OFFICE OF THE PRINCIPAL COMMISSIONER OF CUSTOMS, NS-I
सीमाशुल्क प्रधानआयुक्त का कार्यालय, एनएस-**I**
CENTRALIZED ADJUDICATION CELL (NS-V), JAWAHARLAL NEHRU CUSTOM HOUSE,
केंद्रीकृतअधिनिर्णयनप्रकोष्ठ(एनएस-**v**), जवाहरलालनेहरूसीमाशुल्कभवन,
NHAVA SHEVA, TALUKA-URAN, DIST- RAIGAD, MAHARASHTRA 400707
न्हावाशेवा, तालुका-उरण, जिला- रायगढ़, महाराष्ट्र **-400707**

Date of Order: 21.05.2026 **Date of Issue : 22.05.2026**
आदेश की तिथि : **21.05.2026** जारी किए जाने की तिथि: **22.05.2026**

DIN 20260578NW000000B3D6
F. No. S/10-107/2024-25/Commr./GR II(A-B)/NS-I/CAC/JNCH
SCN No. 1081/2024-25/Commr./Gr.II(A-B)/NS-I/CAC/JNCH dated 12.09.2024

Passed by: Shri YashodhanWanage
पारितकर्ता: श्री यशोधन वनगे

Principal Commissioner of Customs (NS-I), JNCH, Nhava Sheva
प्रधान आयुक्त, सीमाशुल्क (एनएस-**1**), जेएनसीएच, न्हावाशेवा

Order No.: 43**/2026-27 /Pr. Commr./NS-I /CAC /JNCH**
आदेशसं. : 43/**2026-27**/प्र. आयुक्त/एनएस-1/ सीएसी/जेएनसीएच

Name of Party/Noticee: M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210)
पक्षकार (पार्टी)/ नोटिसी का नाम:मेसर्स इंस्पिरा बायो-फार्म प्राइवेट लिमिटेड (आईईसी 0303052210)

ORDER-IN-ORIGINAL
मूलआदेश

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 मूलप्रति की प्रतिलिपि जिस व्यक्ति को जारी की जाती है, उसके उपयोग के लिए नि: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 सीमाशुल्क अधिनियम१९६२ की धारा १२९ (ए) के तहत इस आदेश के विरुद्ध सीईएसटीएटी, पश्चिमीप्रादेशिकन्यायपीठ (वेस्टरीज़नलबेंच), ३४, पी. डी. मेलोरोड, मस्जिद (पूर्व), मुंबई–४००००९को अपील कर सकता है, जो उक्तअधिकरण के सहायक रजिस्ट्रार को संबोधित होगी।

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

3. अपील दाखिल करने संबंधी मुख्यमुद्दे:-

Form - Form No. CA3 in quadruplicate and four copies of the order appealed against (at least one of which should be certified copy).

फार्म - फार्मन. सीए३, चारप्रतियों 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.

समयसीमा- इसआदेशकीसूचनाकीतारीखसे३महीनेकेभीतर

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 & Page 2 of 31interest demanded & penalty imposed is more than Rs. 5 Lakh but not exceeding Rs. 50 lakh.

(ख(पाँच हजार रुपये– जहाँ माँगे गये शुल्क एवं ब्याज की तथा लगायी गयी शास्ति की रकम 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(दसहजाररुपये–जहाँ माँगे गये शुल्क एवं ब्याज की तथा लगायी गयी शास्ति की रकम 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 राष्ट्रीय कृत 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, सीमाशुल्क अधिनियम, १९९२, सीमाशुल्क (अपील) नियम, १९८२ सीमाशुल्क, उत्पादन शुल्क एवं सेवाकर अपील अधिकरण (प्रक्रिया) नियम, १९८२का 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.

4.इस आदेश के विरुद्ध अपील करने के लिए इच्छुक व्यक्ति अपील अनिर्णीत रहने तक उसमें माँगे गये शुल्क अथवा उद्गृहीतशास्ति का ७.५ % जमा करेगा और ऐसे भुगतान का प्रमाण प्रस्तुत करेगा, ऐसान किये जाने पर अपील सीमाशुल्क अधिनियम, १९६२ की धारा १२८ के उपबंधों की अनुपालना न किये जाने के लिए नामंजूर किये जाने की दायी होगी।

1. BRIEF FACTS OF THE CASE:

1.1 M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210), having address at 102, Marine Chambers, 11, New Marine Lines, Mumbai, Maharashtra-400020 (hereinafter referred to as 'the importer') had imported consignment/s of "LACTULOSE SOLUTION USP 70" (hereinafter referred to as 'the subject goods') vide Bill of Entry No. 8159929 dtd 05.10.2023 as mentioned in Annexure-A of the SCN No. 1081/2024-25/Commr./Gr.II(A-B)/NS-I/CAC/JNCH dated 12.09.2024 and classifying the same under HSN CODE 2940 0000 and availed benefit of exemption of customs Notification no. 50/2017 dtd 30.06.2017 under S.N.166(A) & paid IGST@5% (Schedule I of IGST Notification no. 01/2017 under S.N. 180) for the said consignment.

1 .2 The importer had imported consignment/s vide various Bills of Entry (as mentioned in Annexure A of the said SCN) of "LACTULOSE SOLUTION USP70" under CTH 2940 0000 with packing of 1000 KG and availed benefit of S.N. 166(A) of Customs Notification no. 50/2017 dtd 30.06.2017(as amended) & paid lower IGST @5% (Schedule I of IGST Notification no. 01/2017 under S.N. 180) for the said consignment. Exemption under S.N.166(A) of the Customs Notification no. 50/2017 dtd 30.06.2017 (as amended) is applicable to Chapter 28, 29, 30, 38 for Drugs, medicines and diagnostic kits or equipment specified in List 3.

1.3 Relevant portion of the customs exemption notification no. 50/2017 dated 30.06.2017 claimed by the importer is mentioned below:

"In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962) and sub-section (12) of section 3, of Customs Tariff Act, 1975 (51 of 1975), and in supersession of the notification of the Government of India in the Ministry of Finance (Department of Revenue), No. 12/2012-Customs, dated the 17th March, 2012 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R. 185 (E) dated the 17th March, 2012, except as respects things done or omitted to be done before such supersession, the Central Government, on being satisfied that it is, necessary in the public interest so to do, hereby exempts the goods of the description specified in column (3) of the Table below or column (3) of the, said Table read with the relevant List appended hereto, as the case may be, and falling within the Chapter, heading, sub-heading or tariff item of the First Schedule to the said Customs Tariff Act, as are specified in the corresponding entry in column (2) of the said Table, when imported into india:-

a. from so much of the duty of customs leviable thereon under the said First Schedule as is in excess of the amount calculated at the standard rate specified in the corresponding entry in column(4) of the said Table; and

b. from so much of integrated tax leviable there on under sub section (7) of section 3 of said Customs Tariff Act, read with section 5 of the Integrated Goods and Services Tax Act, 2017 (13 of 2017) as is in excess of the amount calculated at the rate specified in the

corresponding entry in column (5) of the said Table, subject to any of the conditions, specified in the Annexure to this notification, the condition number of which is mentioned in the corresponding entry in column(6) of the said Table:

Table

S.N.	Chapter or Heading or sub-heading or tariff Item	Description of goods	Standard rate	Integrated Goods and Services Tax	Condition No.	Amended By Notification No.
(1)	(2)	(3)	(4)	(5)	(6)	
166	28,29,30 or38	The following goods, namely:-				
		(A)Drugs, medicines, diagnostic kits or equipment specified in List 3	5%	-	-	
		(B) Bulk drugs used in the manufacture of drugs or medicines at (A)	5%	-	9	

Condition no.	Condition	
9	If the importer follows the procedure set out in the Customs (Import of Goods at Concessional Rate of Duty or for Specified End Use) Rules, 2022	Substituted By 2/2023 Dt. 01-02-23

1.4 The importer's intention was to avail S.N. 166(A) of Customs Notf. 50/2017 dtd 30.06.2017 (as amended) by declaring under "Chapter 28, 29, 30, 38 as Drugs, medicines and diagnostic kits or equipment specified in List 3" to avoid the Condition no.9 of S.N.166(B),which mandates the procedure set out in the Import of Goods at Concessional Rate of Duty (IGCR) Rules, 2017/2022. Further, List 3 to S.N.166 of Customs Notification

50/2017 dtd 30.06.2017 (as amended) indicates that the List 3 primarily includes finished drugs rather than bulk drugs (APIs). In this regard, following Indicators may be observed:

i. Specific Drug Names:

Items listed are typically administered to patients in their final dosage forms, such as injections, infusions, or oral formulations.

ii. Medical Applications:

The drugs listed are often associated with specific therapeutic uses, such as cancer treatment, immunotherapy, or diagnostic imaging. These applications generally pertain to drugs that have been fully processed into finished products ready for clinical use.

iii. Customs Notification Context:

The context of customs notifications like this one typically involves the importation of finished pharmaceutical products that are intended for immediate use in medical settings, rather than bulk drugs that would require further manufacturing or formulation.

1.4.1 Accordingly, it strongly indicated that the List 3 of the Customs Notification No. 50/2017 (as amended) predominantly focuses on finished drugs rather than bulk drugs. These finished drugs are likely subject to specific customs duty exemptions or reductions to facilitate their import into India for direct clinical use.

1.5 Further the contention being made—that because the definition of "drugs" under the Drugs and Cosmetics Act, 1940, covers both bulk drugs (APIs) and finished medicines, bulk drugs should therefore be included in List 3 of the Customs Notification 50/2017(as amended)—needs to be carefully examined in the context of the specific purpose and language of the customs notification. In this regard following points may be considered:

i. Purpose of the List 3 Medicines:

S.N.166 of Customs Notifications No. 50/2017 dtd 30.06.2017(as amended) appears to grant specific benefits, such as customs duty exemptions or reductions, to encourage the import of critical or life-saving drugs in their finished form. These lists are typically focused on products that are ready for clinical use to ensure their immediate availability in the healthcare system.

List 3 specifically enumerates drugs that are considered essential or important for public health, and these are usually finished products that can be directly administered to patients.

ii. Bulk Drugs vs Finished Products:

Bulk Drugs (APIs): While the definition of "drugs" under the Act does include bulk drugs, these substances generally require further processing or formulation before they can be administered to patients. The intent of the customs notification list seems to prioritize finished products that do not require additional processing.

Finished Products: These are ready-to-use forms, such as tablets, injections, or solutions, which have undergone all necessary manufacturing steps and are immediately available for treatment purposes.

(iii) Legislative Intent and Interpretation:

Customs Policy: The inclusion of items in specific lists like List 3 is a policy decision aimed at achieving certain public health outcomes. The customs authorities may intend to distinguish between bulk drugs, which are raw materials, and finished drugs, which are the end products, when applying duty exemptions.

Interpretation: Just because the Drugs and Cosmetics Act, 1940 covers both bulk and finished drugs under the term "drug" does not automatically mean that bulk drugs should be included in lists intended for finished drugs. The specific language and purpose of the customs notification take precedence.

(iv) Implications for Bulk Drugs:

If bulk drugs were to be included in List 3, it would potentially open the door for different customs treatment for APIs, which might not align with the policy objectives of the notification. The notification might be structured to ensure that duty benefits are extended only to those products that are immediately usable in healthcare settings, which typically means finished drugs rather than bulk drugs.

Accordingly, the inclusion of a substance in List 3 of the customs notification 50/2017(as amended) likely depends on whether it is intended to be used directly in healthcare settings (i.e., as a finished drug). While the Drugs and Cosmetics Act does cover both bulk and finished drugs under the broader definition of "drugs," this does not necessarily imply that bulk drugs should be included in a list that is focused on finished medicines.

1.6 As the terms “Medicine” or “Drugs” are not defined under Customs Act, 1962 & Customs Tariff Act, 1975. In this regard, reference may be taken from Drugs and Cosmetics Act, 1940. Section 3(b) of the Drugs and Cosmetics Act, 1940 defines “drug” in the following terms:

(b) “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;

It appears that Drugs and Cosmetics Act, 1940 define “Drugs” includes finished as well as bulk drugs both, though it does not define bulk drugs explicitly.

1.6.1 As the terms “Bulk Drugs” is not defined under Customs Act, 1962 & Customs Tariff Act, 1975. In this regard, reference may be taken from Drug (Price Control) Order, 2013. In the said Order, Bulk Drugs is defined as,

"Active Pharmaceutical Ingredients or Bulk Drug" means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation.

&

“formulation" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –

(i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

(ii) any medicine included in the Homeopathic system of medicine; and

(iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23of 1940) do not apply.

1.7 As per data available on internet, Lactulose is commonly sold in the Indian market in the following forms:

(i) **Syrup/Liquid**: This is the most common form, usually prescribed for the treatment of constipation and hepatic encephalopathy. The syrup is taken orally, and the dosage depends on the specific condition being treated.

(ii) **Powder for Oral Solution:** Lactulose is also available as a powder that needs to be dissolved in water or another liquid before consumption. This form is less common but is still used for similar indications as the syrup.

(iii) **Tablets:** Although less common than syrup, Lactulose is sometimes available in tablet form for oral consumption.

These products are generally available under various brand names, and the syrup form is the most widely used due to its ease of administration and effectiveness.

1.8 On the basis of the import licenses submitted by the importer, it's reason to believe that Lactulose Concentrate USP/Lactulose Solution USP70—despite its solution form is being imported in bulk quantities, without packing & labeling in the finished forms & without details of dosage. This strongly indicates that it is not a finished drug product, but rather a bulk drug substance (API) that will be further processed or formulated after importation.

1.9 Accordingly, it is clear that the imported goods qualify as “Bulk Drugs” under S.N. 166(B) of Customs Notf. 50/2017 dtd 30.06.2017(as amended) rather than 166(A)of Customs Notf. 50/2017 dtd 30.06.2017(as amended). Further the importer appears as a trader & has not followed the condition 9 described above as well as no Bond detail is found/debited against the Bill of Entry. Therefore, the importer is not eligible for exemption S.N.166 (B) of Customs Notf. 50/2017 dtd 30.06.2017(as amended) wrongly availed by them.

1.10 Further, the importer had claimed IGST rate on the imported goods @5% as per Sr.No.180 of Schedule-I of IGST Levy Notification No.01/2017-Integrated Tax (Rate) dated

28.06.2017 (as amended). In this regard, relevant portion of the IGST rate on the imported items claimed by the importer is tabled below:

Schedule-I

S. No.	Chapter/ Heading / Sub-Heading/ Tariff item	Description of goods	IGST rate
180	30 or any chapter	Drugs or medicines including their salts and eaters and diagnostic test kit, specified in List I Appended to this Schedule	5

List I of Sr. No. 180 appended to Schedule I of the said Notification is as under : (S.N. 24) Lactulose.

1.11 However, it was observed that the imported goods is "Bulk Drugs" rather than "Drugs or medicines including their salts and eaters and diagnostic test kit" as discussed above. Instead the imported item should be qualified/covered under Sr. No. 40 of Schedule- III of IGST Levy Notification No.01/2017-Integrated Tax (Rate) dated 28.06.2017 (as amended). In this regard, relevant portion of the IGST rate on the imported items is tabled below:

Schedule-III

S.No	**Chapter/ Heading/ Sub- Heading/ Tariff item**	**Description of goods**	**IGST rate**
40	29	All organic chemicals other than giberellic acid	18

1.12 To determine whether List 1 under Schedule I of IGST Act, 2017 contains finished drugs or medicines or otherwise, there are several indicators that suggest this interpretation. In this regard, following key indicators may be observed:

i. Reference to "Drugs or Medicines-

Terminology- The language used in the schedule typically refers to "drugs or medicines" which commonly implies products that are in their final form, ready for patient administration. These are products that have completed all stages of manufacturing, including formulation, packaging, and quality control.

ii. Inclusion of Salts, Esters, and Diagnostic Kits-

Finished Products: The inclusion of "salts and esters" alongside "drugs or medicines" suggests that these are specific active forms of drugs that are already incorporated into their final dosage forms.

Diagnostic Kits: The mention of diagnostic kits further supports that List1 is meant for products used directly in health care settings, which are typically finished and ready to use.

iii. Lower IGST Rate (5%):

Facilitation of Access: The 5% IGST rate is generally reserved for essential or life-saving medicines, which are ready for distribution to patients. The lower tax rate helps reduce the cost of these critical drugs to make them more accessible.

iv. Context and Structure of Schedule I:

Finished Goods Focus: Schedule I, in general, focuses on goods that are in their final usable form. The structure of this schedule often distinguishes between bulk substances (which might fall under different schedules with higher IGST rates) and finished products.

v. Regulatory Context:

Healthcare Priority: Regulatory frameworks often prioritize finished drugs and essential medicines in specific lists to ensure they are available at reduced tax rates. This prioritization typically does not extend to raw materials or bulk drugs, which require further processing.

vi. Historical Precedent and Usage:

Established Practice: Historically, lists like List 1 under such schedules have been interpreted and applied to finished drugs rather than bulk drugs, reflecting consistent regulatory practice.

Accordingly, it appeared that List 1 under Schedule I is intended to cover finished drugs or medicines rather than bulk drugs (APIs). Therefore, the lower IGST rate of 5% should be applicable on these products as they are in their final, patient-ready form. Further Bulk drugs, on the other hand, would typically attract IGST rate of 18% under Schedule III of IGST Act, 2017.

1.13 Further in a similar matter, an application for Advance Rulings was filed by the applicant M/s Sterling Bio tech Ltd, Vadodara before Gujarat Authority of Advance Rulings, Ahmadabad**.** The applicant has submitted that they are manufacturing bulk drugs namely Danuorubic in, Epirubicin, Idarubicin and Zoledronin Acid and supplying presently under general heading at Sr. No. 40 covered under chapter 29 of Schedule-III of the Notification No. 01/2017-Ct (rate) dated 28.06.2017 as well as State Notification and Integrated Tax Notification. The applicant further submitted that description of four bulk drugs as stated above specifically not mentioned at Sr.No.40 of Chapter 29 of Schedule-III of Notification No.01/2017-CT(Rate) dated 28.06.2017. However, specific reference is made about the said four bulk drugs in List1 appended to Schedule I which are covered as drugs or medicine including their salts and esters at Sr. No. 180 of the Schedule I of the NotificationNo.01/2017-CT(Rate) dated 28.06.2017.

In this regard, the applicants sought for the Advance Ruling in respect of the following question:

"*Whether the applicant is eligible to claim the benefit of lower rate of 5% {COST- 2.5% +SGST-2.5%}under Sr. No. 180 of Schedule I of the rate schedule for goods under Not.No.01/2017-CT (Rate) dated 28.06.2017 as well as of State Tax Notification*. "

As per Advance Rulings no.GUJ/GAAR/R/54/2020 dated 30.07.2020 passed by the Gujarat Authority of Advance Rulings, Ahmadabad denied the benefit of lower rate of 5% under S.N.180 of Schedule I in terms of above advance rulings which is squarely applicable in the instant case.

In view of the above, it is clear that the applicable IGST rate on the imported items should be 18% as per Sr.No.40 of Schedule-III of IGST Levy Notification No.01/2017-

Integrated Tax (Rate) dated 28.06.2017 (as amended) in terms of above advance rulings which is squarely applicable in the instant case.

1.14 Accordingly, a Consultative Letter No. 321/2024-25/C1 vide F.N.CADT/CIR/ADT/TBA/862-ThBA-CIR-D3/C dated 16-07-2024 was issued to the importer for payment of short levied duty along-with applicable interest and penalty. Vide the aforementioned Consultative letter dated 16-07-2024, the Importer was advised to pay the Differential duty along-with applicable interest and penalty within 15 days of the receipt of the consultative letter in terms of Section 28(4) of the Customs Act 1962. The importer was further advised to avail the benefit of lower penalty in terms of Section 28(5) of the Customs Act, 1962, by early payment of short paid duty and interest along with penalty @ 15%. In response the importer submitted his reply dtd 23.07.2024 & submitted that they completely and strongly disagree with the views expressed in the Consultative letter which does not appear to be sustainable on the ground discussed above.

1.15 Accordingly, the applicability of S.N.166(B) of Customs Notification no. 50/2017 dtd 30.06.2017(as amended) & applicability of IGST @ 18% as per Sr. No. 40 of Sch-III of IGST Notification No. 01/2017-Integrated Tax(Rate) dated 28.06.2017 on the imported goods are very clear and specific, it appeared that the importer had willfully availed the S.N.166(A) of Customs Notification no. 50/2017 dtd 30.06.2017(as amended) for the import of the subject goods to avoid the procedure set out in the IGCR 2017/2022 & paid lower IGST@5% than applicable and thus the provisions of Section 28(4) are invokable in this case.

1.15.1 Relevant Legal Provisions: After the introduction of self-assessment vides Finance Act, 2011, the onus is on the Importer to make true and correct declaration in all aspects including Classification and calculation of duty, but in the instant case the noticee has wrongly availed S.N. 166(A) of Customs Notification no. 50/2017 dtd 30.06.2017(as amended) for the subject goods and paid lower IGST @5% for the import of subject goods. From the foregoing, it appeared that the Importer had willfully availed S.N. 166(A) of Customs Notification no. 50/2017 the goods; that the Importer and Custom Broker have submitted a false declaration under section 46(4) of the said Act. Due to this act of omission of Importer, there has been loss to the government exchequer equal to the differential duty.

1.16 Further data was retrieved for last 05 years for the Bills of Entry filed by the Importer in INNSA1 and from the retrieved data, it is found that imported goods were cleared in INNSA1 with details as follows:

Annexure-A

LACTULOSE CONCENTRATE USP/LACTULOSE Solution USP70	Duty Payable (in INR)	Duty Paid (in INR)	Differential duty payable (in INR)

Assessable Value (A.V.)	BCD_ payable@ 7.5%	SWS_ payable @10%	IGST_ payable@ 18%	EFF_ duty_ payable@27. 735%	Total @10.775%	
165,46,87,260	12,41,01,545	124,10,154	32,24,15,813	45,89, 27,512	17,82,92,552	28,06,34,960

1.17 Accordingly, Show Cause Notice bearing no. 1081/2024-25/Commr./Gr.II(A-B)/NS-I/CAC/JNCH dated 12.09.2024 was issued to M/s. Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) seeking as to why:

1.17.1 Customs duty Exemption under Sr. No. 166(A) of Customs Notification no. 50/2017 dated 30.06.2017(as amended) for the subject gods should not be rejected and Customs duty Exemption under S.N. 166(B) of Customs Notification no. 50/2017 dtd 30.06.2017(as amended) should not be levied.

1.17.2 The IGST rate claimed under Schedule I– Sr. No. 180 of IGST levy Notification No. 01/2017-Integrated Tax (Rate) dated 28.06.2017 for the subject goods should not be rejected and IGST rate under Schedule III – Sr. No. 40 of said notification should not be levied.

1.17.3 Differential duty amount of Rs. 28,06,34,960/- (Rupees Twenty Eight Crore Six Lakh Thirty Four Thousand Nine Hundred Sixty only) with respect to the items covered under Bill of entry as mentioned in Annexure-A of the notice should not be demanded under Section 28(4) of the Customs Act, 1962 along with applicable interest as per Section 28AA of the Customs Act, 1962.

1.17.4 The subject goods as detailed in Annexure A of the notice having a total assessable value of Rs. 165,46,87,260/- (Rupees One Hundred Sixty Five Crore Forty Six Lac Eighty Seven Thousand Two Hundred Sixty only) should not be held liable for confiscation under Section 111(m) of the Customs Act, 1962.

1.17.5 Penalty should not be imposed on the importer under Section 112 and/or Section 114 A of the Customs Act, 1962.

1.17.6 Penalty should not be imposed on the importer under Section 114 AA of the Customs Act, 1962.

WRITTEN SUBMISSIONS

2. M/s. Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) gave written submissions vide their letters dated 27.04.2026 and 18.05.2026, wherein they *inter-alia* stated as below:

2.1 The noticee submitted that the Show Cause Notice dated 12.09.2024 proposed denial of exemption under Sr. No. 166(A) of Notification No.50/2017-Cus dated 30.06.2017 and

denial of concessional IGST under Sr. No.180 of Schedule I of Notification No.1/2017-IGST (Rate) in respect of imports of "Lactulose Solution USP" and "Lactose Concentrate USP" made during September 2019 to June 2024. It was contended that the imported goods were pharmacopeial drugs imported under valid "License to Import Drugs" issued under the Drugs and Cosmetics Rules, 1945 and the imports were cleared after "No Objection" from the Assistant Drug Controller. The noticee submitted that Lactulose is specified at Sr. No.24 of List 3 appended to Notification No.50/2017-Cus and at Sr. No.24 of List I appended to Notification No.1/2017-IGST (Rate), and therefore eligible for concessional BCD and IGST respectively. It was also submitted that the goods were correctly classified under Chapter 29 and had consistently been assessed by Customs at 5% BCD and 5% IGST from 2019 to 2024.

2.2 The noticee submitted that the allegations in the SCN were contrary to settled practice and binding precedents. It was contended that the Department had earlier issued Show Cause Notice No.157/18-19/SIIB(I)/JNCH dated 04.05.2018 on the identical issue alleging that Lactulose imported in bulk packing was not eligible for exemption under the predecessor notification. The said SCN was dropped vide Order-in-Original No.100/2018-19/Commr./NS-I/JNCH dated 31.01.2019 wherein it was held that the term "Drugs" in Clause (A) also covered bulk drugs. It was further submitted that consequential refund claims for duties paid during pendency of the earlier proceedings were sanctioned vide Order-in-Original No.260/22-23/AM(I) dated 07.10.2022. According to the noticee, both the aforesaid orders had been accepted by the Department and had attained finality. Reliance was also placed on Order-in-Original No.288/2025-26/Pr.Commr./NS-I/CAC/JNCH dated 10.12.2025 passed in the case of J.B. Chemicals & Pharmaceuticals Ltd., wherein an identically worded SCN was dropped and the Department had accepted the said order as confirmed through RTI reply dated 21.04.2026.

2.3 The noticee contended that the SCN was not maintainable since it failed to consider the detailed submissions already made in reply to the Consultative Letter dated 16.07.2024. Reliance was placed on the judgment in Tube Investment of India Pvt. Ltd. v. Union of India – 2018 (16) GSTL 376 (Mad.), wherein it was held that when replies are filed to audit objections, the same ought to be considered before issuance of SCN. It was argued that the present SCN had been issued in disregard of binding precedent decisions and without dealing with the submissions already made by the noticee.

2.4 On merits, the noticee submitted that Sr. No.166(A) of Notification No.50/2017-Cus specifically covers "Drugs, medicines, diagnostic kits or equipment specified in List 3" falling under Chapters 28, 29, 30 or 38 and that Sr. No.180 of Schedule I of Notification No.1/2017-IGST (Rate) similarly covers "Drugs or medicines including their salts and esters" specified in List I and falling under Chapter 30 or any Chapter. It was contended that there was no condition in either notification restricting the benefit only to finished formulations or retail packing. According to the noticee, once the imported goods are "Drugs" specified in the relevant list and falling under the specified Chapters, the exemption and concessional IGST become available irrespective of the packing condition. It was emphasized that the Drugs Controller had issued drug import licences for Lactulose USP and the goods conformed to

pharmacopeial standards under the Drugs and Cosmetics Act, 1940, thereby conclusively establishing that the goods were "Drugs".

2.5 The noticee submitted that the contention in the SCN that the notifications were intended only for finished formulations was contrary to the plain language of the notifications and to the structure of the tariff itself. It was argued that Chapters 28 and 29 inherently cover bulk drugs and raw pharmaceutical substances and therefore the inclusion of these Chapters in Sr. No.166(A) and Sr. No.180 clearly demonstrated legislative intent to include bulk drugs. The noticee further contended that the entries did not contain expressions such as "tablets", "capsules", "retail packs" or "finished formulations" and hence no such restriction could be read into the notification. Reliance in this regard was placed on the Supreme Court judgment in Hemraj Gordhandas v. H.H. Dave, Assistant Collector – 1978 (2) ELT J350 (SC), wherein it was held that exemption notifications must be interpreted strictly according to their wording and no supposed intention could be imported into them.

2.6 The noticee further submitted that the structure of exemption notifications relating to drugs had remained substantially identical for more than two decades beginning from Notification No.20/99-Cus, Notification No.17/2001-Cus, Notification No.21/2002-Cus, Notification No.12/2012-Cus and continuing in Notification No.50/2017-Cus. It was argued that throughout this period, Customs had consistently extended the benefit of Clause (A) to listed drugs even when imported in bulk form. Reliance was placed on deliberations of the Conference of Commissioners of Customs on Tariff and Allied Matters held on 21st and 22nd January 2000 at Chennai, wherein it was decided that if a drug was mentioned in the relevant list, the benefit of Clause (A) would be available irrespective of whether the drug was imported in ready-to-use or bulk form. Reference was also made to Order-in-Appeal No.07/2002 AP TE (Air) dated 08.01.2002 recording the said understanding.

2.7 The noticee submitted that the consistent practice of extending exemption under Clause (A) to bulk drugs was reaffirmed in Order-in-Original No.100/2018-19/Commr./NS-I/JNCH dated 31.01.2019 and Order-in-Original dated 31.08.2018 passed by the Commissioner of Customs, Chennai. It was contended that these orders relied upon binding Tribunal precedents such as Burroughs Wellcome (India) Ltd. v. Commissioner of Customs – 2007 (216) ELT 522, Cipla Ltd. v. Commissioner of Customs, Chennai – 2007 (218) ELT 547, Aurobindo Pharma Pvt. Ltd. v. Commissioner of Customs – 2009 (247) ELT 206, CCE v. Hetero Drugs Ltd. – 2010 (262) ELT 490 and Hetero Drugs Ltd. v. Commissioner of Customs – 2017-TIOL-4353-CESTAT-MAD. It was argued that the present SCN was issued in complete disregard of the aforesaid binding precedents and settled assessment practice.

2.8 The noticee also relied upon Para 8 of CBIC Circular No.1053/2/2017-CX dated 10.03.2017, which provides that a long-standing assessment practice prevailing across the country should not be suddenly altered by issuance of SCNs demanding duty and that such issues should first be referred to the Board. It was submitted that the impugned proceedings sought to disturb a settled practice prevailing for over two decades and were therefore contrary to the said Circular.

2.9 With regard to the reliance placed in the SCN on the Advance Ruling in the case of Sterling Biotech Ltd., the noticee contended that the ruling was not binding on other assessees and was distinguishable on facts. It was argued that the ruling proceeded on the premise that the bulk drugs in question could not be directly administered, whereas Lactulose Solution USP imported by the noticee could be used as such without further processing. The noticee submitted that even SIIB had earlier examined one of their consignments imported vide Bill of Entry No.2008749 dated 08.06.2017 and after recording that the goods could be used as such without further processing, had granted exemption. It was further contended that the Advance Ruling was contrary to the findings in Order-in-Original No.100/2018-19/Commr./NS-I/JNCH, contrary to Tribunal decisions and also contrary to the decision of the Appellate Authority for Advance Ruling in Re: Biocon Ltd. – 2020 (43) GSTL 281.

2.10 On limitation, the noticee submitted that the SCN dated 12.09.2024 demanding duty for the period September 2019 to June 2024 was barred by limitation in so far as it travelled beyond the normal period under Section 28(1) of the Customs Act, 1962. It was contended that there was no collusion, wilful misstatement or suppression of facts so as to invoke the extended period under Section 28(4). According to the noticee, the SCN itself did not specify which particular ingredient of Section 28(4) was allegedly applicable. Reliance was placed on the judgments in Aban Lloyd Chiles Offshore Ltd. v. Commissioner of Customs – 2006 (200) ELT 370 (SC), Uniworth Textiles Ltd. v. Commissioner of Customs – 2013 (288) ELT 161, CCE v. HMM Ltd. – 1995 (76) ELT 497 (SC), Raj Bahadur Narain Singh Sugar Mills Ltd. v. Union of India – 1996 (88) ELT 24 (SC) and Kaur & Singh v. CCE – 1997 (94) ELT 289 (SC), wherein it was held that the specific ground for invoking extended limitation must be clearly stated in the SCN.

2.11 The noticee further contended that mere claiming of exemption based on interpretation of notifications does not amount to suppression or misdeclaration when the goods are correctly described in the Bills of Entry. Reliance was placed on Northern Plastics Ltd. v. Collector – 1998 (101) ELT 549 (SC), Commissioner of Customs v. Gaurav Enterprises – 2006 (193) ELT 532 (Bom.), C. Natwarlal & Co. v. Commissioner of Customs – 2012-TIOL-2171-CESTAT-MUM, S. Rajiv & Co. v. Commissioner of Customs – 2014 (302) ELT 412 and Lewek Altair Shipping Pvt. Ltd. v. Commissioner of Customs – 2019 (366) ELT 318 (Tri.-Hyd.), upheld in 2019 (367) ELT A328 (SC). It was submitted that the goods had always been correctly described in the Bills of Entry along with the packing details and the claim of exemption was made under a bona fide belief supported by precedent decisions and past assessments.

2.12 The noticee also submitted that even after the introduction of self-assessment under Section 17 of the Customs Act, the assessments remained subject to verification and reassessment by proper officers under Sections 17(2) and 17(4). Since the self-assessments in the present case were accepted by proper officers, including after examination and query in certain cases, it clearly established that the issue involved interpretation of law and not suppression of facts. Reliance was again placed on Lewek Altair Shipping Pvt. Ltd. v. Commissioner of Customs – 2019 (366) ELT 318 (Tri.-Hyd.), upheld by the Supreme Court.

2.13 On confiscation, the noticee submitted that Section 111(m) of the Customs Act, 1962 was not applicable since the goods had been correctly described in the Bills of Entry and the dispute pertained only to eligibility of exemption notifications. Reliance was placed on Northern Plastics Ltd. v. Collector – 1998 (101) ELT 549 (SC), C. Natwarlal & Co. v. Commissioner of Customs – 2012-TIOL-2171-CESTAT-MUM and S. Rajiv & Co. v. Commissioner of Customs – 2014 (302) ELT 412. It was further argued that classification or exemption claimed by the importer constituted only self-assessment and could not amount to false declaration where the goods were correctly described. Reliance was also placed on Lewek Altair Shipping Pvt. Ltd. v. Commissioner of Customs – 2019 (366) ELT 318 (Tri.-Hyd.), upheld by the Supreme Court.

2.14 Without prejudice, the noticee submitted that the imported goods were no longer available for confiscation and therefore redemption fine could not be imposed. Reliance was placed on Commissioner of Customs v. Raja Impex Pvt. Ltd. – 2008 (229) ELT 185, Shiv Kripa Ispat Pvt. Ltd. v. Commissioner of Customs – 2009 (235) ELT 623, Commissioner of Customs v. Finesse Creation Inc. – 2009 (248) ELT 122 (Bom.), upheld in 2010 (255) ELT A120 (SC), Commissioner v. Sudarshan Cargo Pvt. Ltd. – 2010 (258) ELT 197 (Bom.), Chinku Exports v. Commissioner of Customs – 1999 (112) ELT 400, upheld in 2005 (184) ELT A36 (SC), and Commissioner of Customs v. Air India Ltd. – 2023 (386) ELT 236 (Bom.).

2.15 Regarding penalties, the noticee submitted that since the goods were not liable to confiscation and the duty demand itself was unsustainable, penalties under Sections 112 and 114A were not imposable. It was reiterated that there was no collusion, wilful misstatement or suppression of facts. As regards Section 114AA, the noticee contended that the provision was intended to address export frauds involving false documentation for claiming export incentives. Reliance was placed on Access Worldwide Cargo v. Commissioner of Customs – 2022 (379) ELT 120, Suresh Kumar Agarwal v. Commissioner of Customs – 2024 (6) TMI 779, A.V. Global Corporation v. Commissioner of Customs – 2024 (10) TMI 159 and Riyaz Sayed Abdul Aziz v. Commissioner of Customs – Final Order No. A/86050/2025 dated 04.07.2025. It was submitted that no false or incorrect declaration had been knowingly made by the noticee and therefore penalty under Section 114AA was wholly unsustainable.

2.16 The noticee further submitted through additional written submissions dated 18.05.2026 that the said submissions were to be read along with the detailed reply dated 27.04.2026 filed against the SCN. It was reiterated that there existed a long-standing assessment practice whereby the Assessment Group had reassessed several Bills of Entry filed by the same importer under Section 17(4) of the Customs Act, 1962 and had consistently allowed the benefit of Sr. No.166(A) of Notification No.50/2017-Cus. It was also submitted that in many instances the imported goods were physically examined at the docks pursuant to specific directions to verify eligibility of the exemption notification and even after such examination the benefit of the notification was extended by Customs officers.

2.17 The noticee reiterated that the imported goods, namely Lactulose Concentrate USP, were specifically covered under List 3 appended to Notification No.50/2017-Cus and

therefore squarely eligible for the exemption under Sr. No.166(A). It was contended that the term "Drug" appearing in the said entry could not be artificially restricted to exclude goods imported in bulk form. The noticee further submitted that they possessed Drug Licence No. IL/BD-014529 RC/BD-002725 dated 26.03.2024 issued by the FDA authorities specifically recognizing Lactulose Concentrate USP as a "Drug", thereby conclusively establishing the nature of the imported goods.

2.18 The noticee again relied upon Order-in-Original No.100/2018-19/Commr./NS-I/JNCH dated 31.01.2019 passed by the then Commissioner of Customs, NS-I, wherein the identical issue had been decided in favour of the importer after considering a long line of Tribunal decisions. It was submitted that the said order had been accepted in departmental review and consequential refund had also been granted vide Order-in-Original No.260/2022-23/AM(I) dated 07.10.2022 passed by CRC-I Section. According to the noticee, once the issue regarding applicability of the exemption notification had attained finality in their own case, reopening the same issue through the present SCN was improper and legally unsustainable.

2.19 The noticee also reiterated that the issue had been examined in the Commissioners-in-Conference held in the year 2000 and it had been clarified therein that the benefit of the notification would be available irrespective of whether the goods were imported in bulk form or in ready-to-use form. It was therefore contended that the present proceedings were contrary to the settled departmental understanding prevailing for several years.

2.20 On limitation and penal liability, the noticee submitted that there was neither wilful misstatement, suppression of facts nor collusion in the present case. It was contended that the nature of the goods, including the fact that they were imported in bulk packaging, had always been fully disclosed to the Department and was within the knowledge of Customs officers during assessment, reassessment and examination of the consignments. It was argued that mere claiming of benefit under an exemption notification could not amount to wilful misstatement or suppression of facts. In this regard, reliance was placed upon the Supreme Court judgment in the case of Nizam Sugar Factory and the decision in Lewek Altair Shipping Pvt. Ltd., affirmed by the Hon'ble Supreme Court, along with various Tribunal decisions holding that claiming a notification benefit on interpretational grounds does not amount to misdeclaration.

2.21 The noticee further submitted that once the departmental officers themselves had reassessed the Bills of Entry under Section 17(4) of the Customs Act, 1962 and had approved the exemption benefit, the importer could not subsequently be accused of suppression or misstatement. It was argued that an importer cannot be expected to possess a better understanding of the exemption than the assessing Customs officers who had themselves accepted the assessments after scrutiny and examination.

2.22 The noticee accordingly contended that confiscation under Section 111(m) of the Customs Act, 1962 was wholly unsustainable since the imported goods had been correctly declared and all material facts were within the knowledge of the Department. It was further

submitted that when the goods were not liable to confiscation, no penalty under Section 112 of the Customs Act, 1962 could survive.

2.23 The noticee additionally submitted that the goods were no longer available for confiscation and therefore no redemption fine could be imposed. Reliance in this regard was placed upon the judgment of the Hon'ble Bombay High Court in Commissioner of Customs NS-I v. Frigorifico Allana Pvt. Ltd. – 2024 (12) TMI 101 (Bom.), wherein the High Court had disapproved the practice of adjudicating authorities within Maharashtra relying upon judgments of other High Courts while ignoring binding jurisdictional High Court decisions. It was therefore argued that no redemption fine was imposable in the present case.

2.24 With regard to penalty under Section 114A of the Customs Act, 1962, the noticee reiterated that in absence of wilful misstatement, suppression of facts or collusion, the said provision was not invocable. It was submitted that the goods had always been declared correctly and the exemption benefit had been openly claimed before Customs authorities. Reliance was placed on the decisions in Lewek Altair Shipping Pvt. Ltd., Reliance Industries Ltd. and G.C. Jain, wherein it was held that mere claiming of exemption benefit does not amount to misdeclaration.

2.25 On the proposal for penalty under Section 114AA of the Customs Act, 1962, the noticee submitted that the allegation was founded solely upon the declaration filed under Section 46(4) of the Customs Act, 1962. It was argued that the declaration had been accepted repeatedly by Customs authorities in earlier assessments and there was no knowingly false declaration or document in any material particular. According to the noticee, where exemption is claimed under a bona fide belief supported by past practice and precedent decisions, penalty under Section 114AA cannot be sustained.

2.26 Lastly, the noticee relied upon Order-in-Original No.362/2025-26/Pr.Commr./NS-I/CAC/JNCH dated 16.01.2026 passed by the Principal Commissioner of Customs in another identical matter involving Lactulose, wherein the benefit of Notification No.50/2017-Cus had been extended and proceedings had been dropped. The noticee prayed that similar treatment be accorded in the present case and that the proposals for demand of differential duty, confiscation and imposition of penalties under Sections 112, 114A and 114AA of the Customs Act, 1962 be dropped in entirety.

PERSONAL HEARING

3.1 Opportunity for personal hearing in the matter was granted to the noticee on 18.05.2026 and accordingly, Shri Sanjay Singhal, Advocate and Shri Onar Singh Sekhawat Director of M/s Inspira Bio-Pharm Pvt Ltd appeared on behalf of Noticee. Shri Sanjay Singhal submitted Written Submissions and requested that the same may be taken on record and the case may be decided on the basis of the Written Submissions along with the detailed reply dated 27" April 2026. He submitted that they possess the Drug Licence and the item has been rightly classified under the Notification. He submitted that a similar matter in respect of another importer, who had imported the same goods has been decided vide Order-in-Original

No. 362/2025-26/Pr.Commr/NS - I/CAC/JNCH dated 16.01.2026 and submitted copies of the same and requested that the proceedings initiated by the Show Cause Notice may be dropped.

DISCUSSIONS 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 The adjudicating authority has to take the views/objections of the noticee on board and consider before passing the order. In the instant case, the personal hearing was granted to the noticee's on 18.05.2026 by the Adjudicating Authority which was attended by Advocate Shri Sanjay Singhal and Shri Onar Singh Sekhawat Director of M/s Inspira Bio-Pharm Pvt Ltd**,** accordingly the submissions made by them during the personal hearing have been taken on record in para 3.1 above.

4.3 I find that in compliance to the provisions of Section 28(8) and Section 122A of the Customs Act, 1962 and in terms of the principles of natural justice, opportunities for Personal Hearing (PH) were granted to the Noticee. Show Cause No. 1081/2024-25/COMMR/GR IIA-B) NS-I/CAC/JNCH dated 12.09.2024 has been kept in call book as per para 9.3 of Master Circular dated 10.03.2017 issued vide F.No. 1053/2/2017-CX, pending decision by Hon'ble Bombay High Court in W.P. No. 4660 of 2025 and the same was intimated to notice vide, this office letter dated 08.09.2025. Vide order dated 01.04.2026 Hon'ble Bombay High Courthas disposed of W.P. No. 4660 of 2025 as not pressed. Accordingly, said SCN is taken out of call book for adjudication proceedings. Importer vide their letter dated 06.05.2026 has requested for early hearing. Thus, the principles of natural justice have been followed during the adjudication proceedings. Having complied with the requirement of the principle of natural justice, I proceed to decide the case on merits, bearing in mind the allegations made in the SCN as well as the submissions / contentions made by the Noticee.

4.4 The present proceedings emanate from Show Cause Notice No. 1081/2024-25/COMMR/GR IIA-B) NS-I/CAC/JNCH dated 12.09.2024 issued to M/s Inspira Bio-Pharm Pvt Ltd, alleging that they had cleared the goods viz. "Lactulose Solution USP" under Tariff Heading 29400000 by paying IGST @5%. The SCN alleges that the importer had availed benefits of Notification no. 50/2017-Customs dated 30.06.2017 (as amended), Serial no. 166A. However, as the goods are not imported as finished product and imported in Bulk quantity, therefore, Serial no. 166(A) of the Notification no. 50/2017-Customs dated 30.06.2017 (as amended) will not be applicable in the matter and Serial no. 166 (B) of the said notification would be applicable on the goods. As, serial no. 166(B) of Notification no. 50/2017- Customs dated 30.06.2017 (as amended) is applicable on the goods subject to the adherence of condition no. 9 of the notification and 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 or for Specified End Use) Rules, 2022. 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. 28,06,34,960/- (Rupees Twenty Eight Crore Six Lakh Thirty Four Thousand Nine Hundred Sixty only) was raised on the

importer under Section 28(4) of the Customs Act, 1962, along with applicable interest under Section 28AA. The SCN further proposes holding the goods liable for confiscation under Section 111(m) of the Act, and seeks imposition of penalties upon noticee under Sections112 and /or114A and 114AA of the Customs Act, 1962.

4.5 I find that the importer has submitted that the benefit of Sr No 166(A) of Notification No. 50/2017-Cus dated 30.06.2017 has already been decided by the previous Adjudicating Authority who passed Order-in-Original No. 100/2018-19 dated 31.01.2019 which has been accepted by the department, the goods are eligible for exemption under serial no. 166A of the Notification. They further submitted that the goods are specifically covered under List 3 to the impugned Notification and therefore, are covered by Serial no. 166A of the notification. Accordingly, the importer has prayed for dropping of the demand, interest, penalty, and confiscation proposed in the Show Cause Notice.

4.6 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. Lactulose Solution USP are eligible for exemption under Serial no. 166A of Notification No. 50/2017-Cus dated 30.06.2017 (as amended) or otherwise?

(B) Whether the IGST rate claimed under Schedule I– Sr. No. 180 of IGST levy Notification No. 01/2017-Integrated Tax (Rate) dated 28.06.2017 for the subject goods is correctly claimed or otherwise?

(C) Whether duty amounting to Rs. 28,06,34,960/- (Rupees Twenty Eight Crore Six Lakh Thirty Four Thousand Nine Hundred Sixty only) is recoverable from the importer under Section 28(4) along-with applicable interest as per Section 28AA of the Customs Act, 1962 or otherwise?

(D) Whether the goods as detailed in Annexure A of the notice having a total assessable value of Rs. 165,46,87,260/- (Rupees One Hundred Sixty Five Crore Forty Six Lac Eighty Seven Thousand Two Hundred Sixty only) should be held liable for confiscation under Section 111(m) of the Customs Act, 1962 or otherwise?

(E) Whether penalty should not be imposed on the importer under Sections112 and/or 114A and 114AA of the Customs Act, 1962 or otherwise?

4.7 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. Lactulose Solution USP are eligible for exemption under Serial no. 166A of Notification No. 50/2017-Cus dated 30.06.2017 (as amended) or otherwise?

4.8 I find that , M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) has imported the product Lactulose Solution USP by availing benefit of exemption Notification no. 50/2017-Customs dated 30.06.2017 (as amended), Serial no. 166A. However, the department has alleged that the goods are eligible for benefits under Serial no. 166B 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 and are not finished product, hence, the concessional rate is applicable on the imported goods under Sl. No. 166(B) of Notification No. 50/2017-Customs dated 30.06.2017 (as amended) subject to fulfilment of its conditions. It alleges that, Sl. No. 166(A) of said Notification is not applicable for bulk drugs. The relevant portion of the said Notification is extracted hereunder:

S.N.	Chapter or Heading or sub-heading or tariff Item	Description of goods	Standard rate	Integrated Goods and Services Tax	Condition No.	Amended By Notification No.
(1)	(2)	(3)	(4)	(5)	(6)	
166	28,29,30 or38	The following goods, namely:-				
		(A) Drugs, medicines, diagnostic kits or equipment specified in List 3	5%	-	-	
		(B) Bulk drugs used in the manufacture of drugs or medicines at (A)	5%	-	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 or for Specified End Use) Rules, 2022”.

4.9 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 gelatine capsules;……….."

4.10 From the definitions mentioned hereinabove, 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.

4.11 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. Lactulose Solution USP, 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.

4.12 I find that the Notice has proposed to demand the differential duty under the pretext that the impugned goods are imported in bulk quantity and not the finished product; hence, they are bulk drug and therefore, serial no. 166A 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.

4.13 Moreover, I find that Serial no. 166A of Notification no. 50/2017-Customs dated 30.06.2017 (as amended) is applicable for Drugs/Medicines/Diagnostic kits or Equipment specified in List 3 to the notification. I further find that the impugned product i.e. Lactulose Solution USP is specifically mentioned at Serial no. 24 of List 3 of the subject notification. I find that Serial no. 166A is applicable to the drugs/medicines specified in List 3, therefore, even though the goods viz. Lactulose Solution USP are imported in bulk quantity, since the same is specifically covered under Serial no. 24 of List 3 of the notification and are therefore, eligible for benefits of exemption notification no. 50/2017-Customs dated 30.06.2017 (as amended) under Serial no. 166A. It is clear that when the exemption notification clearly grants benefit to 'drugs/medicines and diagnostic kits specified in List 3' 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. 166A for a drug specified in List 3 just because it is imported in bulk quantity. I find that the notice has alleged that the goods imported by the noticee are covered under chapter 29 of First Schedule of Customs tariff and imported in bulk quantity thus not eligible for notification. In this regard, I find that the notification has covered all the goods within the description mentioned therein which are imported under chapter 28, 29, 30, or 38. As the goods imported under Chapter 29 are also eligible for exemption notification if they fulfil other conditions, the goods imported by the noticee stands eligible for the benefits under the said notification.

4.14 I find that the notice has taken an interpretation of the impugned notification that the benefit of Serial no. 166A is applicable only to the finished products and if the benefit is extended to bulk drugs, it would potentially open the door for different customs treatment for

APIs. I find that the notification nowhere has mentioned that the benefit under Serial no. 166A 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 concessional rate of duty can be extended and such goods are mentioned in List 3 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. 166B. I find that the notification has covered all the drugs/medicines which are specified in List 3. As the goods imported by, M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) are specifically covered under Serial no. 24 of the List 3 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.

4.15 I find that the notice has mentioned that the items of List 3 mentions only finished goods. I find that the stance taken in the notice is contradictory in itself, as the goods imported by the noticee are covered under List 3 of the notification and it is alleged in the notice that the said goods are not finished products. I find that the inclusion of drugs/medicines in List 3 of the notification is not related to the same being finished product or otherwise. I find that the Notification is unambiguous in its categorization and classification of products, including Lactulose, under the relevant entries. There is no justification for reinterpretation when the legislative intent is clear. The notice's contention that the exemption is available only to finished goods is not tenable in law. Nowhere does the notification stipulate such a condition. On the contrary, the language of Serial no. 166A categorically states that "drugs/medicines" mentioned in List 3 are eligible for the duty exemption benefit. I find that the goods under import are specifically mentioned in List 3 of the notification and the presence of the goods in List 3 clearly indicates the legislative intent to allow exemption on their import. I find that it is a settled principle of statutory interpretation that when the text of the notification is clear and unambiguous, no external aids or restrictive interpretations should be resorted to. I find that plethora of judgments have emphasized that a beneficial notification promoting a particular industry or public policy should not be interpreted in a restrictive manner unless explicitly stated, more so, where goods are specifically listed. I rely upon judgment in case of Commissioner of Customs Import (Mumbai) Vs Konan Synthetic Fibres Ltd. {2012-TIOL 29 SC CUS} wherein Hon'ble Apex court held that beneficial notifications should be given a liberal interpretation, especially where their purpose is to promote or encourage certain activities. The Court reiterated that while the eligibility criteria must be strictly met, once eligibility is established, the notification must be construed so as to advance its purpose rather than defeat it.

4.16 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. 166A 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 dated 30.06.2017 (as amended), serial no. 166A.

4.17 I find that serial no. 166B of the impugned notification covers the pharmaceutical products which are not mentioned in List 3 to the Notification but which are used as ingredients for the manufacturing of the products of List 3. Apart from the various items mentioned in List 3 of the Notification No. 50/2017-Customs dated 30.06.2017 (as amended) there may be other drugs, which may be used for manufacture of medicines or drugs covered under List 3. Therefore, those drugs which are not covered under Sl. No. 166A of the Notification No. 50/2017-Customs dated 30.06.2017 (as amended), are covered under Sl. No. 166B, if they are used in the manufacture of drugs specified in List 3. The Show Cause Notice alleges that Lactulose Concentrate USP/Lactulose Solution USP70 were imported in bulk quantities without finished dosage form packaging or labelling and without prescribed dosage details, which indicate that the product is a bulk drug and therefore not eligible for the exemption claimed under said notification. The exemption under Serial no. 166A of Notification No. 50/2017-Customs dated 30.06.2017 (as amended) is product-specific and applies to drugs/medicines specified in List-3 of the said notification without any express condition that such benefit would be denied merely because the product is imported in bulk or without finished packaging. In the instant case imported goods match the description in the List 3 exactly and are clearly mentioned at Sl. No. 24 (Lactulose) of List 3 of Notification No. 50/2017-Customs dated 30.06.2017 (as amended). Therefore, I am of the considered opinion that the goods imported by, M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) i.e. Lactulose Solution USP in bulk quantity have to be treated as a drug and the same is eligible for benefits of Serial no. 166A of the exemption Notification no. 50/2017-Customs dated 30.06.2017 (as amended).

4.18 Even if it is assumed that the goods imported by the noticee are bulk drugs and covered under Serial no. 166B of the impugned notification, in that case also, the noticee becomes eligible for both serial no. 166A as well as 166B. 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."

4.19 I find that after implementation of GST, another importer had filed an application letter dated 12.02.2018 before the jurisdictional Customs Officer, Nagpur to comply with Customs (Import of goods at Concessional Rate of Duty) Rules with respect to another product viz. IOHEXOL USP specified in List 3 to the subject Notification. However, Assistant Commissioner of Customs, Nagpur Customs vide their letter dated 23.04.2018 informed them 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)/9/C-Bond/IGCRD/UNIJULES/CDN-1/2018-19/100 dated 23.04.2018 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.)".

4.20 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 Lifesaving drugs/medicines including their salts and esters and diagnostic test kits* ***specified in List 4****. List 4 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....."*

4.21 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 Chem pharma & 49 others wherein it was held that the goods were eligible for the benefits of Notification under serial no. 167A as it is applicable in the subject case under consideration. 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."

4.22 I further find that the benefits from duties of Customs as available under serial no. 166A and 166B 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 Burroghs Wellcome (I) Ltd. {2007 (216) ELT 522 (Tri.-Mumbai)} Hon'ble CESTAT, Mumbai has passed an order wherein 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……."

4.23 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 Welcome (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 assessees classified them as life saving drugs under Sl. No. 43 (A). 'The Tribunal accepted the assessees contention and held that the drugs imported by them were to be categorized under Sl. No. 43(A) inasmuch 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 are liable 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, insofar 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……."

4.24 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."

Accordingly, I am of the considered opinion that the goods viz. Lactulose Solution USP imported by the importer vide Bills of Entries as per Annexure-A of the notice are eligible for exemption under Serial no. 166A of Notification No. 50/2017-Cus dated 30.06.2017(as amended)

(B) Whether the IGST rate claimed under Schedule I– Sr. No. 180 of IGST levy Notification No. 01/2017-Integrated Tax (Rate) dated 28.06.2017 for the subject goods is correctly claimed or otherwise?

4.25 I find that the SCN has proposed to impose IGST @18% only because the goods, alleged to be not eligible for Serial no. 166A of Notification no. 50/2017-Customs dated 30.06.2017 (as amended) and are imported as bulk drug. I find that goods imported by, M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) are governed by IGST Notification no. 01/2017-IGST (Rate) dated 28.06.2017 as 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 appended to schedule of the notification' are covered under Serial no. 180 of Schedule-I of the said notification i.e. 01/2017- Integrated Tax (Rate) dated 28.06.2017 (as amended). I find that the item Lactulose has been specifically covered at serial no. 24 of List 1 appended to Schedule-I of the said notification 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-A to the notice.

4.26 I find that the notice has relied upon the Advance Ruling in case of M/s. Sterling Biotech Limited, Vadodra and has stated that the said advance ruling is applicable in the instant case also. I find that the applicability of Advance Rulings is governed by Section 28J of the Customs Act, 1962. I find that as per provisions of Section 28J of the Act, *ibid.* the advance ruling pronounced by the authority is applicable only on the applicant who sought it and on the jurisdictional authorities in respect of the applicant. I further find that the Advance Ruling in case of M/s. Sterling Biotech Limited, Vadodra pertains to goods which are distinct and materially different from the goods involved in the present proceedings. I also find that the noticee in the instant case is different from the applicant in the case of ruling relied upon in the notice and also the competent authority who passed the ruling is from different jurisdiction vis-à-vis jurisdiction wherein impugned goods are imported. I also find that the reliance on the said advance ruling in case of M/s. Sterling Biotech Limited, Vadodra cannot be made as the impugned goods are specifically mentioned in List 1 to Schedule-I of the IGST Notification. Also, in the identical issues plethora of judgments have been issued by various Tribunal authorities wherein the benefit of exemption was granted to the respective companies on the ground that the goods are specifically covered by the notifications. Also, as detailed in paras above, the notification is unambiguous regarding its applicability on the goods mentioned in the list attached to it and the notice's contention that the exemption is available only to finished goods is not tenable in law as nowhere does the notification stipulate such a condition. Accordingly, I am of the considered opinion that IGST @ 5% is applicable on the impugned goods imported by , M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) as the same are squarely covered in List 1 to Schedule-I of the IGST Notification No. 01/2017-IGST(Rate) dated 28.06.2017 (as amended).

(C) Whether duty amounting to Rs. 28,06,34,960/- (Rupees Twenty Eight Crore Six Lakh Thirty Four Thousand Nine Hundred Sixty only) is recoverable from the importer under Section 28(4) along-with applicable interest as per Section 28AA of the Customs Act, 1962 or otherwise?

4.27 Since the noticee has rightly availed the benefits of the exemption notification no. 50/2017-Cus dated 30.06.2017 (as amended), Serial no. 166A and has correctly paid IGST under Schedule I of the IGST notification No. 01/2017-IGST (Rate) dated 28.06.2017 (as amended), I am of the considered opinion that the demand of differential duty amounting to Rs. 28,06,34,960/- (Rupees Twenty Eight Crore Six Lakh Thirty Four Thousand Nine Hundred Sixty only**)** as demanded from the importer is not sustainable. As the demand of differential duty is not sustainable, therefore, the interest on duty under Section 28AA also cannot be demanded.

(D) Whether the goods as detailed in Annexure A of the notice having a total assessable value of Rs. 165,46,87,260/- (Rupees One Hundred Sixty Five Crore Forty Six Lac Eighty Seven Thousand Two Hundred Sixty only) should not be held liable for confiscation under Section 111(m) of the Customs Act, 1962 or otherwise?

4.28 In view of the aforesaid discussions and findings, as the noticee has rightly availed serial no. 166A of the notification no. 50/2017-Customsdated 30.06.2017 (as amended) and

Serial no. 180 of Schedule I of IGST notification no. 01/2017-IGST(Rate)dated 28.06.2017 (as amended). 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.

(E) Whether penalty should not be imposed on the importer under Sections 112 and/or 114A and 114AA of the Customs Act, 1962 or otherwise?

4.29 I find that the proposals for penalty in the SCN flow from the allegation that the importer has wrongly availed the benefits of the exemption notification no. 50/2017-Cusdated 30.06.2017 (as amended), Serial no. 166A and has not paid IGST @ rate 18% under Schedule III – Sr. No. 40 of IGST notification no. 01/2017-IGST dated 28.06.2017 (as amended) thereby rendering the goods liable to confiscation and the importer liable to penalty under Sections 112 and/or 114A and 114AA of the Customs Act, 1962.

4.29.1 However, as already discussed under Issues A to D, the importer had rightly availed the notifications benefit under serial no. 166A of the notification no. 50/2017-Customs dated 30.06.2017 (as amended) and correctly claimed the IGST rate under Serial no. 180 of Schedule I of IGST notification no. 01/2017-IGST (Rate) dated 28.06.2017 (as amended) and there has been no shortfall of duty and accordingly, the goods are also not liable for confiscation. It is well settled that penalties under Sections 112, 114A and 114AA can only be imposed where there is clear evidence of mens rea or deliberate intent to evade duty. In the absence of such evidence, mere interpretational differences regarding the scope of a notification cannot justify imposition of penalty.

4.29.2 In light of these findings, I hold that penalties proposed under Sections 112 and/or 114A and 114AA of the Customs Act, 1962 on the importer is not sustainable and liable to be set aside.

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

ORDER

5.1 I order that the demand for differential duty amounting to Rs. 28,06,34,960/- (Rupees Twenty Eight Crore Six Lakh Thirty Four Thousand Nine Hundred Sixty only) from the importer M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) under Section 28(4) of the Customs Act, 1962, is not sustainable and is hereby dropped.

5.2 I order that the proposal to levy interest under Section 28AA of the Customs Act, 1962, is dropped, as the principal demand does not survive.

5.3 I order that the proposal to confiscate the goods having a total assessable value Rs. 165,46,87,260/- (Rupees One Hundred Sixty Five Crore Forty Six Lac Eighty Seven Thousand Two Hundred Sixty only) covered under the Bills of Entry listed in Annexure-A of the SCN under Section 111(m) of the Customs Act, 1962, is not maintainable and is hereby dropped.

5.4 I order that the proposal to impose penalties on M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210) under Sections 112 and/or 114A and 114AA, of the Customs Act, 1962, is not warranted and is hereby dropped.

5.5 I order that the Show Cause Notice No. 1081/2024-25/Commr. /Gr.II (A-B)/NS-I/CAC/JNCH dated 12.09.2024 is hereby dropped in its entirety.

6. 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.

Digitally signed by
Yashodhan Arvind Wanage
Date: 21-05-2026
12:32:48

(यशोधनअ. वनगे /Yashodhan A. Wanage)
प्रधान आयुक्त, सीमाशुल्क / Pr. Commissioner of Customs
एनएस-I, जेएनसीएच / NS-I, JNCH

To,
M/s Inspira Bio-Pharm Pvt Ltd (IEC 0303052210),
102, Marine Chambers, 11, New Marine Lines,
Mumbai, Maharashtra-400020

Copy to:-

1. Asst./Dy. Commissioner of Customs, Audit, JNCH.
2. The Additional Commissioner of Customs, Group II(AB), JNCH.
3. 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.