी. बहिनपती
J. P. BAHINIPATI
रसायन परीक्षक ग्रेड-II
CHEMICAL EXAMINER GR-II
जवाहरलाल नेहरू सीमा शुल्क भवन प्रयोगशाला
Jawaharlal Nehru Custom House Laboratory
नावा शेवा - Nhava Sheva

<p style="text-align: center;">भारतसरकार वित्तमंत्रालय, राजस्वविभाग केंद्रीयअप्रत्यक्षकरएवंसीमाशुल्कबोर्ड जवाहरलालनेहरूसीमाशुल्कभवनप्रयोगशाला जवाहरलालनेहरूसीमाशुल्कभवन न्हावाशेवा, ताल-उरण, जिला- रायगढ़ महाराष्ट्र-400707</p>		<p style="text-align: center;">Government of India Ministry of Finance, Department of Revenue Central Board of Indirect Taxes & Customs Jawaharlal Nehru Custom House Laboratory Jawaharlal Nehru Custom House NhavaSheva, Tal-Uran, Dist-Raigad Maharashtra-400707 TEL: 022-27240261; Email ID. jdjnchlab2019@gmail.com</p>
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F. No.: S/16-16/2025/LAB/JNCH

Date: 12.08.2025

To,

The Deputy Commissioner of Customs,
 Nhava Sheva, Preventive Unit,
 R&I Division, 11th Floor, New Custom House,
 Ballard Estate, Mumbai

Sub.: Testing of samples for goods covered under the SB No. 3766710 dated 22.07.25 -reg.

Sir,

Please refer to letter No.: GEN/INT/Misc/156/2025-NSPU-R & I, dated 11.08.2025 on the subject cited above, queries raised at Sl. No.- 1 & 2 has already been answered vide test report dated 11th August, 2025.

Regarding query No.-3, it is informed that the New Custom House Laboratory, Mumbai is the authorised Laboratory to tests & issue test reports of NDPS Samples/Samples having query regarding NDPS.

Yours faithfully,

P. Karmakar
 12-08-25
(Dr. Parthasarathi Karmakar)
 Chemical Examiner Gr-I (I/c)

Re: Applicability of the NOC for the live consignment on hold by Mumbai Customs (Preventive)

CDSCO North Zone <nzghaziabad@cdsco.nic.in >

Tue, 05 Aug 2025 11:04:26 AM +0530

To "NSPU R I Customs" <nspuri.prev-mum@gov.in>

Cc "drugcontroluk" <drugcontroluk@gmail.com>, "ADC I Office Sub Zone Dehradun" <dehradun-uk@cdsco.nic.in>, "Asstt. Drugs Controller Nhava Sheva JNPT" <jnpt.mumbai@cdsco.nic.in>

Sir,

With reference to below trailing mail, it is informed that the NOC for manufacture of Approved New Drug/ Unapproved drugs/ banned drugs for export purpose are being issued by CDSCO. However, the manufacturing license/ Product permissions are being issued by concerned State Licensing Authority. Hence, further clarification in the matter may be sought from State Licensing Authority, Uttarakhand (drugcontroluk@gmail.com).

Further, it is also informed that this office has already received same matter from Sh. MANTOSH KUMAR, SUPERINTENDENT OF CUSTOMS, EXPORT DOCKS (GDL) vide email dated 29.04.2025 & clarification has already been submitted on 30.04.2025 & 1.05.2025. (Copy attached)

Kind regards,

O/o Deputy Drugs Controller (India),
Central Drugs Standard Control Organisation, (North Zone),
Directorate General of Health Services,
Ministry of Health & Family Welfare, Govt. of India,
CGO Complex-I, Kamla Nehru Nagar, Hapur Chungi, Ghaziabad-201002
(U.P.),
Phone No:- 0120-2719483/ 2750013.

---- On Tue, 29 Jul 2025 14:37:25 +0530 **NSPU R I Customs** <nspuri.prev-mum@gov.in> wrote ---

Please find the letter dated 29.07.2025 on the above subject attached herewith.

Regards


NSPU Section, R & I
R & I
O/o The Commissioner of Customs(P)

3 Attachment(s)

letter to CDSCO.docx with DIN...
157.8 KB

Adobe Scan 29 Jul 2025.pdf
726.7 KB

Re_ NOC No. NA_NOC-TA (E...
260.3 KB

	<p>आयुक्त सीमाशुल्क का कार्यालय (निवारक) OFFICE OF THE COMMISSIONER OF CUSTOMS (PREVENTIVE) त. एवं आ. विभाग, 11 वा तल, नवीन सीमा शुल्क भवन, NHAVA SHEVA PREVENTIVE UNIT, न्हावा शेवा निवारक इकाई, R&I DIVISION, 11TH FLOOR, NEW CUSTOM HOUSE, बेल्गार्ड एस्टेट, मुंबई - 400001 BALLARD ESTATE, MUMBAI - 400 001 Email: nspuri.prev-mum@gov.In</p>
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F. No: GEN/INT/Misc/156/2025-NSPU-R and I

13-08-2025

To,

The Chief Chemical Examiner,
DYCC, NCH,
Ballard Pier,
Mumbai-400001

**Sub: Testing of samples for goods covered under the
shipping bill no. 3766710 dated 22.07.2025-reg.**

This office is investigating a case of goods meant for export under Shipping Bill no. 3766710 dated 22.07.2025. Representative Sample is being forwarded to you for testing of the goods.

The details of the goods meant for export under the said Shipping Bill:

Sr No.	Shipping Bill	Seal No.	Product
1	3766710 dated 22.07.2025	PO 57	Amoxicillin and Brohexine Hydrochloride Dry Suspension Moxbro Forte Syrup

Test Query:

1) You are requested to ascertain any psychotropic or narcotic substance in the sample, if any.

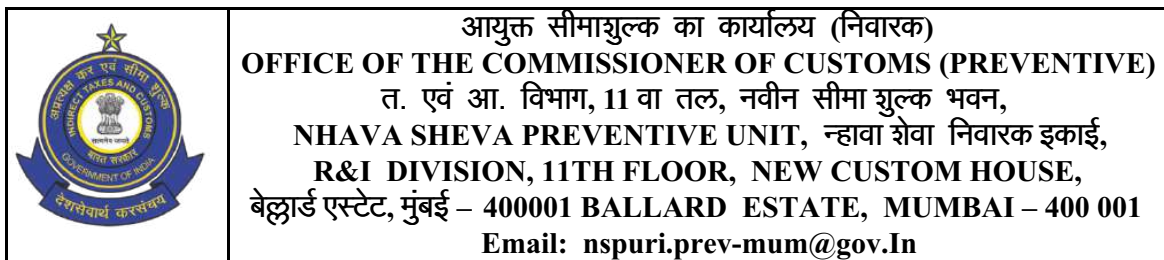
If the above samples cannot be tested at DyCC, please suggest the NABL accredited lab where it can be tested.

Digitally signed by
Naresh Kumar Tiwari
Date: 13-08-2025

17:31:31
(Naresh Kumar Tiwari)

Deputy Commissioner of Customs
NSPU/R&I Mumbai Zone III

Enclosure: One Sealed Sample (Sealed with PO seal 57)



F. No: GEN/INT/Misc/156/2025-NSPU-R&I Date: 22-08-2025

To, DIN: 202508790C000061726A

The Drug Controller & State Licencing Authority,
Office of the Drug Controlling & Licensing Authority
Commissioner Food safety and Drugs Administration,
Dan da Lakhond, Near IT Park, Sahastrdhara road,
Dehradun, Uttarakhand-248001

Sir,

Subject: Noc for manufacture of unapproved/ approved new drug (bulk) for R&D/ Formulation Development/ manufacture of exhibit batches for export purpose-reg.

This office is investigating into export of goods having item Amoxicillin and Bromhexine Hydrochloride Dry Suspension 250 of Brand MOXBRO FORTE SYRUP by M/s Coral Laboratories . The said exporter vide shipping no. 3766710 dated 22.07.2025 has attempted to export the following consignment:

Sr. No.	Item	Brand Name	Manufacturing date	Batch No.	Mfg. Lic. No.:
1.	Amoxicillin and Bromhexine Hydrochloride Dry Suspension 250	Moxbro forte Syrup	03/2025	UFM2501-UFM2510 (10)	42/UA/SC/P-2006

2. A clarification was sought from CDSCO, North Zone regarding validity of NOC- NA/NOC-T&A (Exhibit Batches)/2025/000037 dated 23.04.2025 vide file No. NOC/25/006551 for this consignment as the Manufacturing date is of March/2025 and NOC is dated 23.04.2025. They have stated that Manufacturing License/Product permissions are issued by concerned state licensing authority, Uttarakhand.

3. Also, as per the Circular dated 30.04.2024 issued vide File No. IMP-12/1/2024-eoffice issued by CDSCO states that SLA was supposed to issue manufacturing licence for manufacture of Unapproved/Banned/New Drugs for export purpose after issuance CDSCO NOC.

4. In this regard, it is requested to kindly inform this office if the manufacturing license/product permission for this specific product has been issued from your office after issuance of NOC by CDSCO.

5. This issues with approval of Commissioner of Customs (Preventive), Mumbai.

Yours faithfully,

Digitally signed by
Naresh Kumar Tiwari
Date: 22-08-2025
10:46:26

(Naresh Kumar Tiwari)
Deputy Commissioner of Customs
NSPU/R&I Mumbai Zone III



आयुक्त सीमाशुल्क का कार्यालय (निवारक)
OFFICE OF THE COMMISSIONER OF CUSTOMS (PREVENTIVE)
त. एवं आ. विभाग, 11 वा तल, नवीन सीमा शुल्क भवन,
NHAVA SHEVA PREVENTIVE UNIT, न्हावा शेवा निवारक इकाई,
R&I DIVISION, 11TH FLOOR, NEW CUSTOM HOUSE,
बेल्गार्ड एस्टेट, मुंबई - 400001 BALLARD ESTATE, MUMBAI - 400
001
Email: nspuri.prev-mum@gov.in

F. No: GEN/INT/Misc/156/2025-NSPU-R and I
DIN: 20250879OC000000BC82

Date: 25.08.2025

SEIZURE MEMO UNDER SECTION 110 (1) OF THE CUSTOMS ACT, 1962

Whereas, M/s Coral Industries Pvt. Ltd. (IEC-0394033353) vide SB No. 3766710 dated 22.07.2025 filed by Customs Broker M/s Star India Container Line Pvt. Ltd., has attempted to export the goods i.e. Moxbro Forte Syrup containing Amoxicillin and Bromhexine Hydrochloride without NOC from appropriate authority for export purpose. The details of said Shipping bill are as follows:

S/bill no. and date	Goods description & HS Code	FOB Value (INR)	Quantity	Batch No.
3766710 22.07.2025	Moxbro Forte Syrup (33041030)	25,53,000	50,000 Units	UFM2501 to UFM2510

2. Therefore, the goods of SB No. 3766710 dated 22.07.2025 were examined under Panchanama dated 25.07.2025. It was observed that the goods attempted for export contained a drug composition of Amoxicillin and Bromhexine Hydrochloride as per the labelling. The Certificates of Analysis submitted by the exporter also confirm its composition that it contains Amoxicillin and Bromhexine Hydrochloride. On further scrutiny, it was observed that the said composition of the drugs is prohibited for manufacture for sale, sale and distribution for human use in India vide Gazette notification no. CG-DL-E-02062023-246249 dated 02.06.2023 and vide notification no. S.O. 777(E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016.

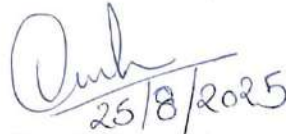
3. Vide letter dated 30.04.2024 issued vide file no. IMP-12/1/2024, Central Government through the Directorate General of Health Services, Drugs Standard Control Organization has stated that NOC's for Manufacture of Unapproved/Banned/New Drugs for export purpose from 15.05.2024 can be obtained from respective Zonal Offices of CDSCO before issuing Manufacturing

License from State Licensing Authority for Manufacture of Unapproved/Banned/New Drugs for export purpose. In this matter, it is observed that the CDSCO NOC dated 23.04.2025 appears to be applicable for further manufacturing rather than for already manufactured goods. It is further to mention that there are certain conditions stipulated in the NOC regarding the manufacturing of the goods, it was further observed that the physical product and its labels are not having basic instructions printed as mandated by the CDSCO NOC dated 23.04.2025 submitted by the exporter.

4. Further, it appears that the exporter M/s. Coral Laboratories Ltd. has not obtained NOC from concerned CDSCO Zonal Office at the time of the manufacturing of the goods. Here, it appears that the manufacturer exporter has not only manufactured an unapproved/banned drug without following laid down procedures. Hence, these goods can neither be exported nor be sent back to domestic Indian territory. Hence, the said goods under reasonable belief appear liable for confiscation under section 113(d) of the Customs Act, 1962.

6. Therefore, in exercise of power conferred on me under section 110(1) of the Customs Act, 1962, I, Umesh Chander, Preventive Officer, Nhava Sheva Preventive Unit, Rummaging and Intelligence division, New Customs House Mumbai-400001, hereby seize the goods to be exported vide SB No. 3766710 dated 22.07.2025 under section 110(1) of the Customs Act, 1962 and hereby direct exporter M/s Coral Industries Pvt. Ltd. (IEC-0394033353) and CFS M/s Conex Terminal Pvt. Ltd. present custodian of the said goods, not to remove, part with or otherwise deal with the said goods except with the permission of the proper officer Nhava Sheva Preventive Unit, Rummaging and Intelligence division, Mumbai.

7. This issues with the approval of Commissioner of Customs (Preventive), R&I, Mumbai Customs Zone-III.



(Umesh Chander)
Preventive Officer
NSPU/R&I

Copy to: M/s Coral Industries Pvt. Ltd. (IEC-0394033353)
2. M/s Conex Terminal Pvt. Ltd.

Lab.no-41/R&I(X)/Mumbai/14.08.2025

File No. :- GEN/INT/Misc/156/2025-NSPU-R and I dt. 13.08.2025

Shipping bill no.:- 3766710 dt. 22.07.2025

Seal No. :- PO 57

REPORT: - The samples as received is unit packing having printed label with description "**Amoxicillin and Bromhexine Hydrochloride Dry Suspension (MOXBRO Forte Syrup)**". The sample is in the form of off white coarse powder kept in brown colored glass bottle with metallic cap. On the basis of chemical, chromatographic and spectrometric examinations, the sample does not answer positive test for Heroin, Morphine, ganja, charas, THC, MDMA, Amphetamine and Diazepam. However, for further identification /confirmation, the samples may be forwarded to any other Government Laboratory, if required.

Sealed remnant sample returned.

Uw
25.08.2025

Rajesh Kumar Verma
Assistant Chemical Examiner


Rmg
25.08.25

CF-II

राजनाथ सिंह
Rajnath Singh
रसायन परीक्षक श्रेणी-II
Chemical Examiner Gr-II
नवीन सीमाशुल्क भवन प्रयोगशाला मुंबई-01
New Custom House Laboratory, Mumbai-01

DIRECTORATE GENERAL OF FOREIGN TRADE

STATEMENT OF BANK REALISATION

1	Firm Name	CORAL LABORATORIES LIMITED				
2	Address/GSTIN	Shed No. 3B, Patanwala Compound, Opp Shreyas, LBS Marg, Ghatkopar West, Mumbai, MAHARASHTRA-400086, GSTIN-27AAACC4421G1Z3				
3	IEC	0394033353				
4	Shipping Bill / Invoice No.	4254270				
5	Shipping Bill / Invoice Date	28-09-2023				
6	Shipping Bill Port	INNSA1				
7	Bank Name	HDFC BANK				
8	Bill ID No.	UB0010				
9	Bank Realisation Certificate No.	HDFC0000291A00635153 Dated 14-02-2025				
10	Date of Realisation of Money by Bank	22-05-2024				
11	Total Realised Value	24,550.00				
12	Commission, Discount, Insurance, Freight and Other Deductions	Commission	Discount	Insurance	Freight	Other
		0.00	0.00	0.00	0.00	0.00
13	Net Realised Value	24,550.00				
14	Currency of Realization	USD				
15	Date and Time of Printing	12-09-2025 03:02:34 PM				
16	QR Code Scan to Validate Online on DGFT Website: https://www.dgft.gov.in		17	Source (Bank / Exporter)	Exporter	

About the statement


- This statement is system generated from the DGFT website. It reproduces the information as available on the date and time of printing of this statement. This / Latest information can be verified by scanning the QR Code or validating from the DGFT website <https://www.dgft.gov.in> > Services > eBRC > View Any eBRC.

Note on the Realised Value

- The realised value (Item 11 above) is denominated in Foreign Currency and may be in CIF, C&F FOB terms or other Incoterms as negotiated between exporter and buyer of the goods and hence it may or may not include Commission, Freight, or Insurance as the case may be. Such details may be obtained from exporters, if needed. Policy Circular No. 06 (RE- 2012) / 2009-14 Dated 10.10.2012 of DGFT explains this in detail.

DIRECTORATE GENERAL OF FOREIGN TRADE

STATEMENT OF BANK REALISATION

1	Firm Name	CORAL LABORATORIES LIMITED				
2	Address/GSTIN	Shed No. 3B, Patanwala Compound, Opp Shreyas, LBS Marg, Ghatkopar West, Mumbai, MAHARASHTRA-400086, GSTIN-27AAACC4421G1Z3				
3	IEC	0394033353				
4	Shipping Bill / Invoice No.	2588618				
5	Shipping Bill / Invoice Date	20-07-2023				
6	Shipping Bill Port	INNSA1				
7	Bank Name	HDFC BANK				
8	Bill ID No.	UB0007				
9	Bank Realisation Certificate No.	HDFC0000291A00635209 Dated 14-02-2025				
10	Date of Realisation of Money by Bank	18-04-2024				
11	Total Realised Value	22,600.00				
12	Commission, Discount, Insurance, Freight and Other Deductions	Commission	Discount	Insurance	Freight	Other
		0.00	0.00	0.00	0.00	0.00
13	Net Realised Value	22,600.00				
14	Currency of Realization	USD				
15	Date and Time of Printing	12-09-2025 03:00:49 PM				
16	QR Code Scan to Validate Online on DGFT Website: https://www.dgft.gov.in		17	Source (Bank / Exporter)	Exporter	

About the statement

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Note on the Realised Value

- The realised value (Item 11 above) is denominated in Foreign Currency and may be in CIF, C&F FOB terms or other Incoterms as negotiated between exporter and buyer of the goods and hence it may or may not include Commission, Freight, or Insurance as the case may be. Such details may be obtained from exporters, if needed. Policy Circular No. 06 (RE- 2012) / 2009-14 Dated 10.10.2012 of DGFT explains this in detail.



We understand your world

HDFC Bank Limited,
I Think Techno Campus, 4th Floor,
Building-Alpha, Next To KanjurMarg Railway Station(East),
Mumbai - 400042

Certificate of Foreign Inward Remittance / GST Invoice

GST Invoice Number :
Issue Date : 31-Aug-2024
To (POS),
CORAL LABORATORIES LTD
NO 3B PATANWALA COMPOUND LBS MARG OPP SHREYAS
CINEMA GHATKOPER(WEST) MAHARASHTRA MUMBAI 400086
State/UT name and state/UT code: Maharashtra 27
PhnNo: 918879250441
Customer GSTIN Registration number :
Customer Plan Number as updated in the account: AAACC4421G

CIN NO: L65920MH1994PLC080618
From (POP):
HDFC Bank Ltd
26A NARAYAN PROP OLD BLDG CHANDIVALI OFF SAKI VIHAR ROAD
ANDHERI E Mumbai Maharashtra
State/UT name and state/UT code: Maharashtra 27
Bank GSTIN Registration number : 27AAACH2702H1Z0

Dear Customer,

We hereby confirm that your Account No :- 02912430000102 has been credited for inward remittance received as per swift details given below:

Inward No	Sender Ref No	Value Date	Credit Date
3008241049900296	2088223242FS	29-Aug-2024	30-Aug-2024
Currency	FCY Amount	Rate	INR Amount
USD	49960.00	0.0000	0.00
Remitter Details		Remitting Bank	Ordering Institute
21310321729 ASAL PHARMA CO APHCO SARL SALINE QUEST NIF NO: 2042789 DJIBOUTI REP OF DJIBOUTI		JPMORGAN CHASE BANK N.A.	304276227 HDFCINAA
Additional information as per swift message field 70 and 72		ROC/2088223242FS///URI/SS202408270 70580 PURCHASE OF MEDICAL PRODUCTS INVOICE UG0168 ACC/ORDERING INSTITUTION ISEADJDX XX CIN 8684BSA /BOOK/2088223242FS	
Purpose of remittance as per Beneficiary		P0103 - Advance receipts against export contracts other than Nepal and Bhutan	
Remarks / Additional Information - if any		EEFC	

In relation to the above remittance we have debited your account :- 02912430000102 with following taxes

Value Of Service	IGST rate%	IGST Amount (A)	CGST rate%	CGST Amount (B)	SGST rate%	SGST Amount (C)	UTGST Rate%	UTGST Amount (D)	Cess Rate%	Cess Amount (E)	Grand Total (A+B+C+D+E)
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

HSN NO : 9971-FINANCIAL & RELATED SERVICES PAN No : AAACH2702H

Please note that as per provisions of Foreign Exchange Management Act (FEMA, 1999), you are required to submit the export documents, in respect of above receipt, to our Bank within 21 days of the date of shipment, and in any case not later than one year from the date of remittance. Non-compliance of this requirement is liable for penal action under the above Act.

Please ensure to quote our above-mentioned inward remittance number, while submitting the export documents against this export advance received.

This is a Computer Generated Advice and does not require signature. In case of any discrepancy & purpose code change, please contact us within 7 days.

Regd Office : HDFC Bank Limited , HDFC Bank House , Senapati Bapat Marg , Lower Parel (West) , Mumbai - 400013



We understand your world

HDFC Bank Limited,
I Think Techno Campus, 4th Floor,
Building-Alpha, Next To KanjurMarg Railway Station(East),
Mumbai - 400042

Certificate of Foreign Inward Remittance / GST Invoice

GST Invoice Number :

Issue Date : 11-Jul-2024

To (PQS),

CORAL LABORATORIES LTD

NO 3B PATANWALA COMPOUND LBS MARG OPP SHREYAS
CINEMA GHATKOPER(WEST) MAHARASHTRA MUMBAI 400086

State/UT name and state/UT code: Maharashtra 27

PhnNo: 918879250441

Customer GSTIN Registration number :

Customer Pan Number as updated in the account: AAACC4421G

CIN NO: L65920MH1994PLC080618

From (POP):

HDFC Bank Ltd

26A NARAYAN PROP OLD BLDG CHANDIVALI OFF SAKI VIHAR ROAD
ANDHERI E Mumbai Maharashtra

State/UT name and state/UT code: Maharashtra 27

Bank GSTIN Registration number : 27AAACH2702H1Z0

Dear Customer,

We hereby confirm that your Account No :- 02912430000102 has been credited for inward remittance received as per swift details given below:

Inward No	Sender Ref No	Value Date	Credit Date
110724049903317	8786207192FS	10-Jul-2024	11-Jul-2024
Currency	FCY Amount	Rate	INR Amount
USD	79919.00	0.0000	0.00
Remitter Details		Remitting Bank	Ordering Institute
21310321729 ASAL PHARMA CO APHCO SARL SALINE QUEST NIF NO: 2042789 DJIBOUTI REP OF DJIBOUTI		JPMORGAN CHASE BANK N.A.	304276227 HDFCINAA
Additional information as per swift message field 70 and 72		ROC/8786207192FS//URI/SS202407089 34924 PURCHASE OF MEDICAL PRODUCTS INVOICE CLL/EXPROF/310/23-24 ACC/ORDERING INSTITUTION ISEADJDX XX CIN 8684BSA /BOOK/8786207192FS	
Purpose of remittance as per Beneficiary		P0103 - Advance receipts against export contracts other than Nepal and Bhutan	
Remarks / Additional Information - if any		EEFC	

In relation to the above remittance we have debited your account :- 02912430000102 with following taxes

Value Of Service	IGST rate%	IGST Amount (A)	CGST rate%	CGST Amount (B)	SGST rate%	SGST Amount (C)	UTGST Rate%	UTGST Amount (D)	Cess Rate%	Cess Amount (E)	Grand Total (A+B+C+D+E)
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

HSN NO : 9971-FINANCIAL & RELATED SERVICES

PAN No : AAACH2702H

Please note that as per provisions of Foreign Exchange Management Act (FEMA, 1999), you are required to submit the export documents, in respect of above receipt, to our Bank within 21 days of the date of shipment, and in any case not later than one year from the date of remittance. Non-compliance of this requirement is liable for penal action under the above Act.

Please ensure to quote our above-mentioned inward remittance number, while submitting the export documents against this export advance received.

This is a Computer Generated Advice and does not require signature. In case of any discrepancy & purpose code change, please contact us within 7 days.

Regd Office : HDFC Bank Limited , HDFC Bank House , Senapati Bapat Marg , Lower Parel (West) , Mumbai - 400013



We understand your world

HDFC Bank Limited,
I Think Techno Campus, 4th Floor,
Building-Alpha, Next To KanjurMarg Railway Station(East),
Mumbai - 400042

Certificate of Foreign Inward Remittance / GST Invoice

GST Invoice Number :
Issue Date : 18-Jun-2025

CIN NO: L65920MH1994PLC080618
From (POP):

To (POS),
CORAL LABORATORIES LTD
PATANWALA COMPOUND OPP SHREYAS LBS MARG
GHATKOPAR WEST MAHARASHTRA MUMBAI 400086
State/UT name and state/UT code: Maharashtra 27
PhnNo: 918879250441
Customer GSTIN Registration number :
Customer Pan Number as updated in the account: AAACC4421G

HDFC Bank Ltd
26A NARAYAN PROP OLD BLDG CHANDIVALI OFF SAKI VIHAR ROAD
ANDHERI E Mumbai Maharashtra
State/UT name and state/UT code: Maharashtra 27
Bank GSTIN Registration number : 27AAACH2702H1Z0

Dear Customer,

We hereby confirm that your Account No :- 02912430000102 has been credited for inward remittance received as per swift details given below:

Inward No 1706251049900037	Sender Ref No 0009443167FS	Value Date 16-Jun-2025	Credit Date 18-Jun-2025
Currency USD	FCY Amount 99935.00	Rate 0.0000	INR Amount 0.00
Remitter Details 21310321729 ASAL PHARMA CO APHCO SARL SALINE OUEST NIF NO: 2042789 DJIBOUTI REP OF DJIBOUTI		Remitting Bank JPMORGAN CHASE BANK N.A.	Ordering Institute 304276227 HDFCINAA
Additional information as per swift message field 70 and 72		ROC/0009443167FS//URI/SS202506149 15680 PURCHASE OF MEDICAL PRODUCTS INVOICE NO:CLL EXPROF 0012 25 26 ACC/ORDERING INSTITUTION ISEADJDX XX CIN 8684BSA /BOOK/0009443167FS	
Purpose of remittance as per Beneficiary		P0103 - Advance receipts against export contracts other than Nepal and Bhutan	
Remarks / Additional Information - if any		EEFC	

In relation to the above remittance we have debited your account :- 02912430000102 with following taxes

Value Of Service	IGST rate%	IGST Amount (A)	CGST rate%	CGST Amount (B)	SGST rate%	SGST Amount (C)	UTGST Rate%	UTGST Amount (D)	Cess Rate%	Cess Amount (E)	Grand Total (A+B+C+D+E)
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

HSN NO : 9971-FINANCIAL & RELATED SERVICES PAN No : AAACH2702H

Please note that as per provisions of Foreign Exchange Management Act (FEMA, 1999), you are required to submit the export documents, in respect of above receipt, to our Bank within 21 days of the date of shipment, and in any case not later than one year from the date of remittance. Non-compliance of this requirement is liable for penal action under the above Act.

Please ensure to quote our above-mentioned inward remittance number, while submitting the export documents against this export advance received.

This is a Computer Generated Advice and does not require signature. In case of any discrepancy & purpose code change, please contact us within 7 days.

Regd Office : HDFC Bank Limited , HDFC Bank House , Senapati Bapat Marg , Lower Parel (West) , Mumbai - 400013



We understand your world

HDFC Bank Limited,
I Think Techno Campus, 4th Floor,
Building-Alpha, Next To KanjurMarg Railway Station(East),
Mumbai - 400042

Certificate of Foreign Inward Remittance / GST Invoice

GST Invoice Number :

Issue Date : 05-Dec-2024

To (POS),

CORAL LABORATORIES LTD

N0 3BIPATANWALA COMPOUND LBS MARG OPP SHREYAS
CINEMA GHATKOPER(WEST) MAHARASHTRA MUMBAI 400086

State/UT name and state/UT code: Maharashtra 27

PhnNo: 918879250441

Customer GSTIN Registration number :

Customer Pan Number as updated in the account: AAACC4421G

Dear Customer,

We here by confirm that your Account No :- 02912430000102 has been credited for inward remittance received as per swift details given below:

CIN NO: L65920MH1994PLC080618

From (POP):

HDFC Bank Ltd

26A NARAYAN PROP OLD BLDG CHANDIVALI OFF SAKI VIHAR ROAD
ANDHERI E Mumbai Maharashtra

State/UT name and state/UT code: Maharashtra 27

Bank GSTIN Registration number : 27AAACH2702H120

Inward No	Sender Ref No	Value Date	Credit Date
0412241049900172	5058722338FS	03-Dec-2024	04-Dec-2024
Currency	FCY Amount	Rate	INR Amount
USD	81935.00	0.0000	0.00
Remitter Details		Remitting Bank	Ordering Institute
21310321729 ASAL PHARMA CO APHCO SARL SALINE QUEST. NIF NO: 2042789 DJIBOUTI REP OF DJIBOUTI		JPMORGAN CHASE BANK N.A.	304276227 HDFCINAA
Additional information as per swift message field 70 and 72		ROC/5058722338FS///URI/SS202411273 27701 PURCHASE OF MEDICAL PRODUCTS INVOICE NO:UG0280,UG0279,UG0015 ACC/ORDERING INSTITUTION ISEADJDX XX CIN 8684BSA /BOOK/5058722338FS	
Purpose of remittance as per Beneficiary		P0103 - Advance receipts against export contracts other than Nepal and Bhutan	
Remarks / Additional Information - if any		EEFC	

In relation to the above remittance we have debited your account :- 02912430000102 with following taxes

Value Of Service	IGST rate%	IGST Amount (A)	CGST rate%	CGST Amount (B)	SGST rate%	SGST Amount (C)	UTGST Rate%	UTGST Amount (D)	Cess Rate%	Cess Amount (E)	Grand Total (A+B+C+D+E)
0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

HSN NO : 9971-FINANCIAL & RELATED SERVICES

PAN No : AAACH2702H

Please note that as per provisions of Foreign Exchange Management Act (FEMA, 1999), you are required to submit the export documents, in respect of above receipt, to our Bank within 21 days of the date of shipment, and in any case not later than one year from the date of remittance. Non-compliance of this requirement is liable for penal action under the above Act.

Please ensure to quote our above-mentioned inward remittance number, while submitting the export documents against this export advance received.

This is a Computer Generated Advice and does not require signature. In case of any discrepancy & purpose code change, please contact us within 7 days.

Regd Office : HDFC Bank Limited , HDFC Bank House , Senapati Bapat Marg , Lower Parel (West) , Mumbai - 400013

Inward Remittance Ref	Date	FIRC	already utilised	FIRC USD Utilised	Bal USD	GST	EXP INV	BILL-AMT	S/BILL	S/BILL DT
0412241049900172	04.12.2024	81935	75050.20	6884.80		UB0034	CLL/EXP/313/23-24	\$ 28,400.00	8911107	05.04.2024
1706251049900037	18.06.2025	99935		83115.2	16819.8	UB0005	CLL/EXP/078/24-25	\$ 31,000.00	1341448	31.05.2024
						UB0015	CLL/EXP/228/24-25	\$ 30,600.00	5045353	23.10.2024
				\$ 90,000.00	\$ 16,819.80			\$ 90,000.00		

Inward Remittance Ref	Date	FIRC	already utilised	FIRC USD Utilised	Bal USD	GST	EXP INV	BILL AMT	S/BILL	S/BILL DT
110724049903317	11.07.2024	\$ 79,919.00	75646.46	\$ 4,272.54		UB0015	CLL/EXP/196/23-24	\$ 24,640.00	5706761	30.11.2023
300824049900296	30.08.2024	49960 bank charge..		45928.46	4031.54	M-46/23-24	CLL/EXP/265/23-24	\$ 7,528.72	7191279	01.02.2024
				40		D0108	CLL/EXP/266/23-24	\$ 8,450.00	8014987	02.03.2024
						M-056	CLL/EXP/315/23-24	\$ 9,622.28	9592795	03.05.2024
		49960		\$ 50,241.00				\$ 50,241.00		

**FOOD SAFETY & DRUGS ADMINISTRATION AUTHORITY,
DIRECTORATE GENERAL OF MEDICAL HEALTH AND FAMILY
WELFARE, SAHASTRADHARA ROAD, DEHRADUN**

File no. 26/1/Drug/47/2019/ 13341

Date: 28 July, 2022

Certificate of Good Manufacturing Practices

Certificate no.: 26/1/Drug/47/2019/

On the basis of the Joint Inspection carried out on 21-07-2022 and 22-07-2022, and further inspected by S.I.D HQ on Date 28-07-2022 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

1- Name & Address of site:

2-

M/s Coral Laboratories Ltd,
Plot No-27, 28, Pharmacy,
Selaqui, Dehradun-248011, Uttarakhand.

3- Manufacturer's license number:

Form 25- 42/UA/2006

Form 28- 42/UA//SC/P-2006

4- Table 1:

Dosage form(s)	Activity(ies)
Tablets (Non Beta Lactum & Beta Lactum)	Manufacturing
Capsule (Hard Gelatin) (Non Beta Lactum & Beta Lactum)	Manufacturing
Oral Liquid Dosage (Syrup & Suspensions) Non Beta Lactum)	Manufacturing
Dry Syrups (Non Beta Lactum & Beta Lactum)	Manufacturing
Preparation for External Application (Ointment, Cream, Ge, Ear Drops, Powder & Shampoo)	Manufacturing
Suppository (Non Beta Lactum)	Manufacturing
Effervescent Tablets (Non Beta Lactum)	Manufacturing

The responsibility for the quality of the individual batches of the pharmaceutical products manufactured through this process lies with the manufacturer.

This certificate remains valid until 27-07-2025. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

The firm is following Good Manufacturing Practices as per World Health Organization (WHO) TRS Guide Lines, in the Manufacturing & testing of the said categories of Products and Items in respect of which the Certificates of Pharmaceuticals products have been issued.

Address of certifying Authority:

Directorate General of Medical Health & Family Welfare,
Sahastradhara Road, Dehradun (Uttarakhand) INDIA.

Name & function of responsible person:

Shri Tajber Singh

Drugs Licensing & Controlling Authority
Uttarakhand.

Email: drugcontroluk@gmail.com

Tel.no. NA

Fax. no. 0135260874



(Handwritten signature)

(Handwritten signature)
28/7/2022

(Tajber Singh)
Drugs Licensing & Controlling Authority,
(Uttarakhand) (Tajber Singh)
Drug Controlling & Licensing Authority
Uttarakhand



CORAL LABORATORIES LTD

AN ISO 9001: 2008 CERTIFIED ORGANIZATION



CORP. OFFICE : #3B, Patanwala Compound, Opp. Shreyas Cinema, L.B.S. Marg, Ghatkopar (West), Mumbai - 400 086. India
Tel. : +91-22-2500 5245, 2500 8208, 2500 5246 • Fax : +91-22-2500 4893 • E-mail : exports@corallab.com • Website : www.corallab.com

CIN NO. U28199MH1997PLC001589

L24231MH1997PLC422233

Date : 24.07.2025

To,
Asstt. Commissioner of Customs,
Export Department, Nhava Sheva,

Dear Sir,

Sub : End Use Clarification against Moxbro Forte Syrup

Ref : Shipping Bill No. 3766710 Dtd. 22.07.2025, our Invoice No. M-28/25-26 dtd 22.07.2025

Dear Sir,

We would like to inform you that Subject product is considered as a Dry Suspension and not a Syrup. A Syrup is defined as a solution of Sucrose in Purified Water as per USP and BP Monograph.

Moxbro Forte Syrup is a dry Suspension which needs to be reconstituted with water and forms a suspension and its usage is like an antibiotic used to treat respiratory tract infections. It is primarily used to treat infections and is administered only for a week. And not used as a "Cough Syrup".

Also we would like to inform you that we have not used any high-risk drug components like Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, and Sorbitol Solution in Moxbro Forte Syrup. So the risk of contamination with diethylene glycol (DEG) or ethylene glycol (EG) is ruled out for this product.

Hence Kindly give export allows on same to proceed for export shipment.

Your support is highly appreciated.

Thanking you,

Yours faithfully,
For CORAL LABORATORIES LTD.



Authorised Signatory

W
07/08/25

From,

Add. Commissioner,
Food Safety & Drug Administration
Sahastradhara Road, Dehradun,
Uttarakhand.

To,

M/s Coral Laboratories Ltd.,
Plot No. 27 & 28, Pharmacy,
Selaqui, Dehradun,
Uttarakhand (India)

File No. 26/1/Drug/47/2019/ 114056
Sub- Extension of Validity of COPP granted under WHO-GMP & COPP certification scheme
& WHO-GMP Certificate.

Dated 01/08/2025

Sir,

In reference to your application dated 19-06-2025 regarding above noted subjects it is
to inform you that the validity of COPP granted under WHO-GMP certification scheme &
* WHO- GMP Certificate is further extended from 27-07-2025 to 26-02-2026 for Six months.



(Tajber Singh) 11/8/2025
Add. Commissioner
Food Safety & Drug Administration
Uttarakhand
ADD. COMMISSIONER
FOOD SAFETY &
DRUG ADMINISTRATION (U.K.)

F. No. 26/1/Drug/47/2019/

Of dated

Copy to- Dy. Drug Controller (North Zone) CDSCO, Govt. of India, Kamla Nehru Nagar,
Hapur Road, Gaziabad, UP.

07/08/25
W

(Tajber Singh)
Add. Commissioner
Food Safety & Drug Administration
Uttarakhand

FOOD SAFETY & DRUGS ADMINISTRATION AUTHORITY,
DIRECTORATE GENERAL OF MEDICAL HEALTH AND FAMILY
WELFARE, SAHASTRADHARA ROAD, DEHRADUN

F.No. 26/1/Drud/47/2019/ 1250

Dated: 11-05-2023

G.L.P. CERTIFICATE

This is to certify that M/s Coral Laboratories Ltd., Plot No. 27 & 28, Pharmacity, Selaqui, Dehradun, Uttarakhand (India) has been licensed under Drugs & Cosmetics Act 1940 & Rules there under. They are holding valid Drug manufacturing license 42/UA//2006 on form 25 & 42/UA/SC/P-2006 on Form-28 valid up to 06-06-2026 to manufacture for sale of Drugs.

In view of report dt. 09-05-2023 of Sr. Inspector of Drugs, Dehradun it is certified that M/s Coral Laboratories Ltd., Plot No. 27 & 28, Pharmacity, Selaqui, Dehradun, Uttarakhand (India) confirm to G.L.P. requirements of Rule 74,78 & 150E and Good Laboratory Practices as laid down under Schedule "L-1" (150-E) of the Drugs & Cosmetics Rule 1945.

This certificate is issued to the firm on their request for submission to Govt. departments / Institutions / Overseas Authority.

This certificate is valid for a period up to Three Year from the date of issue.



Handwritten signature/initials
07/08/23

Handwritten signature
(Tajber Singh) 11/5/2023
Drug Controlling
Uttarakhand

(Tajber Singh)
Drug Controlling & Licensing Authority
Uttarakhand

List of the product specified in Schedule C & C1 and excluding Schedule X to be manufactured at
M/S Coral Laboratories Ltd, Plot No- 27 & 28 , Pharmacy Dehradun Uttarakhand under
License No. 42/UA/SC/P-2006 on Form No. 28

S.NO	Generic Name	Composition	Date of Approval
20	Cefixime For Oral Suspension USP 100 MG/5ML	Composition: Each 5 ml of reconstituted suspension contains: Cefixime Trihydrate USP equivalent to anhydrous Cefixime : 100 mg Excipients: q.s.	13.06.2016 For Export
21	Cefixime Capsules 200 mg	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 200 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
22	Cefixime Capsules 200 mg CORXIME 200 CAPSULES	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 200 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
23	Cefixime Capsules 200 mg DORXIME 200 CAPSULES	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 200 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
24	Cefixime Capsules 400 mg	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 400 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
25	Cefixime Capsules 400 mg DORXIME 400 CAPSULES	Composition: Each hard gelatin capsule contains Cefixime Trihydrate BP equivalent to anhydrous Cefixime: 400 mg Excipients: q.s. Empty gelatin capsule contains approved colours	13.06.2016 For Export
26	Amoxicillin And Bromhexine Hydrochloride Suspension MOXBRO DRY SYRUP	Composition: Each 5 ml of reconstituted syrup contains Amoxicillin Trihydrate BP equivalent to Amoxicillin :125 mg Bromhexine Hydrochloride BP:4 mg Excipients: q.s. Colour: Erythrosine & Tartrazine	13.06.2016 For Export
27	Amoxicillin And Bromhexine Hydrochloride Dry Suspension MOXBRO FORTE SYRUP	Composition: Each 5 ml of reconstituted syrup contains: Amoxicillin Trihydrate BP equivalent to Amoxicillin :250 mg Bromhexine Hydrochloride BP:8 mg Excipients: q.s. Colour: Sunset Yellow	13.06.2016 For Export
28	Cloxacillin Sodium For Oral Solution USP 125 mg/5 ml CLODAX DRY SYRUP	Composition: Each 5 ml of reconstituted syrup contains: Cloxacillin Sodium USP equivalent to Cloxacillin : 125 mg Colour: Sunset Yellow	13.06.2016 For Export



Tajber Singh
29/6/2021
(Tajber Singh)
Drug Controlling & Licensing Authority
Uttarakhand


सत्यमेव जयते

भारत का राजपत्र The Gazette of India

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असाधारण
EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (ii)
PART II—Section 3—Sub-section (ii)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

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स्वास्थ्य और परिवार कल्याण मंत्रालय
(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 2 जून, 2023

का.आ. 2394(अ).—जबकि केंद्र सरकार ने औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए मानव उपयोग के लिए निमेसुलाइड + पेरासिटामोल डिसपर्सिबल गोलियों के निश्चित खुराक संयोजन वाली दवा के बिक्री हेतु विनिर्माण, बिक्री और वितरण को दिनांक 10 मार्च, 2016 के भारत के राजपत्र, असाधारण, भाग II, खंड 3(ii) में प्रकाशित अधिसूचना सां.आ. 712 (अ) के तहत प्रतिषिद्ध किया।

और जबकि, माननीय उच्चतम न्यायालय द्वारा 2017 की सिविल अपील संख्या 22972, भारत संघ और अन्य बनाम फाइजर लिमिटेड और अन्य के मामले में दिनांक 15 दिसंबर, 2017 के अपने फैसले में दिए गए निर्देशों के आलोक में अन्य बातों के साथ-साथ यह उल्लेख करते हुए कि 15 एफडीसी जिसके संबंध में 1988 से पहले अनुमोदित होने का दावा किया गया था, केंद्र सरकार, यदि वह ऐसा चाहती है, तो नए सिरे से जांच कर सकती है कि क्या निर्धारित खुराक संयोजनों, जिसे 1988 से पहले लाइसेंस दिया गया था, को औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क के तहत किसी अधिसूचना का विषय होना चाहिए। इस मामले की भारत सरकार द्वारा गठित एक विशेषज्ञ समिति द्वारा जांच की गई थी जिसने 1 अप्रैल, 2022 को उक्त दवा पर अपनी रिपोर्ट केंद्र सरकार को प्रस्तुत की थी तथा औषधि और सौंदर्य प्रसाधन अधिनियम, 1940 (1940 का 23) की धारा 5 के तहत गठित औषध तकनीकी सलाहकार बोर्ड ने विशेषज्ञ समिति द्वारा प्रस्तुत रिपोर्ट पर सहमति व्यक्त की।

अधिसूचना

नई दिल्ली, 2 जून, 2023

का.आ. 2395(अ).—जबकि केंद्र सरकार ने औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए मानव उपयोग के लिए एमोक्सोलीन + ब्रोमहक्सोलीन के निश्चित खुराक संयोजन वाली दवा के बिक्री हेतु विनिर्माण, बिक्री और वितरण को दिनांक 10 मार्च, 2016 के भारत के राजपत्र, असाधारण, भाग II, खंड 3(ii) में प्रकाशित अधिसूचना का.आ. 777 (अ) के तहत प्रतिषिद्ध किया।

और जबकि, माननीय उच्चतम न्यायालय द्वारा 2017 की सिविल अपील संख्या 22972, भारत संघ और अन्य बनाम फाइजर लिमिटेड और अन्य के मामले में दिनांक 15 दिसंबर, 2017 के अपने फैसले में दिए गए निर्देशों के आलोक में अन्य बातों के साथ-साथ यह उल्लेख करते हुए कि 15 एफडीसी जिसके संबंध में 1988 से पहले अनुमोदित होने का दावा किया गया था, केंद्र सरकार, यदि वह ऐसा चाहती है, तो नए सिरे से जांच कर सकती है कि क्या निर्धारित खुराक संयोजनों, जिसे 1988 से पहले लाइसेंस दिया गया था, को औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क के तहत किसी अधिसूचना का विषय होना चाहिए। इस मामले की भारत सरकार द्वारा गठित एक विशेषज्ञ समिति द्वारा जांच की गई थी जिसने 1 अप्रैल, 2022 को उक्त दवा पर अपनी रिपोर्ट केंद्र सरकार को प्रस्तुत की थी तथा औषधि और सौंदर्य प्रसाधन अधिनियम, 1940 (1940 का 23) की धारा 5 के तहत गठित औषध तकनीकी सलाहकार बोर्ड ने विशेषज्ञ समिति द्वारा प्रस्तुत रिपोर्ट पर सहमति व्यक्त की।

और जबकि, विशेषज्ञ समिति ने सिफारिश की थी कि "इस एफडीसी में शामिल घटकों का कोई थेरोपेटिक औचित्य नहीं है और एफडीसी में इंसानों के लिए जोखिम शामिल हो सकता है। इसलिए व्यापक जनहित में, औषधि और प्रसाधन सामग्री अधिनियम, 1940 की धारा 26क के तहत इस एफडीसी के विनिर्माण, बिक्री या वितरण पर प्रतिबंध लगाना आवश्यक है। उपर्युक्त के आलोक में, रोगियों में दवा के किसी भी प्रकार के उपयोग हेतु विनियमन या प्रतिबंध की अनुमति देना न्यायसंगत नहीं है। इसलिए, धारा 26क के तहत केवल प्रतिषेध किए जाने की सिफारिश की जाती है।"

और जबकि विशेषज्ञ समिति और औषध तकनीकी सलाहकार बोर्ड की सिफारिशों के आधार पर, केंद्र सरकार इस बात से संतुष्ट है कि देश में जनहित में मानव उपयोग के लिए उक्त दवा की बिक्री के लिए विनिर्माण, बिक्री और वितरण पर प्रतिबंध के माध्यम से विनियमन करना आवश्यक और समीचीन है।

इसलिए, अब, भारत सरकार, स्वास्थ्य और परिवार कल्याण मंत्रालय (स्वास्थ्य और परिवार कल्याण विभाग) द्वारा भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (ii) में प्रकाशित अधिसूचना संख्या सां.आ. 777 (अ) दिनांक 10 मार्च, 2016 के अधिक्रमण में उक्त विशेषज्ञ समिति और औषध तकनीकी सलाहकार बोर्ड की सिफारिशों के आधार पर और औषधि तथा सौंदर्य प्रसाधन अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, केंद्र सरकार एमोक्सोलीन + ब्रोमहक्सोलीन की निश्चित खुराक संयोजन वाली दवा के मानव उपयोग के लिए बिक्री के लिए विनिर्माण, बिक्री या वितरण पर तत्काल प्रभाव से रोक लगाती है।

[फा. सं. X.11035/53/2014-डीएफक्यूसी (भाग-IV)]

आराधना पटनायक, संयुक्त सचिव

NOTIFICATION

New Delhi, the 2nd June, 2023

S.O. 2395(E).—Whereas, the Central Government in exercise of the powers conferred by section 26 A of the Drugs and Cosmetics Act, 1940 (23 of 1940) prohibited the manufacture for sale, sale and distribution for human use of drug fixed dose combination of Amoxicillin+ Bromhexine vide notification number S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016;

And whereas, in light of the directions given by the Hon'ble Supreme Court of India in its judgement dated the 15th December, 2017 in the case of Union of India and Anr. v/s Pfizer Ltd. and Ors. Civil Appeal No. 22972 of 2017, *inter alia*, mentioning that in respect of 15 FDCs claimed to be approved prior to 1988, Central Government may, if it so chooses, de novo carry out an inquiry as to whether fixed dose combinations licensed prior to 1988 should be the subject matter of a notification under section 26A of the Drugs and Cosmetics Act, 1940(23 of 1940), the matter was examined by an Expert Committee constituted by Government of India which furnished its report on the 1st April, 2022 in respect of above drug to the Central Government and Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) agreed to the report submitted by the Expert Committee;

And whereas, the Expert Committee recommended that "there is no therapeutic justification for the ingredients contained in this FDC and the FDC may involve risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under Section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended".

And whereas on the basis of the recommendations of the Expert Committee and the Drugs Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient in public interest to regulate by way of prohibition the manufacture for sale, sale and distribution for human use of the said drug in the country.

Now, therefore, in supersession of the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O. 777 (E) dated the 10th March, 2016; on the basis of the recommendations of the said Expert Committee and the Drugs Technical Advisory Board; and in exercise of powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby prohibits the manufacture for sale, sale or distribution for human use of drug fixed dose combination of **Amoxicillin+ Bromhexine** with immediate effect.

[F. No. X.11035/53/2014-DFQC (Part-IV)]

ARADHANA PATNAIK, Jt. Secy.

अधिसूचना

नई दिल्ली, 2 जून, 2023

का.आ. 2396(अ).—जबकि केंद्र सरकार ने औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए मानव उपयोग के लिए फोल्कोडाइन + प्रोमेथेजीन के निश्चित खुराक संयोजन वाली दवा के बिक्री हेतु विनिर्माण, बिक्री और वितरण को दिनांक 10 मार्च, 2016 के भारत के राजपत्र, असाधारण, भाग II, खंड 3(ii) में प्रकाशित अधिसूचना का.आ. 789 (अ) के तहत प्रतिषिद्ध किया।

और जबकि, माननीय उच्चतम न्यायालय द्वारा 2017 की सिविल अपील संख्या 22972, भारत संघ और अन्य बनाम फाइजर लिमिटेड और अन्य के मामले में दिनांक 15 दिसंबर, 2017 के अपने फैसले में दिए गए निर्देशों के आलोक में अन्य बातों के साथ-साथ यह उल्लेख करते हुए कि 15 एफडीसी जिसके संबंध में 1988 से पहले अनुमोदित होने का दावा किया गया था, केंद्र सरकार, यदि वह ऐसा चाहती है, तो नए सिरे से जांच कर सकती है कि क्या निर्धारित खुराक संयोजनों, जिसे 1988 से पहले लाइसेंस दिया गया था, को औषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) की धारा 26क के तहत किसी अधिसूचना का विषय होना चाहिए। इस मामले की भारत सरकार द्वारा गठित एक विशेषज्ञ समिति द्वारा जांच की गई थी जिसने 1 अप्रैल, 2022 को उक्त दवा पर अपनी रिपोर्ट केंद्र सरकार को प्रस्तुत की थी तथा औषधि और सौंदर्य प्रसाधन अधिनियम, 1940 (1940 का 23) की धारा 5 के तहत गठित औषध तकनीकी सलाहकार बोर्ड ने विशेषज्ञ समिति द्वारा प्रस्तुत रिपोर्ट पर सहमति व्यक्त की।


और जबकि, विशेषज्ञ समिति ने सिफारिश की थी कि "इस एफडीसी में शामिल घटकों का कोई थेरोपेटिक औचित्य नहीं है और एफडीसी में इसानों के लिए जोखिम शामिल हो सकता है। इसलिए व्यापक जनहित में, औषधि और प्रसाधन सामग्री अधिनियम, 1940 की धारा 26क के तहत इस एफडीसी के विनिर्माण, बिक्री या वितरण पर प्रतिबंध लगाना आवश्यक है। उपर्युक्त के आलोक में, रोगियों में दवा के किसी भी प्रकार के उपयोग हेतु विनियमन या प्रतिबंध की अनुमति देना न्यायसंगत नहीं है। इसलिए, धारा 26क के तहत केवल प्रतिषेध किए जाने की सिफारिश की जाती है।"

और जबकि विशेषज्ञ समिति और औषध तकनीकी सलाहकार बोर्ड की सिफारिशों के आधार पर, केंद्र सरकार इस बात से संतुष्ट है कि देश में जनहित में मानव उपयोग के लिए उक्त दवा की बिक्री के लिए विनिर्माण, बिक्री और वितरण पर प्रतिबंध के माध्यम से विनियमन करना आवश्यक और समीचीन है।

इसलिए, अब, भारत सरकार, स्वास्थ्य और परिवार कल्याण मंत्रालय (स्वास्थ्य और परिवार कल्याण विभाग) द्वारा भारत के राजपत्र, असाधारण, भाग II, खंड 3, उप-खंड (ii) में प्रकाशित अधिसूचना संख्या का.आ. 789 (अ) दिनांक 10 मार्च, 2016 के अधिक्रमण में उक्त विशेषज्ञ समिति और औषध तकनीकी सलाहकार बोर्ड की सिफारिशों के आधार पर और औषधि तथा सौंदर्य प्रसाधन अधिनियम, 1940 (1940 का 23) की धारा 26क द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, केंद्र सरकार फोल्कोडाइन + प्रोमेथेजीन की निश्चित खुराक संयोजन वाली दवा के मानव उपयोग के लिए बिक्री के लिए विनिर्माण, बिक्री या वितरण पर तत्काल प्रभाव से रोक लगाती है।

[फा. सं. X.11035/53/2014-डीएफक्यूसी (भाग-IV)]

आराधना पटनायक, संयुक्त सचिव

	सीमाशुल्क आयुक्त का कार्यालय, एनएस-II OFFICE OF THE COMMISSIONER OF CUSTOMS, NS-II केंद्रीकृत निर्यात मूल्यांकन प्रकोष्ठ, जवाहरलाल नेहरू सीमा शुल्क भवन CENTRALIZED EXPORT ASSESSMENT CELL, JAWAHARLAL NEHRU CUSTOM HOUSE, न्हावाशेवा, तालुका -उरण, जिला -रायगढ़, महाराष्ट्र 400707-400- NHAVA SHEVA, TALUKA-URAN, DIST-RAIGAD, MAHARASHTRA-400707
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क्र.सं./E.No.:CUS/DOCK/176/2025-Exp.(Docks) Date of Order: 16.06.2025

Date of Issue: 16.06.2025

द.प.सं./DIN: - 20250678NT0000555079

जारीकर्ता /Passed By: Shri Raghu Kiran B., Additional Commissioner of
Customs, CEAC, NS-II, JNCH, Nhava Sheva.

मूलआदेश संख्या/Order-In-Original No.: 309 (L)/2025-26/ADC/CEAC/NS-
II/CAC/JNCH

निर्यातक का नाम/Exporter's Name: M/s. Coral Laboratories Ltd. (IEC-
0394033353)

मूल-आदेश

ORDER-IN-ORIGINAL.

1. यह प्रति जिस व्यक्ति को जारी की जाती है, उसके उपयोग के लिए नि: शुल्क दी जाती है।
This copy is granted free of charge for the use of the person to whom it is issued.

2. इस आदेश के विरुद्ध अपील सीमाशुल्क अधिनियम 1962 की धारा 128 (1) के तहत इस आदेश की
संसूचना की तारीख से साठ दिनों के भीतर सीमाशुल्क आयुक्त (अपील), जवाहरलाल नेहरू सीमाशुल्क भवन, राणा,
ता. उरण, जिला - रायगढ़, महाराष्ट्र -400707 को की जा सकती है। अपील दो प्रतियों में देनी चाहिए और
सीमाशुल्क (अपील) नियमावली, 1982 के अनुसार फॉर्म सी. ए.-1 संलग्नक में की जानी चाहिए। अपील पर
न्यायालय फीस के रूप में 2.00 रुपये मात्र का स्टाम्प लगाया जायेगा और साथ में यह आदेश या इसकी एक प्रति
लगायी जायेगी। यदि इस आदेश की प्रति संलग्न की जाती है तो इस पर न्यायालय फीस के रूप में 2.00 रुपये का
स्टाम्प भी लगाया जायेगा जैसा कि न्यायालय फीस अधिनियम 1870 की अनुसूची 1, मद 6 के अंतर्गत निर्धारित
किया गया है ॥

An appeal against this order lies with the Commissioner of Customs (Appeal),
Jawaharlal Nehru Custom House, Nhava Sheva, Tal: Uran, Dist: Raigad, Maharashtra -
400707 under section 128(1) of the Customs Act, 1962 within sixty days from the date of
communication of this order. The appeal should be in duplicate and should be filed in Form
CA-1 Annexure on the Customs (Appeal) Rules, 1982. The Appeal should bear a Court Fee
stamp of Rs.1.50 only and should be accompanied by this order or a copy thereof. If a copy
of this order is enclosed, it should also bear a Court Fee Stamp of Rs. 1.50 only as prescribed
under Schedule 1, items 6 of the Court Fee Act, 1970.

3. इस निर्णय या आदेश के विरुद्ध अपील करने वाला व्यक्ति अपील अनिर्णीत रहने तक, शुल्क या राशि के

संबंध में विवाद होने पर माँगे गये शुल्क के 7.5% का, अथवा केवल शास्ति के संबंधमें विवाद होने पर शास्ति का भुगतान करेगा।

Any person desirous of appealing against this decision or order shall, pending the appeal, make payment of 7.5% of the duty demanded where duty or duty and penalty are in dispute, or penalty, where penalty alone is in dispute.

Brief Facts of the Case

M/s. Coral Laboratories Ltd. (IEC- 0394033353), a manufacturer Exporter (hereinafter also referred to as the Exporter), having registered address at Plot No. 27/28, Pharma City, Selaqui, Dehradun, Uttarakhand - 248001, filed Shipping Bill No. 9644578 dated 03.04.2025 through their authorised Customs Broker M/s. Expo Freight Private Limited (CHA No. AAACE2126JCH004) for the export of Medicaments i.e. "Moxbro Forte Syrup" under ITC(HS) 30041030 and the shipment was destined to ASAL PHARMA CO (APHCO), Bakaro Medicine Market, Mogadishu, Somalia. The declared Free on Board (FOB) value of the consignment was Rs. 25,68,000/- (USD 30000/-), under Scheme Code- 19 (Drawback) with RoDTEP (Remission of Duties, Taxes on Exported Products) 'Y'. A summary of the shipping bill is as below-

Table-I

S/bill no. and Date	Goods description & HS Code	FOB Value (INR)	Quantity	Batch nos.	Drawback Claimed	RoDTEP Claimed	IGST Paid/LUT
9644578 dated 03.04.2025	Moxbro Forte Syrup, 30041030	25,68,000/-	50,000 nos.	UFM2501 to UFM2510	30,816/-	17,976/-	LUT

2. During scrutiny of the documents presented for inspection/examination, it was observed by the docks officer that the goods attempted for export contain a drug composition of Amoxicillin and Bromhexine Hydrochloride. The Certificates of Analysis submitted by the exporter also confirm its composition that it contains Amoxicillin and Bromhexine Hydrochloride. On further scrutiny, it was observed that the said composition of the drugs is prohibited for manufacture for sale, sale and distribution for human use Vide Gazette notification no. CG-DL-E-02062023-246249 dated 02.06.2023 and vide notification no. S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii),

dated the 10th March, 2016. An excerpt of the said Gazette notification is as follows-

"... And whereas, the expert committee recommended that "there is no therapeutic justification for sale ingredient contained in the FDC and the FDC may invoke risk to human beings. Hence, in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of the Drugs and Cosmetics Act, 1940. In view of the above, any kind of regulation or restriction to allow for use for any use in patients is not justifiable. Therefore, only prohibition under Section 26A is recommended.

And whereas on the basis of the recommendations of the expert committee and the Drug Technical Advisory Board, the Central Government is satisfied that it is necessary and expedient to regulate by way of prohibition the manufacture for sale, sale and distribution for human use in the country."

-this was implemented with immediate effect.

3. In the subject matter, a clarification was sought from the Asst. Drugs Controller (ADC), JNPT regarding exportability of these medicines vide docks office letter number S/6/Gen/153/2025/X/GDL dated 07.04.2025. In their reply vide letter no. 77/ADC-NS/Clarification/2025-26/80 dated 08.04.2025, ADC has informed that "NOC's" for manufacture of unapproved/Banned/New Drugs solely for export purpose to be obtained from respective Zonal Office of CDSCO (Central Drugs Standard Control Organisation) through Online Mode with effect from 15.05.2024, before issuing manufacturing license from SLA for manufacture of Unapproved / Banned / New Drugs for export purpose".

4. The Drug Controller General of India vide its letter bearing no. IMP-12/1/2024-office dated 30.04.2024 has stated that industry must be facilitated to file fresh applications for NOC for manufacture of unapproved/approved new drug/banned drugs solely for export purpose from 15th May, 2024 on online mode through CDSCO Zonal Offices-

"... it has been decided with the approval of Hon'ble HFM vide Ministry F.no. X.11035/210/2018-DR(Pt) dated 21st June, 2023 that industry must be facilitated to file fresh applications for NOC for manufacture of unapproved/approved new drug/banned drugs solely for export purpose from 15th May, 2024 on online mode through CDSCO Zonal Offices. Accordingly, power delegated to State/UT licencing authority stands withdrawn w.e.f. 15th May, 2024 and such NOC's shall be granted by the head of respective CDSCO zonal office w.e.f. 15th May, 2024. Further, All State/UT drugs controllers are required to handover all NOC's issued from 20th August,

2018 to 14th May, 2024 to respective Zonal offices of CDSCO."

5. In this regard, a clarification was sought by the docks officer from the exporter regarding the status of the said composition of the medicine as it is unapproved/banned medicine. The exporter vide their letter dated 15.04.2025, had inter alia stated that they have already submitted all the required documents to CDSCO for obtaining the necessary NOC. It was further informed vide the said letter that the NOC process is still underway and it may take 5-6 working days to be issued. The exporter, then submitted an NOC letter bearing NOC No. NA/NOC-T&A (Exhibit Batches)/2025/000037 granted to them on 23.04.2025 for manufacture of this formulation for export purpose only.

6. On perusal of the said NOC letter, it was observed that the NOC appears to be applicable for further manufacturing rather than for already manufactured goods. It is further to mention that there are certain conditions stipulated in the NOC regarding the manufacturing of the goods, it was further observed that the physical product and its labels are not having basic instructions printed as mandated by the NOC submitted by the exporter.

7. In this matter, it is evident that the exporter M/s. Coral Laboratories Ltd. has neither obtained fresh NOC from concerned CDSCO Zonal Office at the time of the manufacturing of the goods, nor presented the NOC for export at the time of clearance of the goods at the docks, although it was submitted later on, only after the docks officer raised objection regarding the same. Here, it appears that the manufacturer exporter has not only manufactured an unapproved/banned drug without following laid down procedures but also attempted to export it without establishing its unapproved/banned nature, also the labels are not having basic instructions printed as mandated in the NOC granted by the CDSCO.

8. **RELEVANT LEGAL PROVISIONS:** The following provisions of law are applicable in the instant case: -

A. *Foreign Trade (Development and Regulation) Act, 1992*

(i) *Section 11: (1) No export or import shall be made by any person except in accordance with the provisions of this Act, the rules and orders made there under and the foreign trade policy for the time being in force.*

B. *Customs Act, 1962:-*

(i) *Section 2(22): "goods" includes (a) vessels, aircrafts and vehicles; (b) stores; (c) baggage; (d) currency and negotiable instruments; and (e) any other kind of movable property;*

(ii) *Section 2(33): "prohibited goods" means any goods the import or export of which is subject to any prohibition under this Act or any other*

law for the time being in force but does not include any such goods in respect of which the conditions subject to which the goods are permitted to be imported or exported have been complied with;

(iii) Section 11H(a) "illegal export" means the export of any goods in contravention of the provisions of this Act or any other law for the time being in force;

(iv) Section 50: Entry of goods for exportation. -

(1) The Exporter of any goods shall make entry thereof by presenting [electronically] [on the customs automated system] to the proper officer in the case of goods to be exported in a vessel or aircraft, a shipping bill, and in the case of goods to be exported by land, a bill of export [in such form and manner as may be prescribed];

Provided that the [Principal Commissioner of Customs or Commissioner of Customs] may, in cases where it is not feasible to make entry by presenting electronically [on the customs automated system], allow an entry to be presented in any other manner.]

(2) The Exporter of any goods, while presenting a shipping bill or bill of export, shall make and subscribe to a declaration as to the truth of its contents.

(3) The Exporter who presents a shipping bill or bill of export under this section shall ensure the following, namely: -

(a) the accuracy and completeness of the information given therein;

(b) the authenticity and validity of any document supporting it; and

(c) compliance with the restriction or prohibition, if any, relating to the goods under this Act or under any other law for the time being in force.

(v) Section 113: Confiscation of goods attempted to be improperly exported, etc.

"The following goods shall be liable to confiscation:

(d): any goods attempted to be exported or brought within the limits of any customs area for the purpose of being exported, contrary to any prohibition imposed by or under this Act or any other law for the time being in force, shall be liable to confiscation;

(ia): any goods entered for exportation under claim for drawback which do not correspond in any material particular with any information furnished by the exporter or manufacturer under this Act in relation to the fixation of rate of drawback under section 75;]

(ja): any goods entered for exportation under claim of remission or refund of any duty or tax or levy to make a wrongful claim in contravention of the provisions of this Act or any other law for the time being in force

(vi) Section 114(i): Any person who, in relation to any goods, does or omits to do any act which act or omission would render such goods liable to confiscation under section 113, or abets the doing or omission of such an act, shall be liable, in the case of goods in respect of which any prohibition is in force under this Act or any other law for the time being in force, to a penalty not exceeding three times the value of the goods as declared by the Exporter or the value as determined under this Act, whichever is the greater.

9. In view of the above, it appears that, the goods covered under the Shipping Bill No. 9644578 dated 03.04.2025, declared as "Moxbro Forte Syrup", having declared FOB value of Rs. 25,68,000/- were attempted to be improperly exported by the Exporter even when the goods are unapproved/banned in nature vide Gazette notification no. CG-DL-E-02062023-246249 dated 02.06.2023 and vide notification no. S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016. Further, the No objection certificate issue by the CDSCO for export, also does not seem to be applicable for already manufactured goods as the laid down procedure and the conditions stipulated in the NOC regarding labelling and packaging are not complied with, during the manufacturing of the goods.

10. Further, the scope of definition of "prohibited goods" as specified under Section 2 (33) of the Customs Act, 1962 is no more res-integra in light of Judgement dated 17.06.2021 of Hon'ble Supreme Court in the case of Union of India &Ors Vs Raj Grow Impex LLP & Ors [CIVIL APPEAL NO(s). 2217-2218 of 2021 (Arising out of SLP(C) Nos. 14633-14634 of 2020)].

It is settled that "prohibition" under the aforesaid provision would include every type of "prohibition" and would include the "restrictions.

Further, in self-assessment era, it is the responsibility of the Exporter to ensure compliance with the restriction or prohibition, if any, relating to the goods under this Act or under any other law for the time being in force, thus by attempting to export the unapproved/banned drugs without the requisite No Objection Certificate issued by the CDSCO, the exporter has also violated the provisions of section 50 (3) of the Customs Act, 1962 and provisions of section 11 of Foreign Trade (Development and Regulation) Act, 1992. Thus, by these acts of omission and commission, the exporter has rendered the said goods covered under the Shipping Bill No. 9644578

dated 03.04.2025, declared as "Moxbro Forte Syrup", having declared FOB value of Rs. 25,68,000/- liable for confiscation under Section 113(d) of Customs Act, 1962, and the exporter has also claimed drawback and RoDTEP benefits on the improper export of unapproved/banned goods which also makes the goods liable for confiscation under section 113(ia) and 113(ja) respectively of the Customs Act, 1962 and therefore, for attempting to improperly export the goods without the requisite and applicable No Objection Certificate issued by CDSCO, the exporter appears liable for penal actions under the Customs Act, 1962.

11. The exporter, M/s. Coral Laboratories Ltd. (IEC- 0394033353) for their acts of omission and commission in respect of the subject goods to improperly export the banned drugs without requisite and applicable NOC from CDSCO appears to be liable for imposition of penalty under Section 114(i) of the Customs Act, 1962.

WRITTEN SUBMISSION OF THE EXPORTER

12. The exporter M/s. Coral Laboratories Ltd. (IEC- 0394033353), vide their letter dated 28.05.2025 and 04.06.2025 have clarified that they are SME pharma company and are in business since 1981 exporting to around 25 countries, they have done exports with proper formalities and procedures. They are One star export house and having valid Drug manufacturing licence (Lic.no. 42/UA/2006 on form 25 & 42/UA/SC-2006 on form 28 valid up to 06.06.2026), Certificates for Good manufacturing practices (GMP) along with Product permission issued from Drug and Licencing authority of Uttarakhand, that contains the item "Moxbro Forte Syrup" having the composition of Amoxicillin and Bromhexine. However, the manufacturing NOC was not applied due to administrative lapse which they have applied and got the same later on. About the manufacturing of the goods the exporter has stated that the goods were manufactured as per the laid down procedure in Drug licence with complete GMP practice and the same has also been tested in GLP certified laboratories whereby the product is passing in all the parameters.

13. Further, the exporter have added that they are ready to submit a copy of Batch Manufacturing Record (BMR) to verify the product is manufactured as per the proper GMP norms. The conditions stipulated in the Export NOC issued by the CDSCO does not have any hard and fast parameters for manufacturing of this product, except for the labelling conditions which also seem ambiguous. The product was manufactured at

their Dehradun Factory, which has separate building for manufacturing Betalactum products like Moxbro Forte Syrup, is having valid GMP Certificates and has approvals from countries like Ethiopia, Tanzania, Sudan, Kenya, Malawi and Nigeria.

14. The exporter has also requested that their product has stuck up for a long time and losing its shelf life, the export order is on the verge of cancellation and the same product cannot be sold to anyone else as the product contains the name and address of the Importer. The product is for the market of Somalia which is very price sensitive and with the currency depreciation in their country and passage of time thereby losing shelf life, the importer may create issues with product acceptance and product formalities. They have requested for waiver of Show Cause Notice and Personal Hearing in the matter stating that they are losing the shelf life of the product and also that they have accepted the mistake as an administrative lapse on their part; that the grounds for confiscation of goods and imposition of penalty were verbally explained to them and that they were ready to pay the amount of fine and penalty as decided by the department. Further, they also requested for allowing export of the item or allow Back to Town of the goods subject to an undertaking that the subject goods will not be routed for domestic purposes and also for the fulfilment of the conditions stipulated in the NOC issued by the CDSCO.

DISCUSSION AND FINDINGS

15. I have thoroughly examined the facts of this case, the submissions made by the exporter, and the documents on record. The exporter, M/s. Coral Laboratories Ltd. [IEC- 0394033353], have not contested the findings of the department regarding the discrepancies in the consignment under Shipping Bill No. 9644578 dated 03.04.2025 for the export of "Moxbro Forte Syrup" under ITC(HS) 30041030 of the Customs Tariff Act, without requisite and applicable No Objection Certificate issued by CDSCO (Central Drugs Standard Control Organisation). I find that the proposed grounds for confiscation of the goods and imposition of penalty were verbally explained to the exporter and documents shown as stipulated in proviso to Section 124 of Customs Act 1962. The same has been acknowledged by the exporter vide their letter dated 04.06.2025 wherein they requested for waiver of Show Cause Notice and Personal Hearing. Hence the exporter's request for waiver of SCN and PH is accepted. Accordingly, I take up the case for adjudication in the absence of any defense submissions and on merits.

16. I find that an attempt was made by the exporter M/s. Coral Laboratories Ltd. (IEC- 0394033353) to improperly export the impugned goods i.e "Moxbro Forte Syrup" covered under Shipping Bill No. 9644578 dated 03.04.2025, having declared FOB value of Rs. 25,68,000/- with a claim of drawback of Rs. 30,816/- and RoDTEP of Rs. 17,976/- even when the goods are unapproved/banned in nature vide Gazette notification no. CG-DL-E-02062023-246249 dated 02.06.2023 and vide notification no. S.O. 777 (E) published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated the 10th March, 2016. Further, the No objection certificate issued by the CDSCO for export, also does not seem to be applicable for already manufactured goods as the laid down procedure and the conditions regarding labelling and packaging stipulated in the NOC are not complied with, during the manufacturing of the goods.

17. Further, as per the available records, I observe that the exporter submitted the requisite No Objection Certificate (NOC) issued by the CDSCO at a later stage—only after the Docks Officer raised an objection to the export of the said drugs due to the absence of the CDSCO NOC, as mandated by the aforementioned Gazette Notification and clarified by the Assistant Drug Controller, JNPT. This delayed submission constitutes a violation of Section 11 of the Foreign Trade (Development and Regulation) Act, 1992, as well as the relevant provisions of the Foreign Trade Policy (FTP)."

18. I find that, the CDSCO NOC No. NA/NOC-T&A(Exhibit Batches)/2025/000037 dated 23.04.2025 provides specific details pertaining to the exporter, drug name, brand name, quantity, package size, importing country, and other relevant particulars. It also stipulates certain conditions to be adhered to during the manufacturing of the goods. However, as per the observations of the Docks Officer, it is evident that the manufactured goods do not conform to the labelling and packaging requirements specified in the NOC. In response, the exporter have clarified that, apart from labelling and packaging requirements, the NOC does not impose any hard and fast manufacturing conditions. They have further stated that the goods were manufactured in accordance with the approved Drug Licence, following Good Manufacturing Practices (GMP), and that the products were tested in GLP-certified laboratories, passing all required quality parameters. Additionally, the exporter have also agreed to submit copies of the Batch Manufacturing Record (BMR) to verify that the goods were produced as per GMP norms. The exporter has also undertaken not to

divert any portion of the consignment for domestic sale in India and has affirmed compliance with all other conditions stipulated in the NOC.

19. It is well-settled law that any restriction on import or export is to an extent a 'prohibition' and therefore, the expression 'any prohibition' in Section 113(d) of the Act includes restrictions. Restriction is one type of prohibition if a policy condition is not fulfilled or complied with. In the self-assessment era, it is the responsibility of the exporter to ensure compliance with the restriction or prohibition, if any, relating to the goods under this Act or under any other law for the time being in force, thus by attempting to export the impugned goods restricted goods covered under the Shipping Bill No. 9644578 dated 03.04.2025, declared as "Moxbro Forte Syrup", having declared FOB value of Rs. 25,68,000/- liable for confiscation under Section 113(d) of Customs Act, 1962, and the exporter has also claimed drawback and RoDTEP benefits to the tune of Rs. 30,816/- and Rs. 17,976/- respectively on the improper export of restricted goods which also makes the goods liable for confiscation under section 113(ja) and 113(ja) respectively, of the Customs Act, 1962 and therefore, for attempting to improperly export the goods without the requisite and applicable No Objection Certificate issued by CDSCO, the exporter appears liable for penal actions under the Customs Act, 1962.

20. Thus, for their acts of omission and commission as detailed above, attempting to improperly export unapproved/banned drugs with the requisite and applicable NOC, I hold that the exporter, M/s. Coral Laboratories Ltd. (IEC- 0394033353) is liable for penalty under Section 114(i) of the Customs Act 1962.

ORDER

21. In view of the afore-stated facts and circumstances of the case, the documents and evidences on record, and legal aspects as discussed above, I hereby pass the following order:

(i) I order for confiscation of the goods covered under the Shipping Bill No. 9644578 dated 03.04.2025, declared as "Moxbro Forte Syrup", having declared FOB value of Rs. 25,68,000/- under Section 113(d), 113(ja) & 113(ja) of the Customs Act, 1962. However, I impose a Redemption Fine of Rs 1,00,000/- (Rupees One Lakh only) in lieu of confiscation, under Section 125 of the Customs Act, 1962, on the exporter M/s. Coral Laboratories Ltd. (IEC- 0394033353) for limited purpose of Back to town

(BTT) only as requested by M/s. Coral Laboratories Ltd. (IEC-0394033353), Subject to an undertaking that no part of the consignment will be diverted for domestic sale in India, and that all other conditions stipulated in the NOC will be strictly complied with.

(ii) I reject the Drawback and RoDTEP of Rs. 30,816/- and Rs. 17,976/- respectively, claimed under shipping bill 9644578 dated 03.04.2025, as the goods are allowed for limited purpose of Back to Town only.

(iii) I impose a penalty of Rs. 1,00,000/- (Rupees One Lakh only) on the exporter, M/s. Coral Laboratories Pvt. Ltd. (IEC- 0394033353) under Section 114(i) of the Customs Act, 1962, for attempting to improperly export unapproved/banned drugs without the requisite and applicable No objection Certificate for export from the Central Drugs Standard Control Organisation.

22. This order is issued without prejudice to any other action that may be taken against the exporter or any other person(s) concerned with the said goods under the Customs Act, 1962, or any other law for the time being in force in India.

Digitally signed by
Raghu Kiran Batchali
Date: 16-06-2025
10:08:33
(RAGHU KIRAN B.)
ADDITIONAL COMMISSIONER OF
CUSTOMS,
CEAC, NS-II COMMISSIONERATE,
JNCH

To,