	<p align="center">OFFICE OF THE COMMISSIONER OF CUSTOMS, NS-I सीमाशुल्क आयुक्तका कार्यालय, एनएस-1 CENTRALIZED ADJUDICATION CELL, JAWAHARLAL NEHRU CUSTOM HOUSE, केंद्रीकृत अधिनिर्णयन प्रकोष्ठ, जवाहरलाल नेहरू सीमाशुल्क भवन, NHAVA SHEVA, TALUKA-URAN, DIST- RAIGAD, MAHARASHTRA 400707 न्हावाशेवा, तालुका-उरण, जिला- रायगढ़, महाराष्ट्र -400 707</p>
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Date of Order: 10.12.2025

आदेश की तिथि: 10.12.2025

Date of Issue: 11.12.2025

जारी किए जाने की तिथि: 11.12.2025

DIN: 20251278NW0000020870

F.No. S/10-94/2024-25/Commr./Gr. IIAB/NS-I/CAC/JNCH

SCN No. 957/24-25/Commr./Gr.IIAB/NS-1/CAC/JNCH dated 23.08.2024

Passed by: Shri Yashodhan Wanage

पारितकर्ता: श्री. यशोधन वनगे

Principal Commissioner of Customs (NS-I), JNCH, Nhava Sheva

प्रधान आयुक्त, सीमाशुल्क (एनएस-1), जेएनसीएच, न्हावाशेवा

Order No.: 287 /2025-26 /Pr. Commr/NS-I /CAC /JNCH

आदेश सं.: 287/2025-26/प्र. आयुक्त/एनएस-1/ सीएसी/जेएनसीएच

Name of Party/Noticee: M/s. Arco Life Sciences (India) Private Limited (IEC -0304061948).

पक्षकार (पार्टी)/ नोटिसी का नाम: मेसर्स आर्को लाइफ साइंसेज (इंडिया) प्राइवेट लिमिटेड (आईईसी -

0304061948)।

ORDER-IN-ORIGINAL**मूल आदेश**

1. The copy of this order in original is granted free of charge for the use of the person to whom it is issued.

1. इस आदेश की मूल प्रति की प्रतिलिपि जिस व्यक्ति को जारी की जाती है, उसके उपयोग के लिए निः शुल्क दी जाती है।

2. Any Person aggrieved by this order can file an Appeal against this order to CESTAT, West Regional Bench, 34, P D Mello Road, Masjid (East), Mumbai - 400009 addressed to the Assistant Registrar of the said Tribunal under Section 129 A of the Customs Act, 1962.

2. इस आदेश से व्यथित कोई भी व्यक्ति सीमा शुल्क अधिनियम १९६२ की धारा १२९ (ए) के तहत इस आदेश के विरुद्ध सीईएसटीएटी, पश्चिमी प्रादेशिक न्यायपीठ (वेस्ट रीजनल बेंच, ३४, पी. डी. मेलो रोड, मस्जिद (पूर्व), मुंबई- ४००००९ को अपील कर सकता है, जो उक्त अधिकरण के सहायक रजिस्ट्रार को संबोधित होगी।

3. Main points in relation to filing an appeal: -

3. अपील दाखिल करने संबंधी मुख्य मुद्दे:-

Form - Form No. CA-3 in quadruplicate and four copies of the order appealed against (at least one of which should be certified copy).

फार्म - फार्म न. सीए - ३, चार प्रतियों में तथा उस आदेश की चार प्रतियाँ, जिसके खिलाफ अपील की गयी है

(इन चार प्रतियों में से कम से कम एक प्रति प्रमाणित होनी चाहिए)

Time Limit - Within 3 months from the date of communication of this order.

समय सीमा - इस आदेश की सूचना की तारीख से ३ महीने के भीतर

Fee - (a)Rs. One Thousand - Where amount of duty & interest demanded & penalty imposed is Rs. 5 Lakh or less.

फीस- (क) एक हजार रुपये - जहाँ माँगे गये शुल्क एवं ब्याज की तथा लगायी गयी शास्ति की रकम ५ लाख रुपये या उससे कम है।

(b)Rs. Five Thousand - Where amount of duty & interest demanded & penalty imposed is more than Rs. 5 Lakh but not exceeding Rs. 50 lakhs.

(ख) पाँच हजार रुपये -जहाँ माँगे गये शुल्क एवं ब्याज की तथा लगायी गयी शास्ति कीरकम ५ लाख रुपये से अधिक परंतु ५० लाख रुपये से कम है।

(c)Rs. Ten Thousand - Where amount of duty & interest demanded & penalty imposed is more than Rs.50 Lakh.

(ग) दस हजार रुपये -जहाँ माँगे गये शुल्क एवं ब्याज की तथा लगायी गयी शास्ति कीरकम ५० लाख रुपये से अधिक है।

Mode of Payment - A crossed Bank draft, in favour of the Asstt. Registrar, CESTAT, Mumbai payable at Mumbai from a nationalized Bank.

भुगतान की रीति -क्रॉस बैंक ड्राफ्ट जो राष्ट्रीयकृत बैंक द्वारा सहायक रजिस्ट्रार, सीईएसटीएटी, मुंबई के पक्ष में जारी किया गया हो तथा मुंबई में देय हो।

General - For the provision of law & from as referred to above & other related matters, Customs Act, 1962, Customs (Appeal) Rules, 1982, Customs, Excise and Service Tax Appellate Tribunal (Procedure) Rules, 1982 may be referred.

सामान्य - विधि के उपबंधों के लिए तथा ऊपर यथा संदर्भित एवं अन्य संबंधित मामलों के लिए, सीमा शुल्क अधिनियम, १९६२, सीमाशुल्कअपील (नियम, १९८२, सीमा शुल्क, उत्पाद शुल्क एवं सेवाकरअपील अधिकरण (प्रक्रिया) नियम, १९८२ का संदर्भ लिया जाए।

4. Any person desirous of appealing against this order shall, pending the appeal, deposit 7.5% of duty demanded or penalty levied therein and produce proof of such payment along with the appeal, failing which the appeal is liable to be rejected for non-compliance with the provisions of Section 129 of the Customs Act 1962.

इस आदेश के विरुद्ध अपील करने के इच्छुक किसी भी व्यक्ति को, अपील लंबित रहने तक, मांगे गए शुल्क या लगाए गए जुर्माने का 7.5% जमा करना होगा तथा अपील के साथ ऐसे भुगतान का प्रमाण प्रस्तुत करना होगा, अन्यथा अपील सीमा शुल्क अधिनियम 1962 की धारा 129 के प्रावधानों का अनुपालन न करने के कारण अस्वीकृत की जा सके

1. BRIEF FACTS OF THE CASE:

1.1 During the course of Post Clearance Audit, it was noticed that the M/s ARCO LIFE SCIENCES (INDIA) PRIVATE LIMITED (IEC - 0304061948) (hereinafter referred to as 'the importer') had cleared their imported item viz "IOHEXOL USP" and classified the same under tariff heading CTH 29242990 vide Bills of Entry No. as per Annexure I to the SCN and paid BCD @0% and IGST @5% by wrong claim of Sr. No. 167 (A) of notification no. 50/2017-Customs dated 30.06.2017. However, it was noticed that the said Sr. No. provide BCD @Nil for the goods classifiable under Chapter 29 and Sr. No.167(A) was available to following goods:

"Life Saving Drugs/Medicines including their Salt and Esters and diagnostics test kits specified in list 4".

1.2 On examination of the Bills of Entry, commercial invoices, packing list, bills of lading and previous Bill of Entry, it was noticed that importer has imported "IOHEXOL USP" under heading 2924 in bulk quantity. Further on scrutinizing previous Bills of Entry, data analysis also revealed that the importer has cleared the same goods under CTH 29242990 and paid BCD @ 0% and IGST @5% by wrong claiming of Sr. No. 167(A) of notification no. 50/2017-Customs dated 30.06.2017. Since the subject goods has been imported in bulk quantity, hence, Sr. No. 167(B) of the Notification No. 50/2017 dated 30.06.2017 would be applicable in the instant case, where condition No 9 has to be fulfilled by the importer. Condition No. 9 of the Sr No.167(B) is reproduced here-

"(If the importer follows the procedure set out in the Customs (Import of Goods at Concessional 2 rate of duty) Rules, 2017".

But in the instant case Importer has not fulfilled the condition set out in the import of goods at concessional rate of duty Rule, 2017. From the above, it is clear that the benefit of Sr. No. 167(A) of notification no. 50/2017 Customs dated 30.06.2017 does not appear to be admissible for subject goods.

1.3 The details of Bills of Entry indicate the details of import and quantum of differential duty amounting to Rs. 8,11,98,024 /- (Rs. Eight Crore Eleven Lakh Ninety Eight Thousand Twenty Four Only) as per calculation sheet in Annexure-I to the notice, has been short levied and the same is recoverable from Importer along with the applicable interest and penalty.

1.4 In view of Self-assessment under Section 17 of the Customs Act, 1962 read with Section 46 of the Customs Act, 1962 & Regulation 4 of Bill of Entry (Electronic Declaration) Regulation, 2011 it appeared that importer had willful mis-statement and/or suppression of facts with the intention to evade the higher rate of IGST. Therefore, the provision of Section 28(4) of the Customs Act, 1962, in the case where any duty has not been levied or not paid or has been short levied or short paid or erroneously refunded by the reason of willful mis-statement or suppression of facts, is squarely applicable in the case.

1.5 A consultative letter No. 289/2023-24 vide F. No. CADT/CIR/ADT/TBA/763/2024 dated 21/6/2024 was issued to the importer requesting to pay the differential duty of Rs.

8,11,98,024 (Rs. Eight Crore Eleven Thousand Ninety- Eight Thousand Twenty Four only) against the Bills of Entry as mentioned in Annexure-I to the notice. In response to the said consultative letter, letter No. ARCO/2024-25/0130 dated 04.07.2024 was received from importer. They submitted that they completely deny the claim of differential duty payment. They had stated that Arco Life sciences has been importing the said products namely "IOHEXOL USP" under the CTH 29242990 and claiming the benefit under Sr. No 167(A) of the customs notification No 50/2017-Customs dated 30.06.2017 stating "Life Saving Drugs/ Medicines including their salts and Esters and Diagnostic Kits specified in the List 4". As per the above said notification and the interpretation thereto, the goods IOHEXOL USP is clearly mentioned in the LIST 4 under the category of the Drugs in Chapter 29. They also stated that the subject goods are imported under the concessional rate of Duty Rule, 2017 under notification No 68/2017-Customs (N.T) dated 30.06.2017 under clear and direct instructions of the Assistant Commissioner, Customs Division-1, Nagpur-1, Customs Commissionerate Nagpur vide Letter No VIII(39)/11/IGCRD/Return Doct./CDN-1/2018-19/99 dated 24.04.2018. In the pre GST era, the said Goods were imported under the Sr. No 167 (B) of the customs notification No 50/2017-Customs dated 30.06.2017 under the bulk drugs and the concessional rate of duty were availed by the applicable procedure of obtaining a continuity bond under the Condition 9. The same has been examined and it was found that the importer have failed to produce the necessary documents as set out in import of goods at concessional rate of duty Rules, 2017.

1.6 Further, they stated that after the Implementation of the Goods and Services Tax, they were directed by the customs Division Nagpur -1 to Import the said goods under the Sr No 167 (A) when they applied for the continuity bond for import clearance of IOHEXOL USP as per the rules under the Sr No 167(B). Hence, they have not violated any rules of the customs nor have claimed any lower rate of IGST or BCD benefits under our free will but only in direct instructions from the Customs Office. However, on scrutiny it is found that the concessional rate is applicable on the IOHEXOL USP under Sr No 167 (B) of the customs notification No 50/2017-Customs dated 30.06.2017 against the CTH 29420090 whereas, the impugned goods were imported in bulk quantity and claim the benefit of Sr No.167(A) of the Notification No.50/2017 dated 30.06.2017 which is not applicable for bulk drugs.

1.7 Thus, the act of the importer appears to be misleading to clear the subject goods under effective rate of BCD @ 0% and IGST @5% vide Sr. No.167 (A) of Notification no. 50/2017-Customs dated 30.06.2017 which is not applicable for bulk drugs hence, BCD @7.5% and IGST @18% would be applicable in the instant case.

1.8 Accordingly, Show cause notice bearing No. 957/24-25/Commr./Gr.IIAB/NS-1/CAC/JNCH dated 23.08.05 was issued to M/s. Arco Life Sciences (India) Private Limited (IEC- 0304061948) calling them to show cause, as to why:

1.8.1 Differential duty amounting Rs.8,11,98,024/- (Rs. Eight Crore Eleven Lakh Ninety-Eight Thousand Twenty-Four Only) for the Bs/E as mentioned in Annexure-I should not be recovered from the importer under Section 28(4) of Customs Act, 1962 along with applicable interest under Section 28AA of the Customs Act, 1962;

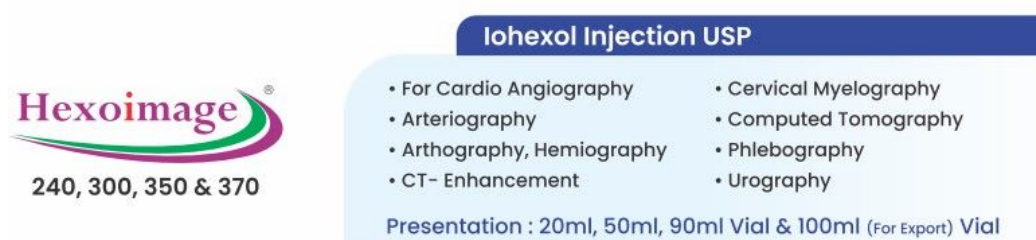
1.8.2 The subject goods should not be confiscated under section 111(m) of the Customs Act, 1962.

1.8.3 Penalty should not be imposed on them under section 112(a), section 114A and section 117 of the Customs Act, 1962.

Written Submissions:

2. M/s. Arco Life Sciences vide their letter dated 06.03.2025 gave written submissions and *inter-alia* submitted as below:

2.1 They are inter alia engaged in the business of manufacture and supply of injectable formulations and contrast media. The Noticee obtained a Registration Certificate for import of drugs into India in Form 41 for import "IOHEXOL IP/USP" and "LEVOFLOXACIN" which signifies that a bulk drug like IOHEXOL USP is considered a drug for the purpose of the Drugs and Cosmetics Law in India. Iohexol Injection manufactured by them is as below:



2.2 Prior to the introduction of GST, the Noticee imported IOHEXOL USP by claiming benefit under Sl. No. 148B of Notification No. 12/2012 on fulfilment of the relevant Condition i.e., compliance with the Customs (Import of Goods at Concessional Rate of Duty) Rules in letter and spirit i.e. Intimation to Deputy Commissioner/Assistant Commissioner of Central Excise having jurisdiction over the factory about intent to avail benefit of exemption notification and Continuity Bond and Surety bond. Further, even during the transition into the GST Regime the Noticee imported IOHEXOL USP. In respect of such imports, the Noticee claimed exemption benefit in compliance with the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2016 (here in after referred to as "IGCRD,2016") in letter and spirit. They submitted copy of intimation letter intimating the Department for procurement of IOHEXOL USP in terms of IGCRD Rules, 2016 and availment of benefit under Sl.No.148 of Notification No.12/2012 (Sl. No. 63 of List 4) and Sl.No.167B of Notification No.50/2017 (Sl.No.55 of List 4). After the introduction of GST, Notification No. 50/17-Cus. dated 30.06.2017 was issued in supersession of Notification No. 12/2012-Cus. dated 17.03.2012. Post introduction of GST, the Noticee filed an application dated 05.03.2018 under the new Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017 (hereinafter referred to as "IGCRD Rules") intimating their intent to import IOHEXOL USP in terms of Sl. No. 167(B) of Notification No. 50/17 read with Notification No.68/17-Cus. (NT). In terms of IGCRD Rules 2017. In response to the Noticee' Application, the Ld. Assistant Commissioner, Customs Division-I, Nagpur-I, Customs Commissionerate, Nagpur (hereinafter referred to as "Ld. Assistant Commissioner, Nagpur") vide letter dated 24.04.2018 clarified that the imported goods (IOHEXOL USP) are covered under Sl. No.

167(A) of Notification No. 50/2017. Consequently, the procedure under the IGCRD Rules is not applicable to the Noticee as there is no condition to follow such procedure under Sl. No. 167(A) of Notification No. 50/2017. They submitted copy of letter dated 24.04.2018. Basis the above response from the jurisdictional custom officials, the Noticee continued imports of IOHEXOL USP in terms of Sl. No.167(A) of the above notification.

2.3 They were issued with a Consultative Letter dated 21.06.2024 by Audit Commissionerate, Mumbai Zone-II wherein it was stated that the imported goods are liable to attract BCD @ 7.5% (merit rate) and IGST@18%. In response to the said consultative letter they filed a detailed reply vide letter dated 04.07.2024 and made the following submissions:

a. The imported goods are mentioned in List 4 under the category of Drugs in Chapter 29 of the First Schedule to Customs Tariff Act. 22

b. During the pre-GST era the goods were imported under Sl. No. 148B of Notification No. 12/2012 as bulk drugs and the concessional duty was availed on fulfillment of the relevant Condition. However, after the introduction of GST, goods were imported by the Noticee under the concessional benefit of Sl. no. 167(A) of Notification No. 50/2017 as instructed by the Ld. Assistant Commissioner, Nagpur vide letter dated 24.04.2018.

c. Thus, the Noticee have not violated any provisions under the Customs Law. No differential duty along with interest and penalty is required to be paid by the Noticee.

2.4 They submitted that the Noticee are eligible to avail the benefit of Sl. No. 167(A) of Notification No. 50/2017 in respect of the imported goods. The term “drug” includes bulk drug and formulation as per Drugs (Prices Control) Order, 1995. Hence, the imported goods are a drug. Notification No. 50/2017 recognizes the items specified in List No. 4 as drugs or medicines. Therefore, if an item is specified in List No. 4 appended to the said Notification then they are drugs or medicines. Notification No. 50/2017 has not defined bulk drug. The term ‘drug includes ‘bulk drug’ in terms of Drug (Price Control) Order, 1995. The said Order defines the terms ‘bulk drug’ and ‘drug’ as under:

“(i) “bulk drug” means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeia or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as used or as an ingredient in any formulation;”

(ii) “drug” includes –

(a) all medicines for internal or external use of human beings or animals and all substances intended to be used for, or in the diagnosis treatment, mitigation, or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(b) such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which caused disease in human beings or animals, as may be specified from time to time by the

Government by Notification in the Official gazette; and

(c) bulk drugs and formulations;”

From the above, it is clear that drugs are inclusive of ‘bulk drugs’ under the Drug (Price Control) Order, 1995. Subsequently, the Drug (Price Control) Order, 1995 was subsumed by Drug (Price Control) Order, 2013 and the definition of the term ‘drugs’ which formed part of the Drug (Price Control) Order, 1995 was done away with as ‘drug’ was defined in the Drugs and Cosmetics Act, 1940. Clause 2(2) of the 2013 Order reads as follows:

“All other words and expressions used herein and not defined but defined in the Act or the Drugs and Cosmetics Act, 1940 (23 of 1940) shall have the meanings respectively assigned to them in the said Acts.”

Reference is made to Section 3(b) of the Drugs and Cosmetics Act, 1940 which provides the definition of the term “drugs.” The relevant portion of the said definition is extracted hereunder: “(b) “drug” includes-

...

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and”

...”

In light of the above, it can be said that since bulk drugs are used in the formulations to make drugs and act as active components / API of a medication that provide the intended therapeutic effect; bulk drugs can be considered as intended to be used as a component of a drug. Hence, it can be concluded that ‘drugs’ as defined in the Drugs and Cosmetics Act, 1940 include bulk drugs.

2.5 Further, they obtained “License to Import Drugs (Excluding Those Specified in Schedule X) to the Drugs and Cosmetics Rules, 1945” in Form-10 from the Central Drugs Standard Control Organization (CDSCO) for import of subject bulk drugs i.e., IOHEXOL USP. This clearly signifies that the license obtained for import of drugs would be applicable for import of bulk drugs also. Thus, even if the imported goods are treated as a bulk drug for the reason that it is used in the manufacture of medicines or formulation, for the purpose of the Notification it would be treated as drugs and hence are covered by Sl. No. 167(A) of Notification No. 50/2017. As IOHEXOL is specified at Item 55 under List 4 of Notification No. 50/2017, therefore, IOHEXOL is covered by Sl. No. 167(A) of Notification No. 50/2017, even if IOHEXOL USP is treated as a bulk drug for the reason that it is used in the manufacture of IOHEXOL Injection USP.

2.6 The goods specified in clause (B) of Sl. No.167 of Notification No. 50/2017 are bulk drugs used in the manufacture of drugs or medicines at (A) above. Apart from the various items mentioned in List 4 of the Notification No.50/2017 there may be other drugs, which may be used for manufacture of medicines or drugs, which are covered under clause (A) of Sl. No. 167. Therefore, those drugs which are not covered under clause (A) of Sl. No. 167 of Notification No. 50/2017, are covered under clause (B) of Sl.No.167, if they are used in the

manufacture of drugs specified in clause (A) of Sl. No. 167 of Notification No. 50/2017. As the imported goods fall under Sl. No. 167(A) of Notification No. 50/2017, there is no need for the Noticee to follow the procedure prescribed in IGCRD Rules. Procedural compliance under these rules is mandatory condition for clause (B) and not for clause (A).

2.7 They submitted that they have rightfully availed the benefit under Sl. No. 167(A) of Notification No.50/2017, in compliance with clear and unambiguous confirmation and approval from the Ld. Assistant Commissioner, Nagpur. The Ld. Assistant Commissioner, Nagpur after due verification of the application and the documents furnished by the Noticee, issued letter dated 24.04.2018 stating that the goods IOHEXOL USP are included under Sl. No. 167(A) of Notification No. 50/2017 and that the IGCRD Rules are not applicable for the import of the said goods. The relevant portion of the said letter dated 24.04.2018 is extracted hereunder:

“Goods i.e., (IOHEXOL USP) are included in (a) of Sr. no. 167 in Notification No. 50/2017-Customs dated 30.06.2017. The Customs, (Import of Goods at Concessional Rate of Duty), Rule 2017 is not applicable for Goods namely IOHEXOL USP as there is no condition in Notification No 50/2017-Customs dated 30.06.2017 regarding following the procedure as per the Customs, (Import of Goods at Concessional Rate of Duty), Rule 2017 which come in force on 01.07.2017 vide Notification No. 68/2017-Customs (N.T).”

2.8 The present issue has been settled in favour of the Noticee by the decision of the Hon’ble Tribunal (Mumbai Bench) rendered in the case of Burroughs Wellcome (I) Limited Vs. CCE – 2007(216) ELT 522. In the said case, the dispute was as to whether the imported bulk drug Polymyxin B Sulphate for use in the manufacture of Neosporin, would be entitled to exemption under Sl. No. 43 of Notification No. 11/1997 was considered. Sl. No. 43 of Notification No.11/1997 in clause (A) specified nil rate of duty for life saving drugs as specified in List 2 to the Notification. Clause (B) of Sl.No.43 of the Notification No.11/97 specified nil rate of duty for bulk drugs used in the manufacture of life saving drugs or medicines at clause (A) of Sl. No. 43. However, for availing the benefit under Sl. No. 43(B), the procedure prescribed under the IGCRD Rules was to be followed. M/s. Burroughs Welcome (India) Limited contended that since Polymyxin B Sulphate is specifically mentioned in List 2 of the Notification No. 11/97-Cus, it is covered under Sl. No. 47A itself and nil rate of duty would be available without following the procedure under 1996 Rules referred to above. The Department contended that in order to claim the benefit under Sl. No. 43(A), the item should be medicines in ready to use form and the item which is used in the manufacture of life savings drugs will not be covered under Sl. No. 43A but would be covered under Sl. No. 43B, subject to the procedure under the 1996 Rules referred above, being followed. After considering the issue in detail, the Tribunal accepted the contentions of Burroughs Welcome (India) Limited that once the items specified in List 2 of the said Notification is life-saving drug and it would be covered under Sl. No.43A only if it is used as medicine in List 2. Further, reference was made to the definition of ‘drug’ as provided in Drugs Control Order which covers bulk drugs. A similar view was taken by the Hon’ble CESTAT, Chennai Bench in the case of Cipla Limited Vs CC, Chennai –2007 (218) ELT 547 (Tri. -Chennai). The aforesaid decisions were followed in the case of Astrix Laboratories Ltd.

Vs Commissioner – 2009 (233) ELT 372 (T) and Aurobindo Pharma Ltd. Vs CCE, Hyderabad–2009 (247) ELT 206 (Tri-Bang). They also relied upon judgments in case of M/s Biocon Ltd. Vs. CC –2017 (9) TMI 1468 and decision of the Hon'ble CESTAT, Ahmedabad in the case of Shri Baser Vs CCEx &St –2024 (12) TMI 270 wherein reliance was placed on the decisions of Cipla Ltd (supra) and Hetero Drugs Ltd. Vs. CC (Airport) – 2017 (9) TMI 1275- CESTAT Chennai to hold that drugs and bulk drugs are one and the same. Thus, the exemption benefit under Sl. No. 108(A) of Notification No. 12/2012-Cus dated 17.03.2012 was extended to the alleged bulk drugs imported by the Company.

2.9 The Apex Court in Hemraj Gordhandas Vs. H H. Dave-1978(2) ELT (350) held that when the taxpayer otherwise qualifies for an exemption within the plain meaning of the terms of the notification, the benefit of the exemption cannot be denied by placing reliance on any apparent intent of the issuing authority. They also placed reliance on the decision of the Hon'ble Apex Court in the case of Baidyanath Ayurved Vs. Excise Commissioner-1999 (110) ELT 363 (SC), wherein it was observed that when there is no room for any observations regarding the intention of the legislature in a taxing statute and that one must look at what is exactly stated therein. They further relied upon judgments of Hon'ble Supreme Court in Sales Tax Commissioner Vs. Modi Sugar Mills- AIR 1961 SC 1047 and ALD Automotive Vs. CTO-2018 (364) ELT3 (SC), CC Vs. Dilip Kumar - 2018 (361) ELT 577 (SC) wherein the Hon'ble Supreme Court has held that the taxing statute has to be strictly construed and nothing is to be read in or implied.

2.10 Based on the above discussion, once from the plain reading of the exemption entries, the impugned goods are covered under Sl. No. 167(A); there is no room for further intendment or contextual reading that is required to interpret the entries. On a strict interpretation, the subject goods are covered by the exemption entries since these are life saving drugs/ medicines under List 4.

2.11 They submitted that in cases where more than one exemption is available in respect of the imported goods, the importer-assessee / Noticee can choose any one of the exemptions which is beneficial to him. The department cannot force any of the above exemptions of their choice onto the Noticee. They relied upon the judgment of Hon'ble Supreme Court in HCL Ltd. Vs. Collector of Customs, New Delhi - 2001 (130) ELT 405 (SC), Share Medical Care Vs. Union of India – 2007 (209) ELT 321 (SC), CCE Vs. Maruthi Foam – 1996(85) RLT 157 (T) and ABB Ltd Vs. CCE- 2009(92) RLT 665 (L.B.).

2.12 Without prejudice and in alternate, it is submitted that Sl. No. 167(B) of Notification No. 50/2017 grants complete exemption from payment of BCD to imported goods. The SCN alleges that since the present goods are imported in bulk quantity, the imported goods are eligible to benefit under Sl. No. 167(B) of Notification No. 50/2017 subject to condition 9 of the said Notification which requires the Noticee to follow the procedure in terms of IGCARD Rules. However, it states that the Noticee claimed the benefit under Sl. No. 167(A) of Notification No. 50/2017 which is alleged to be not applicable for bulk drugs, hence, merit rate of BCD@ 7.5% and IGST @18% would be applicable. They submitted the data pertaining to correlation of the consumption of the imported goods in to the formulations

manufactured by them. It was on the mis-guidance of another department that the Noticee availed benefit of SL. No. 167(A) and not 167(B) when they were already availing 167(B) in the past and complying with the IGCRD condition. Such action of the Noticee on account of the approval by another department cannot be fatal to their case. The actions of the Noticee clearly reflect adherence to the procedural mandates without any intent to bypass or contravene any provisions. Further, any perceived contravention of Condition 9 of the Notification No. 50/2017 is merely procedural and should not impact the Noticee entitlement to the concessional benefit. Thus, even if the imported goods are eligible for benefit under SL. No. 167(B) of Notification No. 50/2017, no BCD shall be applicable on such imported goods. Therefore, the SCN proposing to recover BCD @ 7.5% along SWS and IGST on the imported goods is grossly incorrect and is liable to be dropped.

2.13 The imported goods attract IGST @ 5% by virtue of Sl. No. 180 of Schedule I to Notification No. 01/2017- IGST dated 28.6.2017 (herein after referred to as “Notification No. 01/2017”). Relevant portion of the Schedule I of Notification No. 01/2017 is reproduced under:

S. No.	Chapter/Heading/Sub-heading/Tariff item	Description of Goods
(1)	(2)	(3)
180.	30 or any chapter	Drugs or medicines including their salts and esters and diagnostic test kits, specified in List I appended to this Schedule

The imported goods are covered under Serial no. 193 of List I to notification no. 01/2017. In light of above, the demand proposed for recovery of differential IGST amounting to Rs. 5,17,33,158.79/- (i.e., excess of 13% of IGST) is liable to be dropped. Thus, it was submitted that the SCN proposing to recover excess IGST is liable to be dropped.

2.14 They submitted that in terms of Section 16 read with Section 2(26) of the Central Goods and Services Act, 2017, a registered person is entitled to take input tax credit of IGST charged on the import of goods. Even if the Noticee would have paid IGST instead of availing the exemption benefit at the time of importation, the same would be available as credit to the Noticee. When the finished goods i.e., IOHEOXL injection USP would be cleared on the payment of CGST/SGST, credit of IGST paid at the time of import would be available to the Noticee as credit. Therefore, the entire exercise of present demand of IGST in this case would be revenue neutral as the Noticee would be entitled for the credit in case these duties are demanded from them. They relied upon the judgment in the following decisions wherein it was held that when demand raised for differential duty is a clear revenue neutral exercise, then such demand is not sustainable viz. CCE & C (Appeals) Vs. Narayan Polyplast –2005 (179) ELT 20 (SC), CCE Vs. Narmada Chematur–2005 (179) ELT 276 (SC), CCE Vs. Textile Corporation–2008 (231) ELT 195 (SC), CCE Vs. Jamshedpur Beverages–2007 (214) ELT 321 (SC), CCE Vs. Coca Cola India (Pvt.) Ltd–2007 (213) ELT 490 (SC), Ortho Clinical Diagnostics Vs. CC - 2022 (9) TMI 1109, CC Vs. Sterlite Industries-2013(297) E.L.T.A 150 (Bom.), Rapti Commission Agency Vs. State of U.P.-

(2006) 6 SCC 522 etc.

2.15 SCN cannot be issued under Section 28(4) of the Customs Act in the instant case since Noticee correctly classified the imported goods and availed the exemption benefit under Sl. No. 167(A) of Notification No. 50/2017. Therefore, the demand for differential duty in respect of goods imported till 06.08.2022 (i.e. Beyond two years) is completely barred by limitation. It is a settled law that claim to a classification and/or an exemption notification is a matter of bona-fide belief and in such cases, extended period of limitation is not invokable as held by the Hon'ble Supreme Court in Northern Plastic Vs. CC-1998 (101) ELT 549 (SC). The extended period is not invokable in the present case since no mis-declaration, wilful suppression or mis-statement of facts can be alleged. The goods were correctly described and accordingly, appropriate exemption benefit was availed. The invoices and other imports documents submitted along-with the bills of entry clearly declare the true and correct information regarding nature of these goods. Further, several of the consignments which are in dispute, were subjected to regular assessment procedure of examination and verification by the customs officers before grant of out-of-charge. They relied on the case of Cosmic Dye Chemical Vs. CCE, Bombay -(1995) 6 SCC 117, CCE, Aurangabad Vs. Bajaj Auto Limited-2010 (260) ELT 17 (SC) to support their claim. The SCN has not shown or even referred to any conscious or intentional act of collusion, wilful mis-statement or suppression of fact on the part of the Noticee, i.e., there is no positive act by the Noticee indicating that the Noticee have incorrectly claimed the benefit under Sl. No. 167(A) of Notification No. 50/2017. Further, the Noticee acted on the directions given by the Department vide letter dated 24.04.2018 to avail the benefit of Sl. No.167A. They further relied upon the judgment in case of Midas Fertchem Impex Vs. Principal CC-2023 (1) TM 1998, Padmini Products Vs. CC-1989 (43) ELT 195 (SC), CCE Vs. Chemphar Drugs & Liniments - 1989 (40) ELT 276 (SC) etc. They submitted that extended period is not invokable as the issue involves an interpretation of the law. For their this view they relied upon judgments in case of Singh Brothers Vs. CCE-2009 (14) STR 552, Steel cast Ltd.Vs. CCE - 2009 (14) STR 129 etc.

2.16 The question of levy of interest arises only if the demand of duty is sustainable. As the demand of duty is not sustainable, therefore, the question of levy of any interest under Section 28AA on such duty would not arise. They relied upon the judgment of the Hon'ble Supreme Court of India in the case of Prathibha Processors Vs. UOI - 1996 (88) ELT 12 (SC).

2.17 The Noticee submitted that confiscation provisions under Sections 111 of the Customs Act can be pressed into service only in cases where the assessee has acted with a mala fide intention, and it is proved beyond doubt that there was no mensrea on part of the assessee. They relied upon following judgments in support of their contention viz. Allseas Marine Contractors Vs. CC-2011 (272) ELT 619 (Tri. -Del.) and Sutures India Vs. CC - 2009 (245) ELT 596 (Tri. -Bang). They submitted that it is a well settled position in law, that claiming of an exemption notification does not amount to mis-declaration for which they placed reliance on the decision of Supreme Court in Northern Plastic Ltd. vs. CCE reported in 1998 (101) ELT 549 (SC), Ace Kargoways Pvt. Ltd. vs. CC reported in 2003 (158) ELT 505, CC Vs. Gaurav Enterprises-2006 (193) ELT 532 (Bom.)etc.

2.18 They submitted that penalty under Section 112(a) of the Customs Act is imposable on 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 111, or abets the doing or omission of such an act. This provision can, therefore, be invoked only against a person whose act or omission rendered the goods liable to confiscation. As submitted above, confiscation provisions under Section 111 of the Customs Act can be pressed into service only in cases where the assessee has acted with mala fide intention, and it is proved beyond doubt that there was mensrea on the part of the assessee. Bona fide conduct on part of the assessee does not entail the goods liable for confiscation. Since the imported goods are not liable for confiscation under Section 111 of the Customs Act, the penal provisions under Section 112 have been incorrectly proposed to be invoked in the present case. The SCN does not show case any positive act with a malafide intent on the part of the Noticee to avail the benefit under Sl.No.167 of Notification No.50/2017 with an intent to avail incorrect duty benefit in respect of the import of the subject goods and therefore the penalty is not invocable under Section 112 of the Customs Act, 1962. For this view they relied upon the judgment in case of Shri Ram Vs. State of UP-1975 (3) SCC 495, CC (EP) Vs. P.D. Manjrekar - 2009 (244) ELT 51 (Bom.), Tata Oil Mills Company Ltd. Vs. UOI - 1986 (26) ELT 931 (Bom.) etc. It is to be noted that for the imposition of penalty under Section 112 of the Customs Act, a deliberate commission or omission must be made by the Noticee. However, in the present case, there is no deliberate act or omission on the part of the Noticee. They relied upon the judgment on Hon'ble Apex Court in case of Hindustan Steel Vs. State of Orissa - 1978(2) ELT (J159), Akbar Badruddin Jiwani Vs. Collector of Customs-1990 (47) ELT 161, V. Lakshmiopathy Vs. CC-2003 (153) E.L.T. 640 (Tri.-Bang.) etc.

2.19 Penalty under Section 114A of the Customs Act can be imposed in cases when the duty has not been paid or short-paid/ part-paid by the reason of collusion or any wilful misstatement or suppression of facts. They submitted that since there has been no suppression or wilful mis- statement of facts by the Noticee the demand of duty is not sustainable and therefore, no penalty can be imposed on them. The Noticee has not willfully suppressed or misstated any facts in the instant case, it only availed the benefit of Sl. No. 167(A) of Notification No. 50/2017 under the direction of the Ld. Assistant Commissioner, Nagpur. The Hon'ble Supreme Court in Anand Nishikawa Vs. CCE- (2005) 7 SCC 749 has held that mere failure to declare, without any positive act from the side of the assessee, would not amount to wilful suppression of facts. They further relied upon judgment in case of Pushpam Pharmaceuticals Company Vs. CCE - 1995 (78) ELT 401(SC), Aban Lloyd Off shore Vs. CC-2006 (200) ELT 370 (SC), Tamil Nadu Housing Board Vs. CCE - 1994 (74) ELT 9 (SC), and CCE Vs. Chemphar Drugs - 1989 (40) ELT 276 (SC) etc.

2.20 The SCN without providing any proper reasoning proposed to impose penalty under Section 117 of the Customs Act, 1962. The SCN does not give any reasoning or ground on the basis of which penalty has been imposed on the Noticee and that is why recourse to residuary Section 117 has been taken. Therefore, no penalty under section 117 of the Customs Act, 1962 is imposable on the Noticee.

2.21 They submitted that IGST is levied under Section 5 of the Integrated Goods and

Services Tax Act, 2017 in terms of Section 3(7) of the Customs Tariff Act, 1975. However, the Customs Tariff Act has limited provisions, and it borrows various provisions from the Customs Act, for implementation of its provisions. Section 3(12) of the Customs Tariff Act, which is the borrowing provision with regard to IGST, does not borrow provision for demand of IGST with interest or penalty from the Customs Act. Therefore, it is submitted that demand of IGST along with interest has been incorrectly proposed to be recovered. Also, penalty has been incorrectly proposed to be imposed on the Noticee so far as the IGST component of the demand is concerned and no interest can be recovered. From a plain reading of section 3 of the Customs Tariff Act, 1975, it is evident that all the provisions of Customs Act have not been made applicable to the levy of IGST under the provisions of Section 3 (1) of the Customs Tariff Act. By virtue of Section 3(8) of the Customs Tariff Act only the provisions relating to levy of duty under the Customs Act including the provisions relating to drawback, refunds, and exemption from duties, have been borrowed for the purpose of IGST chargeable under Section 3(7) of the Customs Tariff Act respectively. Therefore, duty cannot be demanded, penalty cannot be imposed, and interest cannot be recovered for non- payment of IGST which is chargeable under Section 3 of the Tariff Act.

2.22 They submitted that the goods imported by the Noticee were cleared for home consumption on the strength of duly assessed bills of entry and 'Out of Charge' orders issued by the proper officer under the authority of the provisions of Section 17 and Section 47 of the Customs Act. The aforesaid orders (Out of Charge), being quasi-judicial orders, can only be set aside by an order of the competent appellate authority in appellate proceedings. It is submitted that quasi-judicial orders cannot be sought to be set aside by mere issuance of a show cause notice, which has proposed to declare the goods to be liable for confiscation. They relied upon judgment in case of CCE Kanpur Vs. Flock (India)-2000 (120) ELT 285 (SC), Priya Blue Industries Vs. CC(Preventive)-2004 (172) ELT 145 (SC), ITC Limited Vs. CCE, Kolkata IV- 2019 (368) ELT 216 (SC) etc.

PERSONAL HEARING

3. Personal hearing in the matter was conducted on 01.08.2025 through virtual mode and Shri Akhilesh Kangsia, Smt. Madhura Khandekar and Smt. Nandita Reddy all advocates and Shri Yash Agarwal and Shri Narendra Agarwal authorized representatives of M/s. Arco Life sciences (I) Pvt. Ltd. appeared for the hearing. During the personal hearing, they reiterated their written submissions and relied upon the compilation of case laws mentioned in the submission. They relied upon the letter dated 24.04.2018 of AC/Customs, Nagpur wherein it was stated that IGCR, 2017 is not applicable on them as the goods are covered under Serial no.167A of Notification No. 50/2017- Customs. They further relied upon Drug Price Control Order (DPCO) wherein Bulk Drugs are covered under the definition of drugs. They submitted that SCNs have conveniently ignored the binding judicial precedents of higher forums which is in utter disregard to the principal of judicial discipline. They referred to judgments in case of M/s. Burroughs Wellcome (I) Ltd. Vs CCE- 2007 (216) ELT 522, Cipla Ltd. Vs CC- 2007 (218) ELT 547 (Tri.-Chennai) and Shri Baser Vs CCEx & St- 2024 (12) TMI 270. They further stated that SCN has incorrectly imposed IGST @18% whereas the imported goods attract IGST @5% by virtue of Serial no. 180 of Notification no. 01/2017-IGST dated 28.06.2017.

DISCUSSION AND FINDINGS

4.1 I have carefully gone through the Show Cause Notice, material on record and facts of the case, as well as written and oral submissions made by the Noticee. Accordingly, I proceed to decide the case on merit.

4.2 I find that on the basis of the Post Clearance Audit, it was noticed that M/s. Arco Life Sciences (I) Pvt. Ltd. had cleared the goods viz. "Iohexol USP" under Tariff Heading 29242990 by paying NIL rate of BCD and IGST @ 5%. It was noticed that the importer had availed benefits of Notification no. 50/2017-Customs, Serial no. 167A. SCN has alleged that as the goods are imported in Bulk quantity, therefore, Serial no. 167(A) of the Notification no. 50/2017-Cus will not be applicable in the matter and Serial no. 167 (B) of the said notification would be applicable on the goods. However, serial no. 167(B) of Notification no. 50/2017-Cus is applicable on the goods subject to the adherence of condition no. 9 of the notification. As per condition no. 9, the importer was required to follow the procedure set out in Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017. However, since the importer did not follow the procedure mentioned in Condition no. 9 of the notification, he was not eligible for the same. Therefore, demand of differential duty to the tune of Rs. 8,11,98,024/- was raised on the importer along with consequential interest and penalties. The importer has submitted that as per the definition in Drug Price Control Order, the drugs include bulk drugs and therefore, the goods are eligible for exemption under serial no. 167A of the Notification. They further submitted letter dated 24.08.2018 of Assistant Commissioner of Customs, Nagpur where in it was stated that the product Iohexol USP is eligible for benefits under Serial no. 167A of Notification no. 50/2017-Customs.

4.3 Chief Commissioner of Customs, Mumbai Zone-II on 20.08.2025, granted extension of time limit to adjudicate the case up to 22.09.2025 as provided under Section 28 (9) of the Customs Act, 1962 which was further extended by three months i.e. up to 22.12.2025 by the competent authority vide order dated 17.09.2025. Therefore, the case was taken up by me for adjudication proceedings within the time limit as per Section 28(9) *ibid*.

4.4 On careful perusal of the Show Cause Notice and case records, I find that following main issues are involved in this case which are required to be decided:

(A) Whether the goods viz. IOHEXOL USP are eligible for exemption under Serial no. 167A of Notification No. 50/2017-Cus dated 30.06.2017 or otherwise?

(B) Whether duty amounting to Rs. 8,11,98,024/- is recoverable from the importer under Section 28(4) of the Customs Act, 1962 or otherwise?

(C) Whether the goods imported vide Bills of Entry as detailed in Annexure-I to the notice are liable for confiscation under Section 111(m) of the Customs Act, 1962 or otherwise?

(D) Whether the penalty is imposable on the importer under Section 112, 114A and 117 of the Customs Act, 1962 or otherwise?

5. After having framed the substantive issues raised in the SCN which are required to be

decided, I now proceed to examine each of the issues individually for detailed analysis based on the facts and circumstances mentioned in the SCN, provision of the Customs Act, 1962, nuances of various judicial pronouncements as well as Noticee's oral and written submissions and documents / evidences available on record.

(A) Whether the goods viz. IOHEXOL USP are eligible for exemption under Serial no. 167A of Notification No. 50/2017-Cus dated 30.06.2017 or otherwise?

5.1 I find that M/s. Arco Life Sciences Pvt. Ltd. has imported the product IOHEXOL USP by availing benefit of exemption Notification no. 50/2017-Customs dated 30.06.2017, Serial no. 167A. However, the department has alleged that the goods are eligible for benefits under Serial no. 167B of the said notification subject to the adherence of condition no. 9 of the notification. SCN alleges that the subject goods were imported in bulk quantity hence, the concessional rate is applicable on the imported goods under Sl. No. 167(B) of Notification No. 50/2017 subject to fulfilment of its conditions. It alleges that, Sl. No. 167(A) of Notification No. 50/2017 is not applicable for bulk drugs. The relevant portion of the said Notification is extracted hereunder:

S. No.	Chapter or Heading or sub-heading or tariff item	Description of goods	Standard rate	Integrated Goods and Services Tax	Condition No.
(1)	(2)	(3)	(4)	(5)	(6)
167	28, 29, 30 or 38	The following goods, namely:-			
		(A) Life saving drugs /medicines including their salts and esters and diagnostic test kits specified in List 4.	Nil	-	-
		(B) Bulk drugs used in the manufacture of life saving drugs Or medicines at (A)	Nil	-	9

Condition no.9 of the notification is as below:

"If the importer follows the procedure set out in Customs (Import of goods at concessional rate of duty) Rules, 2017".

5.2 I find that the notice has alleged that the subject goods are imported in Bulk quantity and therefore they are bulk drugs. I find that 'Bulk drugs' is not defined in Customs Act, 1962 or the rules & regulations framed there under. Therefore, the definition of the same are required to be drawn from the relevant legal provisions applicable to the drugs. I find that the drugs and medicines are governed by Drugs and Cosmetics Act and the definition of drugs &

Bulk Drugs are mentioned under Drugs (Price Control) Order, 1995 and the drug is defined as under:

“(i) *“bulk drug” means any pharmaceutical, chemical, biological or plant product including its salts, esters, stereo-isomers and derivatives, conforming to pharmacopoeial or other standards specified in the Second Schedule to the Drugs and Cosmetics Act, 1940 (23 of 1940), and which is used as such or as an ingredient in any formulation”.*

(ii) *“drug” includes—*

(a) *all medicines for internal or external use of human beings or animals and all substances intended to be used for, or in the diagnosis treatment, mitigation, or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;*

(b) *such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Government by Notification in the Official gazette; and*

(c) *bulk drugs and formulations;”*

I find that the same definition of Bulk drug or active pharmaceutical ingredient has been included in Section 2(1)(b) of The Drugs (Price Control) Order, 2013 also. Further, drug has been defined under Section 3(b) of the Drugs and Cosmetics Act, 1940 which defined drugs as under:

“drug” includes—(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules;”

5.3 From the definitions mentioned herein above, I find that the drugs include bulk drugs as per Section 2(1)(b) of The Drugs (Price Control) Order, 2013. Also, as per Section 3(b)(iii) of the Drugs and Cosmetics Act, 1940, drugs include all substances intended for use as components of a drug. Therefore, the bulk drugs which are used as an ingredient in formulations to make drugs are squarely covered within the definition of drug in accordance with the Drugs and Cosmetics Act, 1940.

5.4 As discussed in paras *supra*, drugs cover bulk drugs also. Accordingly, wherever bulk drugs are mentioned in above Notification, the benefits as applicable to ‘drugs’ shall also be applicable to ‘bulk drugs’. Further, I find that the noticee has given submissions that for the import of the impugned item i.e. IOHEXOL, they had procured ‘Licences to import Drugs’

from the competent authorities which also shows that even though the item imported by the noticee is alleged to be bulk drug in the Show Cause Notice, however, licence to import drugs issued to them, also brings out that the item imported by the noticee is nothing but drug.

5.5 Moreover, I find that Serial no. 167A of Notification no. 50/2017- Customs dated 30.06.2017 is applicable for the Life Saving Drugs/ Medicines specified in List 4 to the notification. I further find that the impugned product i.e. IOHEXOL is specifically mentioned at Serial no. 55 of List 4 of the impugned notification. I find that Serial no. 167A is applicable not only for the drugs/medicines but also their salts & esters, therefore, even though the goods viz. IOHEXOL is imported in bulk quantity, since the same is specifically covered under Serial no. 55 of List 4 of the notification and are therefore, eligible for benefits of exemption notification no. 50/2017- Customs under Serial no. 167A. It is clear that when the exemption notification clearly grants benefit to 'all life saving drugs/ medicines including their salts, esters and diagnostic kits specified in List 4' irrespective of the classification under Chapter 29, 30, no further restriction can be supplied to restrict the usage of the benefit. I also observe that notification nowhere restricts benefit of Serial no. 167A for a drug specified in List 4 just because it is imported in bulk quantity.

5.6 I find that the Notice has proposed to demand the differential duty under the pretext that the impugned goods are imported in bulk quantity; hence, they are bulk drug and therefore, serial no.167A of the said notification is not applicable on the same. I find that the Show Cause Notice has wrongly interpreted that the drugs which are imported in bulk quantity will be considered as bulk drugs. As discussed in detail in aforementioned paras, bulk drugs have been clearly defined in the Drug (Price Control Order), 2013 as any pharmaceutical product or its salts which are used as such or as an ingredient for formulation of the drugs and nowhere it mentions or even indicates that drugs imported in bulk quantity would be considered as bulk drug. Therefore, I find that the interpretation made in the notice that the drugs imported in bulk quantity would be considered as bulk drugs is flawed and unsustainable, more so when the bulk drugs have been clearly defined in the relevant legal provisions. I also find that the Show Cause Notice makes bare allegation without substantiating or relying upon any documents or evidences in support of their claim that the drugs imported in bulk quantity would be considered as bulk drugs. Therefore, I find that conjoint reading of definition of drug/bulk drug along with serial no. 167A of the notification made it adequately clear that the drug even if imported in the form of bulk quantity will be eligible for the benefits of the exemption notification no. 50/2017-Customs, serial no. 167A.

5.7 I find that the notice has taken an interpretation of the impugned notification that the benefit of Serial no. 167A is applicable only to the finished products. I find that the notification nowhere has mentioned that the benefit under Serial no. 167A can be extended only to the finished products and not to the goods imported in bulk quantity. I find that the notification has categorically mentioned the list of the products to which benefit of NIL rate of duty can be extended and such goods are mentioned in List 4 to the notification. Had the intention of the notification been to provide exemption benefit only to the finished products, it would have explicitly mentioned the same as a condition as done in case of Serial no. 167B.

I find that the notification has covered all the life saving drugs/medicines including their salts which are specified in List 4. As the goods imported by M/s. Arco Life Sciences (I) Pvt. Ltd. are specifically covered under Serial no. 55 of the List and as discussed in detail in paras supra, the goods are covered within the ambit of definition of 'Drugs', therefore, the impugned goods are eligible for benefit of NIL rate of duty.

5.8 I find that serial no.167 B of the impugned notification covers the pharmaceutical products which are not mentioned in List 4 to the Notification but which are used as an ingredient for the manufacturing of the products of List 4. Apart from the various items mentioned in List 4 of the Notification No. 50/2017 there may be other drugs, which may be used for manufacture of medicines or drugs covered under List 4. Therefore, those drugs which are not covered under Sl. No. 167A of the Notification No. 50/2017, are covered under Sl. No. 167B, if they are used in the manufacture of drugs specified in List 4. In the instant case, the goods imported by the noticee are specifically mentioned at serial no. 55 of List 4 and imported as drugs with appropriate licences. Further, Importer has provided copy of label and COA indicating ingredients of Iohexol Injection USP is Iohexol. Therefore, I am of the considered opinion that the goods imported by M/s. Arco Life Sciences (India) Pvt. Ltd. i.e. Iohexol in bulk quantity has to be treated as a drug and the same is eligible for benefits of Serial no. 167A of the exemption Notification no. 50/2017-Customs.

5.9 Even if it is assumed that the goods imported by the noticee are bulk drugs and covered under Serial no. 167B of the impugned notification, in that case also, the noticee becomes eligible for both serial no. 167A as well as 167B. In this regard, I find that it is a settled law that if two entries in an exemption notification are applicable to the given goods, then the importer can legitimately claim under the more advantageous entry. In this regard, I rely upon judgment of Hon'ble Supreme Court in case of HCL Limited Vs Collector of Customs {2001 (130) ELT 405 SC} vide which it was held that where there are two exemption notifications that cover the goods in question, the assessee is entitled to the benefit of that exemption notification which gives him greater relief, regardless of the fact that that notification is general in its terms and the other notification is more specific to the goods. Similar stance was taken by Hon'ble Apex Court in case of Share Medical Case Vs UOI {2007 (209) ELT 321 (SC)} and Collector of Central Excise, Baroda Vs Indian Petro Chemicals {1997 (92) E.L.T. 13 SC}. In case of Indian Petro Chemicals supra the hon'ble court held as under:

"We have read the judgment and order of the Customs, Excise and Gold (Control) Appellate Tribunal under appeal. It came to the conclusion that two exemption notifications were applicable and gave to the assessee the benefit of that notification which was more beneficial to it. Having read the judgment and order and heard learned counsel, we see no good reason to interfere with the judgment and order under appeal. The appeal is dismissed."

5.10 I find that after implementation of GST the importer had filed an application before the jurisdictional Customs Officer, Nagpur to comply with Customs (Import of goods at Concessional Rate of Duty) Rules. However, Assistant Commissioner of Customs, Nagpur

Customs vide their letter dated 24.04.2018 informed the noticee that the goods i.e. IOHEXOL USP are included in (A) of Serial no. 167 of Notification no. 50/2017-Customs and the Customs (Import of goods at Concessional Rate of Duty) Rules, 2017 are not applicable on them. Assistant Commissioner, Customs Division-I, Customs Commissionerate, Nagpur vide his letter F. No. VIII(39)/11/IGCRD/Return Doct./CDN-1/2018-19 dated 24.04.2018 stated as below:

“Goods i.e. (IOHEXOL USP) are included in (a) of Sr. no.167 in Notification no.50/2017-Customs dated 30.06.2017. The Customs, (Import of Goods at Concessional Rate of Duty), Rule 2017 is not applicable for Goods namely IOHEXOL USP as there is no condition in Notification no. 50/2017-Customs dated 30.06.2017 regarding following the procedure as per the Customs, (Import of Goods at Concessional Rate of Duty), Rule 2017 which come in force on 01.07.2017 vide Notification no. 68/2017-Customs (N.T.)”.

I find that the importer opted for Serial no. 167A of the said notification only after advice/directions from Assistant Commissioner of Customs, Nagpur.

5.11 I further find that the Office of the Pr. Commissioner of Customs (Preventive), Nhava Sheva Preventive Unit, R&I, Mumbai had also initiated investigation in the identical matter of eligibility of serial no.167A of Notification no. 50/2017- Customs for import of IOHEXOL against another importer. In that case, the investigating agency found that the importer had correctly availed the notification benefit and issued a letter to the importer to that effect. Relevant part of the said letter dated 15.03.2024 of Preventive Unit is as follows:

“It is to inform that as per S.No.167(A) of Notification No.50/2017-Cus dated 30.06.2017 as amended, provides exemption in respect of import of Life saving drugs/ medicines including their salts and esters and diagnostic test kits specified in List4. List4 to notification no. 50/2017-Cus contains the various Drugs/Medicines, Iohexol by name and description appear in List 4 at item no. 55. Further, definition of life saving drugs has not been given in the notification. Further, on the basis of the literature available on the internet and provided by the importer in this case, it appears that importer has availed the correct notification benefit.....

5.12 Moreover, I also find that the Commissioner of Customs, NS-1, JNCH, Nhava Sheva has also taken an identical position in Order-in-Original no. 100/2018-19/Commr./NS-I/JNCH dated 31.01.2019 in case of M/s. Abil Chempharma &49 others wherein it was held that the goods were eligible for the benefits of Notification under serial no. 167A as it is applicable at the moment. Relevant part of the order is as below:

“.....9.In view of the aforesaid, only logical conclusion that can be drawn in the present proceedings is that goods classifiable under Chapter 28, 29 and 30 of the tariff, if specified in the List 3 of the Notification no.12/2017-Cus., would remain eligible for the exemption provided under Sr.no.147(A) of that notification as well as that provided under sr. no.108(A) of the Notification No. 12/2012-CE dated 17.03.2012. the fact that such goods are bulk drugs and not formulations would not have any effect on the eligibility for the benefits

extended under the said exemption notifications. Therefore, the proposals contained in the Show Cause Notices listed in table annexed to this order fail on merits. Therefore, I do not consider it necessary to dwell on the issue of limitation. The proceedings initiated vide the aforementioned show cause notices stands concluded.”

5.13 I find that the benefits from duties of Customs as available under serial no.167A and 167B is not unprecedented and such notifications were in existence & available to the importers earlier also vide different notification numbers. However, the conditions of the notifications have been identical as in the instant case. I find that the matter at hand is not *Res Integra* and has already been settled by various judicial forums. I find that in case of *Burroughs Wellcome (I) Ltd.* {2007 (216) ELT 522 (Tri.-Mumbai)} Hon’ble CESTAT, Mumbai has passed an order where in identical matter was raised. At the relevant period, Serial no. 43 of Notification no. 11/1997 was under dispute which is similar to notification no. 50/2017- in question. Hon’ble Tribunal held as under:

“.....However, in the instant case, we find that the phrase “life saving drugs” has not been defined either in the notification or in the Drugs (Prices Control) Order. Moreover, “drugs” have been defined to include “bulk drugs”. As such life saving drugs can also include “bulk drugs”. Accordingly, we are of the view that even though the appellants had earlier claimed exemption for the impugned goods stating these to be bulk drugs, they cannot be precluded from claiming the exemption for life saving drugs in respect of the very same impugned goods as no further verification is required to be made at the original stage. Moreover, we also find that both the impugned goods are specifically listed in List 2 annexed to the notification as required under serial No. 43(A). Such specific inclusion does not require any further verification to be done at the original level.

13. We also find that by not defining the life saving drugs in the relevant notifications, the intention of the Government is to give as a wider coverage to the term as possible and the same is borne out in the Budget Circular for the year 1995 which, in Paragraph 23.1, says that life saving drugs are being exempted under the generic description and without any reference to forms.

14. In view of our findings as above, we hold that the impugned goods in respect of both the appellants being specified in List 2 to the relevant notifications, are entitled to exemption from basic and additional customs duty under serial No. 43(A) under Notification 11/97 and under similar provisions in the successor notifications during the relevant time.....”

5.14 I find that similar view was taken by Hon’ble CESTAT, Chennai in case of *Cipla Limited Vs CC, Chennai* {2007 (218) ELT 547 (Tri.- Chennai)} wherein the Hon’ble Tribunal held that even though the items imported by Cipla are used in the manufacture of drugs or medicines, the imported items itself being specified in List 3, the same would be covered by Sl. No.80(A) of the Customs Notification No.21/2002 and Sl. No.47A of Notification No.4/2006 and therefore would be wholly exempt from the Basic Customs Duty and CVD. For this purpose, the Tribunal referred to and relied upon the decision of Tribunal, Mumbai Bench, in the case of *Burroughs Wellcome (India) Limited*, referred above. Relevant portion of the above decision reads as under:

“.....4.M/s. Burroughs Wellcome(I) Ltd. had imported Polymyxin B Sulphate and used the same along with some other ingredients in the manufacture of Neosporin. M/s. Pfizer Ltd. had imported Cefoperazone Sodium and used the same for manufacture of Cefoperazone Sodium Injections. The issue before the Tribunal was whether the above parties were eligible for the benefit of exemption from payment of CVD on the items imported by them, under Sl. No.43(A) of Notification No.11/97-CE and under the corresponding entries of successor Notifications. It was not in dispute that the imported items figured in List 2 appended to Sl. No. 43 (A) of the above Notification. While the Revenue classified the goods as ‘bulk drugs’ under Sl. No. 43(B), the assessee classified them as life saving drugs under Sl. No. 43 (A). ‘The Tribunal accepted the assessee’s contention and held that the drugs imported by them were to be categorized under Sl. No.43(A) in as much as they found mention in List 2. It was further held that, as Sl.No.43(A) was more beneficial than 43(B), the assessee was not precluded from claiming such benefit at a later stage. It is settled law that, where two exemption Notifications are applicable to a given goods which is otherwise chargeable to duty, the assessee is entitled to avail the benefit of that Notification which is more beneficial vide Indian Oil Corporation Ltd. v. CCE - 1991 (53) 347 (Tribunal), CCE v. Indian Petrochemicals - 1997 (92) E.L.T. 13 (S.C.) and H.C.L. Ltd. v. CC - 2001(130)E.L.T.405(S.C.).Applying the same principle, we hold the view that,if two entries in an Exemption Notification are applicable to a given goods, the assessee can legitimately claim under the more advantageous entry. Therefore, we are inclined to follow, with approval, the view taken by the co-ordinate Bench in the case of Burroughs Wellcome (I) Ltd .& Pfizer Ltd.

5.In the instant case, admittedly, the ‘bulk drugs’ imported by the appellants were specifically mentioned in List 3 appended to Sl.No.80(A) of Customs Notification No.21/02 and a reliable to be considered as ‘drugs’ mentioned at 80(A). It is beyond doubt that ‘bulk drugs’ are also ‘drugs’. They are so defined under the Drugs (Prices Control) Order, 1995 also. The imported goods, which are specified in List 3, must fall within the coverage of ‘drugs specified in List 3’ and consequently the benefit of Sl.No.80(A) would be admissible to them in relation to BCD. It would follow that, in so far as CVD is concerned, the benefit of Sl.No.47(A) of the Central Excise Notification would be available to the goods. We have taken this view upon strict interpretation of the language used in the description of goods under the relevant entries of the Notification, in terms of the Apex Court’s ruling in Gujarat State Fertilisers Co.v.CCE-1997(91)E.L.T.3(S.C.) and other cases cited by learned DR. In the result, all the appeals filed against the appellate Commissioner’s order on merits are bound to succeed ”

5.15 I find that similar view was taken by CESTAT, Bangalore in case of Astrix Laboratories Ltd. Vs CC, Hyderabad-I {2009(233) ELT 372 (Tri.-Bangalore)}. Relevant part of the order is as below:

“.....5.1 In the case of M/s. Burroughs Wellcome (I) Ltd. (supra), the question was as to whether the bulk drugs Polymyxin B Sulphate for use in the manufacture of Neosporin would be entitled to the benefit of the exemption under Sl. No. 43 of the Notification No. 11/97 was considered. Sl. No .43 of the said Notification in Clause (A) specified nil rate of duty for life

saving drugs is specified in List - 2 to the Notification. Clause (B) of Sl. No. 43 of the Notification No. 11/97 specified nil rate of duty for bulk drugs used in the manufacture of life saving drugs or medicines at Clause (A) of Sl. No. 43. However, for availing the benefit under Sl. No. 43(B), the procedure prescribed under the Customs (Import of Goods at Concessional Rate of Duty for manufacture of Excisable Goods) Rules, 1996 is to be followed. This has been followed and there is no denial of the same. In view of this position, the ratio of the judgment cited supra would also apply to the facts of this case, as the facts were similar and the benefit of the Notification was given.

5.2 It is further seen that Nevirapine is specifically mentioned in List-3 of the Notification No. 21/2002-Cus., hence, it is a drug covered under Sl. No. 47(A) of Notification No. 4/2006-C.E. dated 1-3-2006. It is also seen that all drugs or medicines including their salts and esters and diagnostic test kits which are specified in List-3 of List-4 of the Notification No. 21/2002-Cus., dated 1-3-2002 are exempted, when they are manufactured in India. Thus, both the items find a specific entry in Sl.No.117 and 118 respectively of List-3 of Notification No.21/2002-Cus., dated 1-3-2002. Therefore, the term "drug" has to be considered to include bulk drug and formulation as per Drugs (Prices Control) Order, 1995 and hence, both the items being bulk drugs are entitled for the benefit of the Notification. The impugned orders are not correct and legal and hence, they are set aside by allowing these appeals."

5.16 I find that the SCN has proposed to impose IGST @18% only because the goods, alleged to be not eligible for Serial no.167A of Notification no.50/2017-Customs dated 30.06.2017.I find that goods imported by M/s. Arco Life Sciences (I) Pvt. Ltd. are governed by IGST Notificaiton no. 01/2017-IGSTas amended for applicability of IGST duty on the same. I find that the drugs or medicines including their salts and esters & diagnostic kits, of Chapter 30 or any other chapter & specified in List 1 of the notification are covered under Serial no. 180 of Schedule-I of the said notification i.e. 01/2017-Integrated Tax (Rate). I find that the item IOHEXOL has been specifically covered at serial no. 177 of List 1 of Schedule-I and therefore, IGST@ 5% is applicable on the said goods which has been duly paid by the importer in the Bills of Entry as detailed in Annexure- I to the notice.

5.17 In view of the above, I am of the considered opinion that the demand of differential duty amounting to Rs. 8,11,98,024/- as demanded from the importer is not sustainable as the noticee has rightly availed the benefits of the exemption notification no. 50/2017-Cus, Serial no. 167A . As the demand of differential duty is not sustainable, therefore, the interest on duty also cannot be demanded.

5.18 In view of the aforesaid discussions and findings, as the noticee has rightly availed serial no. 167A of the notification no. 50/2017-Customs. Therefore, there is no mis-declaration on part of the noticee in that regard and the goods are not found to be liable for confiscation under Section 111(m) of the Customs Act, 1962 as proposed in the notice.

5.19 I find that the importer has rightly availed the notification benefit and there has been no shortfall of duty and the goods are also not liable for confiscation. Therefore, the penalty under Section 112, 114A and 117 of the Customs Act, 1962 on the importer are not sustainable and are liable to be set aside.

6. In view above, I pass the following order:

ORDER

6.1 I drop the demand of differential duty amounting to Rs. 8,11,98,024/- (Rupees Eight Crore Eleven Lakh Ninety Eight Thousand Twenty Four Only) from the importer M/s. Arco Life Sciences (I) Pvt. Ltd.

6.2 I order that the proposal to confiscate the goods covered under the Bills of Entry listed in Annexure-I of the SCN under Section 111(m) of the Customs Act, 1962, is not maintainable and is hereby dropped.

6.3 I order that the proposal to impose penalties on M/s. Arco Life Sciences (I) Pvt. Ltd. under Sections 112(a), 114A and 117 of the Customs Act, 1962, is not warranted and is hereby dropped.

6.4 I order that the Show Cause Notice No. 957/24-25/Commr./Gr.IIAB/NS-1/CAC/JNCH dated 23.08.2024 is hereby dropped in its entirety.

7. This order is issued without prejudice to any other action that may be taken in respect of the goods in question and/or the persons/ firms concerned, covered or not covered by this show cause notice, under the provisions of Customs Act, 1962, and/or any other law for the time being in force in the Republic of India.

(यशोधन अ. वनगे /Yashodhan A. Wanage)
प्रधान आयुक्त, सीमा शुल्क / Pr. Commissioner of Customs
एनएस-1, जेएनसीएच / NS-I, JNCH

To

M/s. Arco Life Sciences (India) Private Limited (IEC -
0304061948) C-86 MIDC Area, Hingna,
Nagpur, Maharashtra-440016.

Copy to:

1. Asst./Dy. Commissioner of Customs, Audit, JNCH.
2. The Additional Commissioner of Customs, Group II (AB), JNCH.
3. AC/DC, Chief Commissioner's Office, JNCH
4. AC/DC, Centralized Revenue Recovery Cell, JNCH
5. Superintendent (P), CHS Section, JNCH—For display on JNCH Notice Board.

6. EDI Section for displaying on website

7. Office Copy