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
NHAVA SHEVA, TALUKA-URAN, DIST- RAIGAD, MAHARASHTRA-400707

F. No. CUS/DOCK/33/2026-Exp (Docks) **Date of Order:** 04 **.03.2026**

Date of Issue: 04 **.03.2026**

DIN NO.: 20260378NT000062196A

जारीकर्ता /Passed By: **Shri Raghu Kiran B.**
Commissioner of Customs (in-situ),
CEAC, NS-II, JNCH, Nhava Sheva

मूल आदेश संख्या/Order-In-Original No.:1727/2025-26/ADC/CEAC/NS-II/JNCH

निर्यातक का नाम/Exporter's Name: M/s Medley Pharmaceuticals Limited (IEC: 0391007807)

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, शेवा, ता. उरण, जिला - रायगढ़, महाराष्ट्र -400707 को की जा सकती है । अपील दो प्रतियों में होनी 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 स्टांप 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 स्टांप 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 शास्ति के संबंध में विवाद होने पर माँगे गये शुल्क के 7.5% का, अथवा केवल शास्ति के संबंध में 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 Medley Pharmaceuticals Limited (IEC: 0391007807) having registered address at Medley House, D 2 MIDC Area, 16th Road, Andheri East, Mumbai, Maharashtra – 400093 (hereinafter called as "**the Exporter**" or "**the Noticee**" has filed a Shipping Bill No. 8366818 dated 31.12.2025 through their authorized Customs Broker firm, M/s. Shree Shine Shipping Services (ACAFS1610CCH002) (hereinafter referred to as "**the CB**") for the export of "Pharmaceutical Products, viz. Medicaments Coldrid Tablets (Pack of 10x1x9T) (Free QTY 2500 Pack)" having Manufacturing date 12/2025 and expiry date 11/202, under ITC(HS) 30045090 (hereinafter called as "**the goods**"). The consignee of the goods is M/s. Al Razi Pharmacy, Kingdom of Bahrain. The details of the goods are as under:

TABLE – I

Sr. No.	S/Bill No. & Date	Description of Goods	Declared Qty. (Nos)	RITC	FOB Value (in Rs.)	Drawback Claimed (in Rs.)	RoDTEP Claimed (in Rs.)	IGST Claimed (in Rs.)
1	8366818 dated 31.12.2025	Medicaments Coldrid Tablets (Pack of 10x1x9T)	2500	3004 5090	27,93,064.50	33,516.77	19,551.45	1,39,777.34

2. OBSERVATIONS OF THE DOCKS OFFICER AND EXAMINATION OF THE GOODS: During scrutiny of the documents, the Docks Officer observed that goods covered under the above-mentioned S/Bill, i.e. Coldrid Tablets having composition of: **DAY TABS:** Paracetamol BP: 500 mg Phenylephrine Hydrochloride BP: 5 mg Caffeine Anhydrous BP: 15 mg Chlorpheniramine Maleate BP: 2 mg; **NIGHT TABS**: Paracetamol BP: 500 mg Phenylephrine Hydrochloride BP: 10 mg Chlorpheniramine Maleate BP: 4 mg were classified under RITC 3004 5090. The tablets are having the combination of Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine. These tablets are Banned/Restricted as per Sr. No. 105 of List of Drugs Prohibited for Manufacture and Sale through Gazetted Notifications issued by the Ministry of Health & Family Welfare u/s. 26A of the Drugs & Cosmetics Act, 1940. Accordingly, it is mandated that export of the Pharmaceutical Products having above combination are Banned/Restricted for export without NOC from Central Drugs Standard Control Organization ('**CDSCO**' in short).

2.1 As per the CDSCO Notification vide IMP/12-1/2024-eoffice dated 30.04.2024, an NOC for manufacture of Unapproved/Banned/New Drugs for export purpose from 15.05.2024 must be acquired from respective Zonal Offices of CDSCO before issuing Manufacturing License from State Licensing Authority for Manufacture of Unapproved/Banned/New Drugs for export purpose through online mode. However, the exporter has applied for CDSCO NOC vide application no. EXP/FS/UPD/FF/2026/83215 dated 02.01.2026 for the said banned drug.

2.2 Further, it is observed that the composition declared in the invoice and product list does not correspond with the composition approved in the said CDSCO NOC. The discrepancies between the product list and CDSCO NOC are highlighted in the table below:

TABLE – II

Composition declared in the product list and invoice	**Composition approved in the CDSCO NOC**
(Day Tablet) Chlorpheniramine Maleate - 2 mg	Chlorpheniramine Maleate- 2.1 mg
(Night Tablet) Chlorpheniramine Maleate - 4 mg	Chlorpheniramine Maleate- 4.2 mg

2.3 These facts were brought to the notice of the Exporter through their authorized CB. In response, the Exporter produced a No Objection Certificate (NOC) No. NA/NOC/-Export/2026/000401 dated 07.01.2026 from CDSCO wherein NOC was granted to the Exporter to manufacture 4500000 Coldrid brand tablets comprising of the above-mentioned combination for export purpose only. However, it was noticed by the Docks Officer that the goods had marking of Manufacturing Date as 12/2025, whereas, NOC to manufacture of the said Tablets was given by CDSCO on 07.01.2026. Therefore, it is apparent that the goods were manufactured before granting NOC by CDSCO and are attempted to be exported vide S/Bill No. 8366818 dated 31.12.2025 before obtaining NOC from CDSCO and the same was obtained subsequently on 07.01.2026. Therefore, it is apparent that the requisite NOC was not available with the Exporter at the time of filing of the S/Bill.

2.4. In this matter, it is evident that the exporter M/s Medley Pharmaceuticals Limited has not obtained fresh NOC from concerned CDSCO Zonal Office and subsequently manufacturing license/product permission from state licensing Authority before the manufacturing of said goods which are attempted to be exported vide Shipping Bill No. 8366818 dated 31.12.2025. It is also re-iterated that the consignment containing Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine is 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.

3. The Exporter has produced a NOC from CDSCO for 'Manufacture' and 'Export Only' of the impugned goods, however, the Docks Officer noticed that the subject CDSCO NOC is post-dated, i.e. issued after manufacture of the goods and carted the same for export at JNCH Port. Therefore, the issue was referred to CEAC Section, JNCH for adjudication purpose.

4. <u>RELEVANT LEGAL PROVISIONS</u>:

A. <u>The Customs Act, 1962</u>:

(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) of the Customs Act, 1962****: "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 of the Customs Act, 1962: 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 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."

(vi) **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."*

(vii) **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."*

(viii) **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*

(ix) ***Section 114 (i) of the Customs Act, 1962****: 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.*

B. **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.*

C. **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 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.

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. **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."

F. CDSCO Notification vide IMP/12-1/2024-eoffice dated 30.04.2024 –

"... 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.

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."

5. Whereas, from the above observations, the following facts emerge that:

5.1 M/s Medley Pharmaceuticals Limited (IEC: 0391007807) has filed a Shipping Bill No. 8366818 dated 31.12.2025 for the export of "Pharmaceutical Products, viz. Medicaments Coldrid Tablets (Pack of 10x1x9T) (Free QTY 2500 Pack)" to Baharain. The declared FOB Value of the said goods covered under above mentioned S/Bill is Rs. 27,93,064.50/- and the Exporter has claimed Drawback amounting to Rs. 33,516.77/-; RoDTEP amounting to Rs. 19,551.45/- and IGST Refund amounting to Rs. 1,39,777.34/-. The tablets contain a fixed dose combination of Caffeine, Paracetamol, Phenylephrine, and Chlorpheniramine. Export of this drug combination is prohibited/restricted without obtaining prior No Objection Certificate (NOC) from the Central Drugs Standard Control Organization (CDSCO), as prescribed under the Drugs and Cosmetics Act, 1940, read with CDSCO Notification No. IMP/12-1/2024-eoffice dated 30.04.2024. It is observed that the exporter attempted to export the goods improperly despite the fact that the said fixed dose combination is unapproved/banned, as notified vide Gazette Notification No. S.O. 950(E), published in the Gazette of India, Extraordinary, Part II, Section 3(ii), dated 10.03.2016. Further, the Central Government has prohibited the manufacture for sale and distribution for human use of the fixed dose combination of Caffeine, Paracetamol, Phenylephrine, and Chlorpheniramine in India. Hence, the said consignment can neither be sold in India nor can be exported to abroad.

5.2 The Exporter filed the said Shipping Bill on 31.12.2025 without possessing a valid CDSCO NOC. The NOC relied upon by the Exporter bears No. NA/NOC/-Export/2026/000401 dated 07.01.2026, which is clearly post-dated vis-à-vis:

- the manufacturing date (12/2025) marked on the cartons, and
- the date of filing of the Shipping Bill (31.12.2025).

Thus, the impugned goods were manufactured and attempted to be exported prior to grant of mandatory CDSCO NOC, rendering the export attempt non-compliant and unauthorized.

5.3 The composition declared in the invoice and product list does not exactly match the composition approved under the CDSCO NOC, as detailed in Para 2.2 above. This discrepancy further establishes that the Exporter failed to ensure accuracy, authenticity and validity of the documents submitted to Customs at the time of filing the Shipping Bill.

5.4 It is pertinent to mention here that 'Restricted Goods' under the Customs Act are items whose import or export is not absolutely prohibited but requires prior authorization in the form of an Import/Export License from the DGFT or other Competent Authorities, CDSCO in present case. Examples of Restricted Goods for export under Indian law include certain chemicals, pharmaceuticals, drones and specific electronics. Without the necessary license or fulfilment of prescribed conditions, Restricted Goods are liable for confiscation, and the importer or exporter may face fine/penalties u/s. 113 & 114 of the Customs Act, 1962.

5.5 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 goods covered under the subject Shipping Bill No. 8366818 dated 31.12.2025 i.e. "Medicaments Coldrid Tablets" having FOB value of Rs. 27,93,064.50/- liable for confiscation u/s. 113 (d) of the 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 Section 114 (i) of the Customs Act, 1962.

5.6 Section 50 (3) of the Customs Act, 1962 mandates that the Exporter who presents a Shipping Bill under the said Section shall ensure the 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. As the Exporter had not made declaration truthfully in the said Shipping Bill, M/s. Medley Pharmaceuticals Limited has contravened these provisions in as much as they have filed S/Bill without having valid NOC issued by the CDSCO. Thus, it appears that the said goods were attempted to be exported in violation of Section 50 (3) of the Customs Act, 1962 read with Section 11 (1) of Foreign Trade (Development & Regulation) Act 1992.

5.7 The attempt to export the impugned goods is considered as violation of Restriction imposed by CDSCO under Drugs & Cosmetics Act, 1940 appears to fall under the ambit of Section 11H (a) of Customs Act, 1962, as the act amounts to 'illegal export' by them in as much as they attempted to export the goods in contravention to provisions of section 50 (3) of the Customs Act, 1962 read with Section 11 of Foreign Trade (Development and Regulation) Act, 1992. As discussed herein above, the subject goods covered under Shipping Bill No. 8366818 dated 31.12.2025 i.e. "Medicaments Coldrid Tablets" is a Restricted Item in terms of its constituents.

5.8 Any Prohibition referred to in the Section 113 (d) of the Customs Act, 1962 apply to any type of Prohibition, i.e. complete or partial. It is well settled law that any Restriction on import or export is to an extent a 'Prohibition' and therefore, expression 'any Prohibition' in section 113 (d) of Customs Act, 1962 includes restrictions. 'Restriction' is one type of 'Prohibition', if policy condition is not fulfilled or complied with. In the instant case, goods do not fulfil the condition for their export as they violate the provisions specified in Drugs & Cosmetics Act, 1940, provisions of Foreign Trade (Development and Regulation)

Act, 1992 and provisions of the Customs Act, 1962 as discussed above, they are to be deemed 'Prohibited'. In view of the above, goods covered under the subject Shipping Bill No. 8366818 dated 31.12.2025 i.e. "Medicaments Coldrid Tablets" having FOB value of Rs. 27,93,064.50/- are therefore liable to be confiscated u/s. 113 (d) of the Customs Act, 1962. These acts of omission and commission on the part of the Exporting firm rendered them liable for penal action u/s. 114 (i) *ibid.*

5.9. It is thus cogent and clear that the Exporter, M/s. Medley Pharmaceuticals Limited had attempted to export "Medicaments Coldrid Tablets" (a Restricted Item due to its constituents) under 8366818 dated 31.12.2025 without fulfilling the conditions of Restriction imposed by the CDSCO under the provisions of Drugs and Cosmetics Act, 1940, and thereby acted in a manner which rendered the said goods liable for confiscation in terms of the provisions of Section 113(d), 113(ia), & 113(ja) of the Customs Act, 1962.

5.10 It further appears that the Exporter, M/s. Medley Pharmaceuticals Limited have rendered themselves liable to penal action in terms of Section 114 (i) of the Customs Act, 1962 on account of attempting to export improperly as their acts of omission and commission have rendered the goods liable for confiscation u/s. 113(d) *ibid.*

WRITTEN SUBMISSION

6. The exporter, vide their letter dated 20.01.2026, have submitted that they have applied for NOC on SUGAM portal and at the time of application they have given all the details including customers PO copy, on the basis of that they have received NOC. Further they have submitted Manufacturing License validity Certificate no. DCD/D&D/LA/2021-22/2132 dated 28.02.2022 issued by the Drugs Licensing Authority, UT of DNH, Daman & Diu, Daman which is valid upto 31.12.2026. Further, vide letter dated 17.02.2026 they have submitted another No Objection Certificate (NOC) No. NA/NOC/-Export/2025/017210 dated 29.10.2025 from CDSCO wherein NOC was granted to the Exporter to manufacture 732000 Coldrid brand tablets comprising of the above-mentioned combination for export purpose only. Further, they have voluntarily requested a waiver of the Show Cause Notice and Personal Hearing and requested to decide the case on merits and allow them to export the shipment.

RECORDING OF PERSONAL HEARING

7. The Exporter vide letter dated 17.02.2026 addressed to the Asstt. Commissioner, CEAC, JNCH voluntarily requested for waiver of SCN and PH in the matter and to decide the case on merits. Accordingly, in terms of first proviso to Section 124 of the Customs Act, 1962, written notice has not been given to the Exporter. However, at the request of the Exporter, grounds on which it is proposed to confiscate the goods or to impose penalty have been orally explained to the them. The Exporter requested to take a lenient view and grant permission to export the goods to the desired destination as they have the manufacturing license from the state licensing authority and also the requisite CDSCO NOC.

DISCUSSION AND FINDINGS

8. I have carefully gone through the facts of the case, the documents relied upon, the written submissions dated 20.01.2026 and 17.02.2026 filed by M/s Medley Pharmaceuticals Limited (hereinafter referred to as "the Exporter"), and the relevant legal provisions under the Customs Act, 1962, the Foreign Trade (Development and Regulation) Act, 1992, the Drugs and Cosmetics Act, 1940 and the applicable Rules framed thereunder.

8.1 The issue for determination in the present case is whether the goods described as *"Medicaments Coldrid Tablets (Pack of 10x1x9T)"* covered under Shipping Bill No. 8366818 dated 31.12.2025, having FOB value of Rs. 27,93,064.50/-, are liable to confiscation under Section 113(d), 113(ia) and 113(ja) of the Customs Act, 1962 and whether the Exporter is liable for penalty under Section 114(i) ibid., in view of the fact that the said goods contain a fixed dose combination of Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine, which is prohibited/restricted under the Drugs and Cosmetics Act, 1940 unless prior No Objection Certificate (NOC) is obtained from CDSCO for manufacture for export purpose.

8.2 It is an admitted position on record that the Exporter filed the subject Shipping Bill on 31.12.2025 and the goods bore Manufacturing Date as 12/2025. At the time of filing of the Shipping Bill, the Exporter did not possess a valid CDSCO NOC covering the impugned goods. The NOC initially produced by the Exporter is No. NA/NOC/-Export/2026/000401 dated 07.01.2026, which is clearly subsequent to both the date of manufacture (12/2025) and the date of filing of the Shipping Bill (31.12.2025). Therefore, the goods were manufactured and presented for export without prior approval from CDSCO as mandated under Section 26A of the Drugs and Cosmetics Act, 1940 read with CDSCO Notification dated 30.04.2024, which requires that NOC must be obtained before issuance of manufacturing licence by the State Licensing Authority for manufacture of banned/unapproved drugs solely for export.

8.3 I find that the Exporter, vide letter dated 20.01.2026, submitted a copy of Manufacturing Licence Validity Certificate No. DCD/D&D/LA/2021-22/2132 dated 28.02.2022 issued by the Drugs Licensing Authority, UT of DNH, Daman & Diu, Daman, which is stated to be valid up to 31.12.2026. The Exporter has contended that they are a duly licensed manufacturer and have applied for CDSCO NOC through the SUGAM portal by furnishing all requisite details including the customer's purchase order. I have perused the said manufacturing licence. While the licence evidences that the Exporter is authorized by the State Licensing Authority to manufacture pharmaceutical products, it is pertinent to note that in view of the CDSCO Notification dated 30.04.2024, w.e.f. 15.05.2024, manufacturers are mandatorily required to obtain prior NOC from the respective CDSCO Zonal Office before issuance/endorsement of manufacturing permission for unapproved/banned drugs meant solely for export. Therefore, possession of a general manufacturing licence issued by the State Licensing Authority does not, by itself, dispense with the requirement of obtaining prior CDSCO NOC for the specific banned/unapproved fixed dose combination in question.

8.4 Section 50(3)(c) of the Customs Act, 1962 casts a statutory obligation upon the exporter to ensure compliance with the restriction or prohibition relating to the goods under the Customs Act or any other law for the time being in force. The Exporter, by filing the Shipping Bill without possessing the mandatory CDSCO NOC at the relevant time, failed to discharge this obligation.

The subsequent procurement of NOC dated 07.01.2026 cannot cure the illegality committed at the time of manufacture and filing of the Shipping Bill. Compliance must exist at the time of export attempt and cannot be validated retrospectively.

8.5 Further, I find that discrepancies were observed between the composition declared in the invoice/product list and the composition approved in the CDSCO NOC (difference in Chlorpheniramine Maleate content). Though the variation appears marginal, it establishes that the documents furnished at the time of export were not in strict conformity with the regulatory approval. This further reflects non-fulfilment of the requirement of accuracy and authenticity mandated under Section 50(3)(a) and (b) of the Customs Act, 1962.

8.6 The Exporter has subsequently produced another CDSCO NOC bearing No. NA/NOC/-Export/2025/017210 dated 29.10.2025 permitting manufacture of 7,32,000 Coldrid brand tablets for export purpose. However, it is not satisfactorily established on record that the impugned batch manufactured in 12/2025 and covered under the present Shipping Bill was manufactured strictly against and within the quantitative and compositional parameters of the said NOC. In absence of clear co-relation between the batch exported and the NOC dated 29.10.2025, the benefit of doubt cannot automatically be extended.

8.7 Under Section 2(33) of the Customs Act, 1962, "prohibited goods" include goods whose export is subject to any prohibition under this Act or any other law for the time being in force, unless the conditions subject to which such goods are permitted to be exported have been complied with. In the present case, export of the impugned fixed dose combination is subject to prior NOC from CDSCO. Non-compliance with this mandatory condition renders the goods "prohibited goods" within the meaning of Section 2(33).

8.8 It is well settled that the expression "any prohibition" occurring in Section 113(d) includes restrictions as well. Therefore, where export is permitted only upon fulfilment of certain statutory conditions, failure to satisfy such conditions amounts to export contrary to prohibition. Accordingly, I find that the impugned goods were brought into the customs area for export in contravention of the prohibition/restriction imposed under the Drugs and Cosmetics Act, 1940 read with CDSCO Notification dated 30.04.2024 and Section 11 of the Foreign Trade (Development and Regulation) Act, 1992.

8.9 In view of the above, the goods are liable to confiscation under Section 113(d) of the Customs Act, 1962. Since the Shipping Bill was filed under claim of drawback, RoDTEP and IGST refund, the attempt to export goods in violation of statutory restrictions also attracts Section 113(ia) and 113(ja) of the Customs Act, 1962. When the goods themselves are liable to confiscation and the export is held improper, the claim of drawback under Section 75 read with Rule 14 of the Drawback Rules, 2017 cannot be allowed. Similarly, RoDTEP and IGST refund benefits, being contingent upon lawful export, are not admissible in respect of goods held to be prohibited.

8.10 Section 114(i) of the Customs Act, 1962 provides for imposition of penalty on any person who, by act or omission, renders goods liable to confiscation under Section 113. In the present case, the Exporter, being fully aware of the regulatory requirement of prior CDSCO NOC for manufacture and

export of the said fixed dose combination, proceeded to manufacture and file Shipping Bill without ensuring valid authorization at the relevant time. Such act squarely attracts penal liability under Section 114(i). However, I also take note of the fact that the Exporter has voluntarily waived Show Cause Notice and Personal Hearing, produced additional documents, and requested leniency. There is no evidence on record to suggest mala fide intent to divert goods into the domestic market. The violation appears to be procedural but substantive in nature, as prior approval is a mandatory pre-condition.

8.11 Accordingly, I hold that the impugned goods covered under Shipping Bill No. 8366818 dated 31.12.2025, having FOB value of Rs. 27,93,064.50/-, are liable to confiscation under Section 113(d), 113(ia) and 113(ja) of the Customs Act, 1962. Further, the Exporter, M/s Medley Pharmaceuticals Limited, is liable to penalty under Section 114(i) of the Customs Act, 1962 for attempting to export goods in contravention of statutory restrictions.

9. In view of the above discussions, I pass the following order.

ORDER

(i) I order confiscation of the impugned goods covered under Shipping Bill No. 8366818 dated 31.12.2025 having FOB value of Rs. 27,93,064.50/-, filed by the Exporter, M/s Medley Pharmaceuticals Limited (IEC: 0391007807), under Section 113(d), (ia) & (ja) of the Customs Act, 1962 as the goods being 'Restricted' in nature. However, I give an option to the exporter, **M/s Medley Pharmaceuticals Limited**, to redeem the confiscated goods for export on payment of Redemption Fine of **Rs 2,00,000/- (Rupees Two Lakhs only)** in terms of the provisions of the Customs Act, 1962;

(ii) I impose penalty of **Rs 1,00,000/- (Rupees One Lakh only)** on the Exporter, **M/s Medley Pharmaceuticals Limited** (IEC: 0391007807) under Section 114 (i) of the Customs Act, 1962;

10. This order is issued without prejudice to any other action that may be taken against the Noticee(s) 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.

04/03/26

(**RAGHU KIRAN B.**)
Commissioner of Customs (in-situ)
CEAC, NS-II, JNCH.

To,

M/s. Medley Pharmaceuticals Limited (IEC: 0391007807),
Medley House D 2 MIDC Area,
16th Road, Andheri East, Mumbai,
Maharashtra - 400093

Copy to:

1. The DC/AC, CAC, JNCH
2. The DC/AC, Review Cell, JNCH, Nhava Sheva.
3. The DC/AC, CRRC Cell, JNCH, Nhava Sheva.
4. Supdt. /CHS, JNCH for display on Notice Board.
5. Supdt. /EDI, JNCH for uploading on JNCH website.
6. Office Copy.