

# OFFICE OF THE COMMISSIONER OF CUSTOMS, NS-I सीमाशुल्क आयुक्तकाकार्यालय, एनएस-I

# CENTRALIZED ADJUDICATION CELL, JAWAHARLAL NEHRU CUSTOM HOUSE,

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

न्हावाशेवा, तालुका-उरण, जिला- रायगढ़, महाराष्ट्र -400 707

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: 20251278NW000000CB50

F.No. S/10-122/2024-25/Commr./Gr. IIAB/NS-I/CAC/JNCH

SCN No. 1256/24-25/Commr,/Gr.IIAB/NS-1/CAC/JNCH dated 15.10.2024

Passed by: Shri Yashodhan Wanage

पारितकर्ता: श्री. यशोधन वनगे

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

प्रधानआयुक्त, सीमाशुल्क (एनएस-1), जेएनसीएच, न्हावाशेवा

Order No.: 288/2025-26 /Pr. Commr/NS-I /CAC /JNCH

आदेशसं.: 288/2025-26/ प्र. आयुक्त/एनएस-1/ सीएसी/जेएनसीएच

Name of Party/Noticee: M/s. J B Chemicals and Pharmaceuticals Limited (IEC 0388063262)

पक्षकार (पार्टी)/ नोटिसी का नाम: मेसर्स जे बी केमिकल्स एंड फार्मास्युटिकल्स लिमिटेड (आईईसी 0388063262)

# <u>ORDER-IN-ORIGINAL</u> 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 मूल प्रति 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 सीमा शुल्क अधिनियम १९६२ की धारा १२९ (ए (के तहत इस आदेश के विरुद्ध सीईएसटीएटी, पश्चिमी प्रादेशिक न्यायपीठ (वेस्ट रीज़नल 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: -
- अपील दाखिल करने संबंधी मुख्य मुद्दे:-

Form - Form No. CA-3in 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 ड्राफ्टजो 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, सीमाशुल्क अपील (नियम, १९८२, सीमा शुल्क, उत्पाद शुल्क एवं सेवाकर अपील 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 M/s. J B Chemicals And Pharmaceuticals Limited (IEC 0388063262) (hereinafter referred to as 'the importer') had imported consignment/s of "Iohexol USP" (hereinafter referred to as 'the subject goods') under CTH 29242990 vide Bill of Entry No. 3299111 dated 02.05.2024 as mentioned in Annexure-A to the Show cause Notice and availed benefit of exemption of customs Notification no. 50/2017 dated 30.06.2017 under S.N.167(A) alongwith IGST paid @5% (Schedule I of IGST Notification no. 01/2017 under S.N. 180) for the said consignment.
- 1.2 The importer has imported consignment/s of "Iohexol USP" under CTH 29242990 with packing of 25 Kgs/Drum and availed benefit of S.N. 167(A) of customs Notification no. 50/2017 dated 30.06.2017(as amended) along with IGST paid @5% (Schedule I of IGST Notification no. 01/2017 under S.N. 180) for the said consignment. Exemption of S.N.167(A) of the Customs Notification no. 50/2017 dated 30.06.2017(as amended) is applicable to Chapter 28, 29, 30, 38 for Lifesaving drugs/medicines including their salts and esters and diagnostic test kits specified in List 4 & Iohexol (S.N.55) is specified in the list 4, appended to S.N. 167(A).
- **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 thereon 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** 

N.	sub-	Description of	Standard rate		Condition	Amended By Notification No.
(1)	(2)	(3)	(4)	(5)	(6)	
167	28, 29, 30 or 38	The following goods, namely:- Provided that nothing contained in this S. No. shall have effect after the 31st March, 2025				(1) Proviso Inserted By 02/2023 Dt. 01-02-23
		(A)Lifesaving drugs/medicines including their salts and esters and diagnostic test kits specified in List 4.	1 111	-	-	
		(B) Bulk drugs used in the manufacture of life saving drugs or medicines at (A)	Nil	-	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	Ву	2/2023	Dt.

1.4 The importer's intention was to avail S.N. 167(A) of Customs Notification 50/2017 dated 30.06.2017 (as amended) by declaring it as "Lifesaving drugs/medicines including their

salts and esters and diagnostic test kits specified in List 4" to avoid the Condition no. 9 of S.N. 167(B), which mandates the procedure set out in the Import of Goods at Concessional Rate of Duty (IGCRD) Rules, 2017/2022. Further, the two entries under the same Serial Number (in the instant case, S.No.167(A) and S.No.167(B) of the Customs Notification No. 50/2017) represent different approaches to achieving the same ultimate goal of ensuring the availability of lifesaving drugs or medicines including their salts and esters and diagnostic test kits specified in List 4" at affordable prices by offering customs duty exemptions i.e. both entries work toward the same ultimate aim but through different methods or pathways.

**1.4.1** Whereas, the overall purpose of both S.N.167(A) and 167(B) is to reduce the cost and enhance the availability of critical, lifesaving medicines by Reducing customs duties on finished lifesaving drugs and diagnostic kits under S.N.167(A) & Reducing customs duties on bulk drugs (APIs) under S.N. 167(B) that are used to manufacture these lifesaving drugs. It appears that both entries aim to make these drugs more affordable for the healthcare system and ultimately for patients by two Different Methods to Achieve the Same Goal.

## **1.4.2** S.No.167(A)–For Finished Drugs:

Objective: Directly reduce the cost of importing finished, ready-to-use lifesaving medicines and diagnostic kits.

Method: Finished drugs and diagnostic kits (as listed in List 4) are exempt from customs duties when imported, making them cheaper for immediate use in healthcare.

Target Products: Fully formulated, packaged, and ready-to-administer medicines that can go straight to hospitals, pharmacies, or patients without any further manufacturing.

Example: An antiretroviral drug imported as finished tablets for immediate distribution would be exempt from customs duties under 167(A).

#### 1.4.3 S.No.167(B)—For Bulk Drugs (APIs) Used in Manufacturing:

Objective: Support local manufacturing of lifesaving drugs by reducing the cost of importing raw materials (APIs), used in the manufacturing of life saving drugs or medicines mentioned in the said List 4.

Method: Exempting bulk drugs (APIs) used to manufacture the finished drugs listed under 167(A) from customs duties.

Target Products: Active Pharmaceutical Ingredients (APIs) that are imported in bulk and require further processing or formulation into finished drugs. These APIs are essential raw materials for local manufacturers to produce lifesaving drugs.

Example: Iohexol, an API, is imported to be further formulated into diagnostic contrast agents. The Iohexol would be classified under 167(B) as it is not yet in its finished, patient-ready form.

In view of above, it indicates that the S.N.167(A) is aimed at facilitating the immediate availability of lifesaving drugs by importing the final product, while S.N.167(B) is aimed at

promoting domestic pharmaceutical manufacturing by lowering the costs of importing the necessary raw materials (APIs) for local production of these lifesaving drugs.

- **1.5** Further, the List 4 to S.N.167 of Customs Notification 50/2017 dated 30.06.2017 (as amended) indicates that the List 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.
- 1.6 In view of the above, it strongly suggests that the List 4 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.
- 1.7 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, therefore bulk drugs should be included in List 4 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 4 Medicines:

S.N.167 of Customs Notifications No. 50/2017 dated 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 4 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 appears 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 purpose.

# (iii) Legislative Intent and Interpretation:

Customs Policy: The inclusion of items in specific lists like List 4 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 List4, 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 4 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,1940 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.

**1.8** 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:

## a. "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;

The Drugs and Cosmetics Act, 1940 defines "Drugs" includes finished as well as bulk drugs both, though it does not define bulk drugs explicitly.

b. As the term "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 (23 of 1940) do not apply.
- **1.9** Further, as per data available on internet (www.gehealthcare.com & www.mayoclinic.org), it appeared that Iohexol can be administered both orally and through injection depending on the specific imaging needs:
- (i) Injection: This is the most common method for procedures like CT scans, angiography, and myelography. It can be administered via intravenous (IV) or intrathecal routes to enhance the contrast of internal body structures such as blood vessels and the spinal cord.
- (ii) Oral Administration: Iohexol can also be ingested orally for gastrointestinal imaging. It is used to improve the visualization of the stomach, intestines, and bowels during CT scans of the abdomen or pelvis.

Both forms of administration are designed to improve the clarity of medical imaging for better diagnosis [oai\_citation:2,www.gehealthcare.com](https://www.gehealthcare.com/-/media/289efbbcf4f04d88ba79b21787183f3b.pdf?la=en-us) [oai\_citation:1,Iohexol (Oral Route) Proper Use - Mayo Clinic](https://www.mayoclinic.org/drugs-supplements/iohexol-oral-route/proper-use/drg-20406805?p=1).

**1.10** Certificate of Analysis (CoA) issued by M/s Zhejiang Starry Pharmaceutical Co. Ltd was submitted by the importer describes the imported goods "Iohexol" with packing of 25 Kg/Drum with characteristics as white to off-white, hygroscopic, odorless powder which indicates it as bulk drug (API) likely be used to manufacture a finished drug, after further formulation processes. The distinction between a bulk drug (API) and a finished drug product can be made based on several key factors as follows:

Basis	Finished Drug	Bulk Drug (API)
(i)Form of the Substance	A finished drug would	The Certificate of Analysis
	typically be in a final dosage	(CoA) describes Iohexol as a
	form, such as tablets, capsules,	"hygroscopic, odorless

manufacturing steps to be converted into a finished drup product.  (ii)Purpose and Use  A finished drug product is The primary use of Iohexol intended for direct use in this context is as an ingredice patients, following regulatory for further formulation into approval for safety, efficacy, drug product. The CoA do and proper labeling.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.  (iii)Packaging  and Finished drug products are The CoA mentions that the substance is ready for direct use be patients.		injections, or oral liquids,	powder." This indicates that it
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		a finished drug would include	documentation often focus on
product's formulation, dosage, chemical composition of the		information on the final	the purity, identity, and
		product's formulation, dosage,	chemical composition of the
administration route, and substance, as this is critical for		administration route, and	substance, as this is critical for
packaging. ensuring the quality of the		packaging.	ensuring the quality of the
API before it is used			API before it is used to
produce the final dru			produce the final drug
product.			product.

(v)Testing	The product must meet Focus on chemical purity,
	specific criteria for safety, potency, identity of the active
	efficacy and quality before it ingredient, impurity profiles
	can be released for public use and physical properties like
	solubility & stability.
(vi)Representative Image	product image is found on Bulk drug labelis found in Bill
	website (www.indiamart.com) of the Entry no.3299111 dated
	with product name as 02.05.2024 with product name
	Contrapaque-350, with details as Iohexol USP & Gross Wt
	as Iohexol Injection USP 350 27.9 Kgs, Net Wt 25 Kgs,
	mg, non ionic water soluble Batch no.C049-2310203
	contrast medium.

On the basis of above details & description given in the CoA—where Iohexol is presented as a powder, analysed for purity and impurities, packed in large quantities and without any specific strength—it is reasonable to conclude that this is a bulk drug (API) rather than a finished pharmaceutical product.

- 1.11 In view of above, it was clear that the imported goods qualifies as "Bulk Drugs" under S.N. 167(B) of Customs Notf. 50/2017 dated 30.06.2017(as amended) rather than 167(A) of Customs Notf. 50/2017 dated 30.06.2017(as amended). Therefore, the Importer was not eligible for exemption under S.N.167(A) of Customs Notf. 50/2017 dated 30.06.2017(as amended) wrongly availed by them. Further, the importer was also not eligible for exemption under S.N. 167(B) of Customs Notf. 50/2017 dated 30.06.2017(as amended) as they have not followed the requirements of condition 9 which mandates following the procedure set out in IGCRD, 2017/2022.
- 1.12 It was also observed that 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/	Description of goods	IGST
	Sub-Heading/		rate
	Tariff item		

180	30 or any chapter	Drugs or medicines including their salts and eaters and	5
		diagnostic test kit, specified in List I appended to this	
		Schedule	

List I of Sr. No. 180 appended to Schedule I of the said Notification is as under:

(S.N. 177) Iohexol

- (a) Indium(III) inbleomycin
- (b) Indium113 Sterile generator and elution accessories
- (c) Indium113 in brain scanning kit
- (d) Indium113 in liver scanning kit
- **1.13** However, it was observed that the imported goods was "Bulk Drugs" rather than "Drugs or medicines including their salts and eaters and diagnostic test kit" as discussed above. Instead, the imported item qualifies 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/	Description of goods	IGST
	Sub-Heading/ Tariff		rate
	item		
40	29	All organic chemicals other than giberellic acid	18

- **1.14** 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 alreadyincorporated into their finaldosageforms.

Diagnostic Kits: The mention of diagnostic kits further supports that List 1 is meant for products used directly in healthcare 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. For example:

- 1. Vaccines (e.g., BCG vaccine, MMR vaccine, Pneumococcal vaccines, etc.)
- 2. **Injectable Solutions** (e.g., Amikacin injection, Clindamycin injection, Eptifibatide injection, etc.)
- 3. Oral Tablets/Capsules (e.g., Baclofen, Methotrexate, etc.)
- 4. **Diagnostic Kits** (e.g., Troponin-T test kit, HIV antibody test kits, etc.)
- 5. **Monoclonal antibodies** (e.g. like Bevacizumab, Daclizumab, etc.)
- 6. **Combination Products** (e.g., DTaP-IPV-Hib combined vaccine, Ticarcillin Disodium and Potassium Clavulanate combination, etc.)

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.

Accordingly, it appears 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.

1.15 Further in a similar matter, an application for Advance Rulings was filed by the applicant M/s Sterling Biotech Ltd, Vadodara before Gujrat Authority of Advance Rulings, Ahmadabad. The applicant has submitted that they are manufacturing bulk drugs namely Danuorubicin, 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 viz. Danuorubicin, Epirubicin, Idarubicin and Zoledronin in List 1 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 Notification No. 01/2017-CT (Rate) dated 28.06.2017.

In this regard, the applicant 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% {CGST- 25.% + 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 was 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).

- 1.16 Accordingly, Consultative Letter No. 291/2024-25/C-2 vide F.No.: a CADT/CIR/ADT/TBA/773/2024 dated 25.06.2024 was issued to the importer for payment of short levied duty along with applicable interest and penalty. Vide the aforementioned Consultative letter dated 25.06.2024, the Importer was advised to pay the Differential duty alongwith 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%.
- **1.17** In response to aforesaid Consultative Letter, the importer submitted their reply letter dated 23.08.2024 as below:
- **1.17.1** BCD is Nil for S.N. 167(A) & is also Nil for S.N.167(B) of the Customs Notification No. 50/2017 dated 30.06.2017 but subject to conditions set out in the Import of Goods at Concessional Rate of Duty (IGCR) Rules, 2017/2022. They stated that notification itself considers "IOHEXOL" as drug only. Therefore denial of exemptions as drug under S.N. 167(A) was incorrect and if two entries in an exemption notification are applicable to given goods, the importer can legitimately claim under the more advantageous entry.
- **1.17.2** They stated that based on intelligence developed by the Commissioner of Customs(P), NSPU, an investigation was carried out in relation to import of "Iohexol" vide B/E no. 7967069 dated 23.09.2023. Contention was raised for the availment of undue benefit of S.N. 167(A) of Notf. No.50/2017. In this regard, they had submitted copy of Closure letter dated 15.03.2024 issued by the Asstt Commissioner of Customs(P), NSPU for closing the investigation against the importer was carried out in relation to import of "Iohexol" vide B/E no. 7967069 dated 23.09.2023.
- **1.17.3** Further, they stated that in the said CL, there had been no reasoning put forth for considering it as bulk drugs except the reason that it has been packed in 25KG/drum and "Iohexol" imported by them is a complete product in itself and reflect in S.N. 167(A) of the Customs Notification No. 50/2017.
- **1.17.4** Importer had denied to pay IGST@18% on the imported goods as "Iohexol" in itself to be treated as drugs & hence to be covered under IGST@5%.
- **1.17.5** Under Section 28J of the Customs Act, 1962, Advance Ruling of M/s Sterling Biotech Ltd, is binding only on the applicant who had obtained/sought it but not applicable to the their case.

- **1.18** Importer's submissions were countered in the following ways:
- **1.18.1** Though BCD is Nil for S.N. 167 (A) & is also Nil for S.N.167 (B) of the Customs Notification No. 50/2017 dated 30.06.2017 but subject to conditions set out in the Import of Goods at Concessional Rate of Duty (IGCR) Rules, 2017/2022, the importer was not eligible for the S.N.167(A) of the aforesaid Notf. as the importer is importing bulk drugs. On the other side, the importer was also not eligible for the S.N.167(B) of the aforesaid Notf. as the importer has not followed the procedure that mandate to follow conditions set out in the Import of Goods at Concessional Rate of Duty (IGCR) Rules, 2017/2022.
- **1.18.2** Importer stated that notification itself considers "IOHEXOL" as drug only. In this regard, it appears that the List 4 of the Customs Notification No. 50/2017 (as amended) predominantly covers finished drugs rather than bulk drugs. These finished drugs are likely subject to reduced customs duty to facilitate their import into India for direct clinical use. The importer is not eligible for the S.N.167(A) of the aforesaid Notf. as the importer is importing bulk drugs in bulk 25 Kgs packages.
- 1.18.3 Importer stated that if two entries in an exemption notification are applicable to given goods, the importer can legitimately claim under the more advantageous entry. In this regard, it appears that S.N.167(A) of the Notf. 50/2017 is aimed at facilitating the immediate availability of lifesaving drugs by importing the final product, while S.N.167(B) of the Notf. 50/2017 is aimed at promoting domestic pharmaceutical manufacturing by lowering the costs of importing the necessary raw materials (APIs) for local production of these lifesaving drugs. The importer is not eligible for the S.N.167(A) of the aforesaid Notf. as the importer is importing bulk drugs. Since the goods imported are not readily usable they cannot be treated as goods of similar nature to that of readily usable drugs, so to make the importer eligible to claim the benefit of an entry, not eligible to them.
- **1.18.4** Importer stated that in the consultative letter, no justification has been put forth by the department for considering the imported goods as bulk drugs, except for reason that the imported goods are packed in 25KG/drum. In this regard, it was found that the details & description provided in the Certificate of Analysis (CoA) issued by the supplier Zhejiang Starry Pharmaceuticals Co. Ltd, show that Iohexolin the form of 'White to Off White, hygroscopic, odourless powder', analysed for purity and impurities, packed in large quantities and conforming to USP Current Version and TCS09(01)-010-05 standard. Accordingly, it may be it is reasonable to conclude that this is a bulk drug (API) rather than a finished pharmaceutical product.
- **1.18.5** The importer has also stated that the imported goods are complete product in itself however they are silent as to whether the imported goods are readily consumed by the patient in the imported form without being subjected to any further processing. Further vide End Use Declaration dated 17.05.2024 submitted by the importer against Bill of Entry 3296156 dated 02.05.2024, they have stated that

"We hereby confirm that we have imported the Iohexol 4000.00 kg which will be consumed for our finished product- UNIPAQUE INJ 300MG & CONTRAPAQUE INJ 240MG & IOHEXOL 350MG INJ USP"

In view of the above, it was clear that the imported goods needs further processing to manufacture the finished product. Accordingly, mere use of the word 'Iohexol' doesn't make it a finished drug as such.

- **1.18.6** As regard of IGST, it appears that List 1 under Schedule I of IGST Act, 2017 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. In the instant case, as the importer is importing "Iohexol USP" bulk drugs, therefore the imported goods would typically attract IGST rate of 18% under Schedule III of IGST Act, 2017
- **1.18.7** In the matter of Advance Ruling of M/s Sterling Biotech Ltd, as the case appears to be similar to the present case, 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 and confirms IGST @18% under Sr. No. 40 of Sch III of Not. No. 01/2017 dated 28.06.2017, therefore in terms of above advance rulings which is squarely applicable in the instant case, bulk drug import appears to attract IGST @18%.
- 1.19 Further a letter dated 11.09.2024 was sent to the importer to submit "Detailed manufacturing process", "manufacturing flow chart" as well as "end use of the goods imported" under the BEs mentioned in the C.L. along with supporting documents. In this regard, the importer has submitted their reply vide letter dated 26.09.2024 and it is found that that Bulk solution is formed after adding weighed quantities of Tromethamine USP, Edetate Calcium Disodium USP &Iohexol USP, followed by pH adjustment with HCL. The Bulk solution is then subjected to filtration and nitrogen purging before it is transferred to vials. The importer has not provided with any manufacturing process to substantiate their claim that the imported bulk drug is a complete drug in itself. However after going through website <a href="https://environmentclearance.nic.in/writereaddata/Online/TOR/0\_0\_22\_Sep\_2015\_15314153\_01Appendix&attachment.pdf">https://environmentclearance.nic.in/writereaddata/Online/TOR/0\_0\_22\_Sep\_2015\_15314153\_01Appendix&attachment.pdf</a>

It was found that, M/S. UNIQUE CHEMICALS (A div of J B CHEMICALS & PHARMACEUTICALS LTD) PANOLI has submitted DETAILS OF MANUFACTURING PROCESS as described as under:

#### "24). Iohexol/Iopamidol/iodixanol

2,4,6- Tri iodoisophthaloylChlori de & 2-Amino-1,3-propanediol treated with Lactic acid, to give crude Iopamidol. Crystallized from IPA, FILTERED, dried to give Iopamidol. IOHEXOL: 5-amino — N,N(2,3 Dihydroxy propyl &isophthalamide TRIIODO DERIVATIVE treated with 3-Chloro, 2—propanediol. The product is cryatallized from IPA, filtered & dried to give, Iohexol"

Based on the above fact, the Raw Materials to manufacture Iohexol are as under:

- (i) 5-Amino-N,N'(2,3-Dihydroxypropyl)&isophthalamideTriiodo Derivative
- (ii) 3-Chloro, 2 –propanediol

Therefore the Bulk Drug to manufacture Iohexol is Iohexol only which is subjected to treatment with products on shown above, and with the process of crystallization, filtering, and drying. This bulk drug is used to prepare injectable contrast agents for diagnostic imaging.

As per website of the importer (<a href="https://jbpharma.com/download/contrapaque-iohexol-non-ionic-contrast-media/?wpdmdl=2363&refresh=67021d973d66d1728191895">https://jbpharma.com/download/contrapaque-iohexol-non-ionic-contrast-media/?wpdmdl=2363&refresh=67021d973d66d1728191895</a>) Iohexol is sold as CONTRAPAQUE INJ 300MG & CONTRAPAQUE INJ 350MG andit appears that the imported goods are "Iohexol USP" in 25kg/drum packing as bulk drug & is subjected to manufacturing process to convert it into finished drugs/medicine as aforesaid above. From the above, it appears that Iohexol Bulk drug in itself is only bulk drug required to manufacture the Iohexol as injection or contrast medium. Therefore, it appears that the Importer is not eligible for S.N.167(A) of Customs Notification no. 50/2017 dated 30.06.2017(as amended) for the import of the subject goods.

**1.20** Section 2(72) of CGST Act, 2017 defines the term "manufacture" as under:

"Manufacture means processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use and the term "manufacturer" shall be construed accordingly."

In view of the above, it suggests that, if the importer is merely selling Iohexol in bulk form, they may be classified as a trader, not a manufacturer, under GST& if the importer processes the Iohexol bulk drug into a new product (e.g., a final formulation for medical use), this activity may be considered manufacturing under the GST definition. The importer is undertaking a manufacturing process & although the name of the finished goods is "Iohexol" only. However the character and the use of the product has undergone substantiate change during the manufacturing process and the importer is importing "Iohexol USP" bulk drugs, after processing & converting the same into finished products viz. CONTRAPAQUE INJ 240MG, CONTRAPAQUE INJ 300MG & CONTRAPAQUE INJ 350MG.

- 1.21 The importer had classified the same goods under 03 different CTH 29242990, 30039090 & 30049099 at different times viz. declared the aforesaid goods under CTH 29242990 in Bill of Entry no. 3296156 dated 02.05.2024, under CTH 30039090 in Bill of Entry no. 6819023 dated 14.04.2021. However as per COA submitted & uploaded in e-Sanchit by the importer, the imported goods i.e. Iohexol USP appears to be same in each case i.e. Iohexol USP. It further appears that Chapter 29 of the Customs Tariff Act, 1975 covers organic chemicals, including APIs and bulk drugs. This classification is specifically for the raw or bulk form of chemical compounds used in various industries, including pharmaceuticals. While for finished pharmaceutical products, such as Iohexol in injectable form, the classification would fall under Chapter 30.
- **1.21.1** The importer had submitted vide their letter dated 23.08.2024 that CAS number of Iohexol is 66108-95-0 and its IUPAC name is N,N'-bis(2,3-dihydroxypropyl)-5-[N-(2,3-dihydroxypropyl) acetamido]-2,4,6-triiodoisophthalamide.

As per data available on internet, it was observed that the chemical structure of Iohexol depicted above illustrates its heterocyclic nature. It contains a benzene ring bonded to three iodine atoms and several functional groups with nitrogen, making it a heterocyclic compound. The presence of nitrogen atoms in the side chains and the complex structure contribute to its classification under "heterocyclic compounds" in Chapter 29 of the HSN code and heading 2933 covers Heterocyclic Compounds with Nitrogen Hetero-Atom(S) only. It covers chemical compounds used as Active Pharmaceutical Ingredients (APIs) but not in finished dosage forms. This classification is used for bulk drugs or Active Pharmaceutical Ingredients (APIs) that are used in the manufacturing of finished pharmaceutical products.

In view of the above, it indicates that the imported goods i.e. Iohexol USP may be classified correctly under "Others" of Heading 2933 i.e. HSN 2933 9990.

- **1.21.2** Further, the applicability of S.N.167(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 appears that the importer had wilfully availed the S.N.167(A) of Customs Notification no. 50/2017 dtd 30.06.2017(as amended) for the import of the subject goods thereby to avoid condition no. 9 which mandates the procedure set out in the IGCRD 2017/2022 & paid lower IGST@5% than applicable and thus the provisions of Section 28 (4) are invokable in this case.
- **1.22** Further data was retrieved for last 05 years for the Bills of Entry filed by the Importer in INNSA1 for the import of "Iohexol USP". From the retrieved data, it is found that imported goods were cleared in INNSA1 with details as per Annexure-A attached to Show Cause Notice.
- **1.23** Accordingly, Show Cause Notice bearing No. 1256 /2024-25/COMMR/GR II(A-B)/NS-I/CAC/JNCH dated 15.10.2025 was issued to M/s. J B Chemicals and Pharmaceuticals Limited (IEC 0388063262) seeking as to why:
- **1.23.1** Classification under CTH 29242990, 30039090 & 30049099 should not rejected for the subject goods and the subject goods should not be classified under CTH 29339990.

- **1.23.2** Customs duty Exemption under S.N. 167(A) of Customs Notification no. 50/2017 dtd 30.06.2017(as amended) for the subject goods should not be rejected.
- **1.23.3** 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.
- **1.23.4** Differential duty amount of Rs. 64,92,31,496/- (Rupees Sixty Four Crore Ninety Two Lakh Thirty One Thousand Four Hundred Ninety Six only) with respect to the items covered under Bill of entry as mentioned in Annexure-A of this 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
- **1.23.5** The subject goods as detailed in Annexure-A of this notice having a total assessable value of Rs. 297,95,85,444/- (Rupees Two Hundred Ninety Seven Crore Ninety Five Lacs Eighty Five Thousand Four Hundred Forty Four only) should not be held liable for confiscation under Section 111(m) of the Customs Act, 1962.
- **1.23.6** Penalty should not be imposed on the importer under Section 1124(a) and/or 114A of the Customs Act, 1962.
- **1.23.7** Penalty should not be imposed on the importer under Section 114AA of the Customs Act, 1962.
- **1.23.8** Penalty should not be imposed on the importer under Section 117 of the Customs Act, 1962.

## **WRITTEN SUBMISSIONS**

- 2. M/s. JB Chemicals & Pharmaceuticals Limited gave written submissions through their authorized representatives vide their letter dated 08.08.2025, wherein they *inter-alia* submitted as below:
- 2.1 The Noticees have been regularly importing various APIs required for manufacturing of various pharmaceutical formulations. They have obtained a valid "licence to import drugs (excluding those specified in Schedule X) to the Drugs and Cosmetic Rules, 1945" bearing License Number IL/BD-012904 RC/BD-002080 dated 13.01.2023 in Form 10 read with Rule 23 and 27 of the Drugs and Cosmetic Rules, 1945 for import of Iohexol USP. Form 10 is the requisite license for import of drugs including the bulk drugs such as Iohexol USP imported by them. They also obtained a Registration Certificate for import of drugs into India in Form 41 for import of Iohexol USP, vide Registration Certificate No. RC/BD-002080. This also signifies that a bulk drug like Iohexol USP is considered a drug for the purpose of the Drugs and Cosmetics Law in India. They manufacture Iohexol injections (ampules/vials) using the imported goods and sell the same under the brand name Contrapaque.

2.2 Prior to the introduction of GST, they imported Iohexol USP by claiming benefit under Sl. No. 83(A) of Notification No.21/2002-Cus. dated 01.03.02.

S. No.	Chapter or Heading or sub— heading or tariff item	Description of goods	Standard rate	Additional duty rate	Condition No.
(1)	(2)	(3)	(4)	(5)	(6)
83	28, 29, 30 or	The following goods,			
	38	namely:-			
		(A) Lifesaving drugs	Nil	-	-
		/medicines including their			
		salts and esters and diagnostic			
		test kits specified in List 4.			
		(B) Bulk drugs used in the	Nil	-	5
		manufacture of life saving			
		drugs or medicines at (A)			

Subsequently, the above Sl. No. / Notification was superseded by Sl. No. 148A of Notification No. 12/2012-Cus. dated 17.03.2012 and they continued availing the very same exemption even under Sl. No. 148A. After the introduction of GST, Notification No. 50/17-Cus. dated 30.06.2017 was issued in supersession of Notification No. 12/2012-Cus.Accordingly, they imported Iohexol USP in terms of Sl. No. 167(A) of Notification No. 50/2017.

- 2.3 In 2023, the Nhava Sheva Preventative Unit, R&I, NCH initiated investigation against them in connection with 'Iohexol' imported vide Bill of Entry No. 7967069 dated 23.09.23 under Tariff Item 3003 90 90 and by availing benefit of Sl. No. 167(A) of Notification No. 50/2017. After submission of sought documents, the Assistant Commissioner of Customs (P) NSPU, R&I Division, NCH, Mumbai vide Letter F. No. MISC/NSPU/112//2023-24 R&I dated 15.03.2024 intimated the Noticees about closure of the above investigation.
- 2.4 SCN neither mentioned the period in dispute nor the details of the specific Bills of Entry (Annexure-A) under which the goods in question were imported by the Noticees, making it challenging for the Noticees to identify and review the relevant transactions. Further, the SCN also did not specify the split-up between the customs duty and IGST proposed to be recovered. Thereafter, the Noticees filed reminder letters for issuance of the complete copy of the SCN along with annexures.
- 2.5 SCN is not an empty formality or a ritual without a purpose, it is the foundation of any proceeding. A reasonable opportunity to defend the case can be said to have been given only if the Noticees are informed about the totality of the allegations levelled against him. They relied upon the decision in case of CCE Vs. Brindavan Beverages (P) Ltd. 2007-TIOL-118-SC-CX. SCN has not provided any literature or reasoning stating that "Johexol

USP" is not eligible for concessional rate of duty under Sl. No. 167(A) of Notification No. 50/2017 and not eligible to IGST at 18% under Sl. No. 40 of Schedule III of Notification No. 01/2017. The SCN is vague, cryptic and has totally ignored the nature and characteristics of the imported goods. They relied upon the decision in case of Electronik Lab Vs. CC -2005 (187) ELT 362wherein Tribunal set aside the penalty on the ground that the same cannot be imposed based on presumptions and assumptions.

- 2.6 The SCN neither mentions the period in dispute nor the details of the specific Bills of Entry under which the goods in question were imported by the Noticees, making it challenging for the Noticees to identify and review the relevant transactions. Further, the SCN also does not specify the split-up between the customs duty and IGST proposed to be recovered. They relied upon the judgment in case of Riddhi Siddhi Collection Vs. Union of India 2019 (368) E.L.T. 852 (Bom.) wherein it washeld that service of the show cause notice is not complete until and unless the entire show cause notice along with annexures and relied upon documents are served upon the Noticees. They also relied upon judgment in case of VV Mineral Vs. CCEx. 2016 (332) ELT 289 (Mad). The SCN served to them does not bear any signature of the Ld. Commissioner and merely states that it is signed on 15.10.2024 at 11:44:21 minutes, however, without bearing any physical signature. Further, the signature status as "signed by Dhirendra Singh Garbyal date: 15-10-2025 11:44:21" appears to be text typed out and is not the digital signature.
- 2.7 They submitted that they are eligible to avail the benefit of Sl. No. 167(A) of Notification No. 50/2017 in respect of the imported goods. 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 pharmacopoeial 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 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) <u>bulk drugs and formulations;</u>"

From the above, it is clear that drugs are inclusive of 'bulk drugs' under the Drug (Price Control) Order, 1995.

2.8 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."

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..."

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.

- 2.9 The goods specified in Sl. No. 167(B) 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 not covered under Sl. No. 167(A). Therefore, those drugs which are not covered under Sl. No. 167(A) of Notification No. 50/2017, are covered under Sl. No. 167(B), if they are used in the manufacture of drugs specified Sl. No. 167(A) 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 Noticees to follow the procedure prescribed in IGCRD Rules. Procedural compliance under these rules is mandatory condition for clause (B) and not for clause (A).
- 2.10 The present issue has been settled in their favour by the decision of Tribunal (Mumbai Bench) rendered in the case of Burroughs Wellcome (India) Limited Vs. CCE 2007 (216) ELT 522.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) 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.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), Shri Baser Vs. CCEx& St – 2024 (12) TMI 270and Hetero Drugs Ltd. Vs. CC (Airport) – 2017 (9) TMI 1275-CESTAT Chennai, M/s Biocon Ltd. Vs. CC –2017 (9) TMI 1468. Judicial discipline requires the adjudicating authority to follow the decision of the higher authority. For their this view they relied upon judgment in case of Union of India Vs. Kamlakshi Finance Corporation - 1991 (55) ELT 433 (SC) and Veena Commercial Corporation Vs. Union of India - 1993 (68) ELT 596.

- 2.11 It is a settled principle that benefit of any Notification has to be extended by giving a plain meaning to the description without resorting to intent of such notifications/ circulars etc. They relied upon judgment in case of Hemraj Gordhandas Vs. HH. Dave 1978 (2) ELT (350) wherein Hon'ble court held that when the taxpayer otherwise qualifies for an exemption within the plain meaning of the terms of the notification, benefit of the exemption cannot be denied by placing reliance on any apparent intent of the issuing authority. They also placed reliance on judgment in case of Baidyanath Ayurved Vs. Excise Commissioner 1999 (110) ELT 363 (SC), Sales Tax Commissioner Vs. Modi Sugar Mills AIR 1961 SC 1047, ALD Automotive Vs. CTO 2018 (364) ELT 3 (SC), Sri Sathya Sai Institute of Higher Medical Sciences Vs. UOI 2003 (158) ELT 675 (SC) etc.
- 2.12 Considering that Notification No. 50/2017 is a beneficial notification which incentivizes domestic industries in India, the entries mentioned in the exemption notification must be construed liberally and in case of ambiguity, the entries in the notification should be interpreted in favour of the assesse. In this regard, they placed reliance on the decision in the case of Government of Kerela Vs. Mother Superior Adoration Convent 2021 (376) ELT 242 (SC), CC Vs Dilip Kumar- 2018 (361) ELT 577 (SC). Since Notification No. 50/2017 is a beneficial exemption, the ambit of Sl. No. 167(A) which grants exemption to "Lifesaving drugs/medicines including their salts and esters and diagnostic test kits specified in List 4" will be construed to be wide enough to cover the subject goods imported by them.
- As already established above, the imported goods are lifesaving drugs. The second criteria for availment of exemption / concession under Sl.No. 167(A) of Notification No. 50/2017 is that such lifesaving drugs shall be specifically covered under List 4 under Chapter 28, 29, 30, and 38 of the First Schedule to the Tariff Act. Benefit under the said Notification is open to goods falling under Chapters 28, 29, 30 or 38 of the First Schedule to Customs Tariff Act, 1975. In the present case, Sl. No. 167(A) of Notification No. 50/2017 grants benefit clearly irrespective of whether the goods are classifiable under Chapter 29 or 30 as long as the goods imported are "Lifesaving drugs /medicines including their salts and esters and diagnostic test kits specified in List 4." Therefore, irrespective of the fact that the subject goods are classifiable under Chapter 29 or 30 of the First Schedule to Customs Tariff Act, 1975, the benefit under the Notification has been appropriately claimed by the Noticees, since the subject goods are lifesaving drugs specified under Sl. No. 55 (Iohexol) of List 4 of Notification No. 50/2017. They relied upon the judgment in case of Hindustan Aeronautics Vs. CC – 2019 (370) ELT 699 (Tri - Bang) wherein the Hon'ble CESTAT Bangalore held that imported Cargo sling, if classifiable as part of helicopter under Chapter 88 of the Customs Tariff Act, 1975, will be eligible for the benefit of the exemption notification as is applicable

to the parts of the helicopter irrespective of the classification. They also relied upon judgment in case of High Energy Batteries Vs. CC - 2002 (142) ELT 266, Industrial Perforation Vs. CCE - 2020 (371) ELT 604 (Tri-Cal), CCE & ST Vs. Amrutha International - 2018 (12) TMI 6 - CESTAT HYDERABAD, Goodwill Engineering Works Vs. CC - 2010 (253) ELT 131, Gemini Instratech Vs. CCE, 2014 (300) ELT 446 (Tri. – Mumbai). Above decisions makes it clear that when the exemption Notification clearly grants benefit to all "Lifesaving drugs/medicines including their salts and esters and diagnostic test kits specified in List 4" irrespective of their classification under Chapter 29, 30, etc. of First Schedule to Customs Tariff Act, no further restrictions can be supplied to restrict the usage of the benefit. Hence, in the present case, the only parameter to be eligible for the benefit is that the goods, irrespective of their classification, must be whether the goods being "Lifesaving drugs/medicines including their salts and esters and diagnostic test kits" are covered under List 4 of Schedule I of Notification No. 01/2017.

- 2.14 The present SCN proposes to recover differential duty in respect of goods imported under the cover of Advance Authorisation obtained by the Noticees. They reproduced Para 4.12 of Foreign Trade Policyviz. Accounting of Input and submitted that all inputs are permitted to be imported under the Advance Authorisation scheme and the only requirement under this scheme is to declare the correct name and description of the imported inputs, which should match with the name and description endorsed in the Shipping Bill at the time of exports. There is no provision mandating that the tariff classification must be indicated / adhered to for the purpose of availing the exemption benefit under Advance Authorisation Scheme under the Foreign Trade Policy. Thus, any allegation of mis-classification in respect of goods imported under Advance Authorisation scheme is completely misplaced. They relied upon judgment in case of Svan Toyal Packaging Industries Pvt. Ltd. Vs. Principal Commissioner of Customs (Import) – 2025-VIL-292-CESTAT-DEL-CU wherein it was held that customs tariff classification of the imported materials is not relevant for allowing exemption from customs duty against the Advance Authorizations, where such imported materials were covered for import in the Advance Authorisations issued to the Appellant.
- 2.15 The primary purpose for the Government to encourage exports and allow export benefit is to promote exports and earn foreign exchange. The Government provides export incentive schemes like Advance Authorisation, EPCG License, DBK, RoDTEP, etc. to promote India as a world trading partner and facilitate exports by offsetting the costs incurred during the export process. The policy of the Government is designed to ensure that the exporters are not burdened with the local taxes and levies that would make the export goods less competitive in the foreign markets. Thus, the realization of export proceeds is a fundamental criterion for availing the export benefits. They have submitted that the denial of exemption benefit to the Noticees on account of misclassification or incorrect availment of benefit under Sl. No. 167(A) of Notification No. 50/2017 defeats the very purpose of the Government's incentive scheme (Advance Authorisation) for exports.
- **2.16** They submitted that they can provide co-relation of the imported Iohexol USP used in the manufacture of the contrast media and any perceived contravention of Condition No. 9 of

Notification No. 50/2017 is merely procedural and should not impact the Noticees entitlement to the concessional benefit. For this view they relied on the decision ofHetero Drugs Ltd. *Supra* wherein it was held that the condition attached to Sl. No. 80 (B) of Notification No. 21/2002-Cus dated 01.03.2002 being a procedural one, non-compliance cannot be a ground for denying benefit especially because drug in Sl.No.80 (A) does not have any conditions attached to it.

- 2.17 In cases where more than one exemption is available in respect of the imported goods, the importer-assessee / Noticees can choose any one of the exemptions which is beneficial to him and the department cannot force any of the above exemptions of their choice on to the Noticees. For their this view they relied upon judgment in case of HCL Ltd. Vs. Collector of Customs - 2001 (130) ELT 405 (SC), Share Medical Care Vs. UOI - 2007 (209) ELT 321 (SC), CCE Vs. Maruthi Foam - 1996(85) RLT 157 (T), ABB Ltd Vs. CCE- 2009(92) RLT 665 (L.B.). They also placed reliance on the judgment in Coca Cola Limited – 2009 (94) RLT 401 (Bom.) wherein it was held that the principle of specific being preferred over general will not be applicable in respect of exemption Notification. In the instant case, as discussed *infra*, the benefit under Sl. No. 167(A) and 167(B) of Notification No. 50/2017 were both available in respect of the imported goods. Sl. No. 167(A) is without any condition, whereas Sl. No. 167(B) requires procedural compliance under the IGCRD Rules. Any perceived contravention of Condition 9 of the Notification No. 50/2017 is merely procedural and should not impact the Noticees entitlement to the concessional benefit. Thus, the present goods are also eligible to benefit under Sl. No. 167(B) of Notification No. 50/2017 and SCN is incorrect in denying both the independent exemption benefits under Sl. No. 167(A) and 167(B) to the Noticees.
- **2.18** The importation of life saving drugs specified in List 4 whether they are imported in bulk form or not are all subject to nil customs duty. Consequently, any failure to comply with Condition No. 9 of Notification No. 50/2017 does not result in any financial loss to the Government revenue.
- **2.19** With regard to proposal of invoking 18% IGST in terms of Serial no. 40 of Schedule III of Notification No. 01/2017 they submitted that Sl. No. 180 of Schedule I of Notification No. 01/2017 prescribes IGST at 5% on drugs or medicines including their salts and esters and diagnostic test kits, specified in List 1 appended to this Schedule when classifiable under Chapter 30 or any chapter under the First Schedule to the said Notification. Sl. No. 176 appended to Schedule I covers Iohexol. They reproduced relevant part of the notification:

Schedule I – 5%

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

List 1 [see S. No. 180 of the Schedule I]

(177) Iohexol

Sl. No. 40 of Schedule III of Notification No. 01/2017 prescribes IGST at 18% in respect of all organic chemicals other than gibberellic acid classifiable under Chapter 29 of the First Schedule to Customs Tariff Act, 1975. As submitted above, 'drugs' as defined in the Drugs and Cosmetics Act, 1940 read with Section 3(b) of the Drugs and Cosmetics Act, 1940 includes bulk drugs. In the present case, the Noticees are importing Iohexol USP in 25 Kgs/Drum packages for use in manufacture of contrast media. Further, the Noticees also obtained License to Import Drugs in Form-10 from the CDSCO for import of Iohexol USP. This clearly signifies that the license obtained for import of drugs would be applicable for import of bulk drugs also. Further, even if the imported goods are treated as a bulk drugs 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. 180 of Notification No. 01/2017. Thus, the imported goods are drugs for the purposes of Notification No. 01/2017.

- **2.20** SCN places reliance on the Gujarat Advance Ruling in M/s Sterling Biotech Ltd. bearing Advance Ruling No. GUJ/GAAR/R/54/2020 to disallow lower rate of IGST at 5% under Sl. No.180 of Notification No. 01/2017 on the subject imports. They submitted the Advance Rulings under the GST law are binding only on the applicant who sought the ruling and in relation to the specific transaction that was subject matter of the ruling. The present case clearly involves a different taxpayer and transaction, rendering the said Advance Ruling relied in the SCN inapplicable. Also, courts in various cases have consistently held that advance rulings do not constitute general precedents or a precedent for other taxpayers. The said Advance Ruling was never appealed by M/s Sterling Biotech since the Company was no longer in operation shortly after the issuance of the Advance Ruling. Thus, the said Advance Ruling cited in the SCN does not apply to the present case as Advance Ruling is specific to the importers / assessee.
- 2.21 As per the provisions 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 and even if the Noticees would have paid IGST at 18% under Sl. No. 40 of Schedule III of Notification No. 01/2017 instead of discharging IGST at 5% under Sl. No. 180 of Schedule I to Notification No. 01/2017 at the time of importation, the same would be available as credit to the Noticees. When the finished goods such as Iohexol Injections (ampules/vials) manufactured using imported goods would be cleared on the payment of CGST/SGST, credit of IGST paid at the time of import would be available to the Noticees as credit. Therefore, if they had paid IGST at a higher rate of 18%, they would have taken credit of the same and would have paid that much lesser CGST/SGST on the finished products cleared by them. They relied upon judgment in case of 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) etc.
- 2.22 They submitted that SCN cannot be issued under Section 28(4) of the Customs Act since the instant case is not that of short levy, non-levy, refund, etc. as the Noticees 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 from 14.10.2019 to 14.10.2022 or prior to 14.10.2019 is completely barred by limitation. In matters of availment of benefit under exemption notification, extended period of limitation is not invocable. They relied upon judgment in case of 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. With respect to the consignments in dispute, the goods for which duty is demanded, were assessed by officers as well as under the RMS and cleared for home consumption. The goods were correctly described and accordingly, the appropriate exemption benefit was availed. The invoices and other import documents submitted along with the bills of entry clearly declare true and correct information regarding the 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 upon judgment in case of Cosmic Dye Chemical Vs. CCE, Bombay – (1995) 6 SCC 117, CCE, Aurangabad Vs. Bajaj Auto Limited – 2010 (260) ELT 17 (SC) etc. In the present case, the SCN has not shown or even referred to any conscious or intentional act of collusion, wilfulmis-statement or suppression of fact on the part of the Noticees indicating that the Noticees have incorrectly claimed the benefit under Sl. No. 167(A) of Notification No. 50/2017 or incorrectly discharged lower rate of IGST under Notification No. 01/2017.

- 2.23 They submitted that the Customs department NSPU had investigated this very issue of claim to exemption and later on closed the investigation vide letter dated 15.03.24. Therefore, the Customs department cannot issue a subsequent SCN for extended period by alleging misstatement or suppression of facts. They relied upon judgment in case of Nizam Sugar Factory Vs. CCE 2008 (9) STR 314 (SC)and ECE Industries Vs. CCE- 2004 (164) ELT 236 (SC). They also submit that there is no allegation in the SCN of mis-declaration as far as description and value is concerned and the only allegation is of classification and wrongful availment of exemption benefit which does not amount to misdeclaration and extended period of limitation is not invokable. They relied upon judgment in case of Coastal Energy Vs. CCE & ST, Guntur 2014 (310) ELT 97 (Tri-Bang), Northern Plastic Vs. CCE 1998 (101) ELT 549 (SC), GV Exim Vs. CC 2003 (160) ELT 900 etc.
- 2.24 They submitted that 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 and relied upon judgment in case of Prathibha Processors Vs. UOI 1996 (88) ELT 12 (SC).
- 2.25 They 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 mens rea on part of the assessee. Bonafide conduct on part of the assessee does not entail the goods liable to confiscation. They relied upon judgment in case of Allseas Marine Contractors Vs. CC 2011 (272) ELT 619 (Tri. -Del.), Sutures India Vs. CC 2009 (245) ELT 596 (Tri. -Bang). The only dispute in the present case is regarding the classification adopted and consequent availment of

exemption benefit. The invoices and other import documents submitted along with the bills of entry clearly declared the true value, exemption notification, etc. at the time of import. They submitted that classification of imported goods and eligibility to exemption notifications was not objected by the Department at the time filing of Bills of Entry. It is a well settled position in law, that claiming of an exemption notification does not amount to mis-declaration. They placed reliance on the decision of Supreme Court in Northern Plastic Ltd. vs. CCE -1998 (101) ELT 549 (SC). They relied upon various other judgments in support of their claim that the goods imported by them are not liable for confiscation under Section 111 of the Customs Act, 1962 viz. Ace Kargoways Pvt. Ltd. vs. CC -2003(158) ELT 505, CC Vs. Maruti Udyog Ltd. - 2002 (141) E.L.T. 392, J K Industries Vs. CC - 1996 (88) ELT 41, CC Vs. Gaurav Enterprises - 2006 (193) ELT 532 (Bom.) etc.

- 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 and 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 mens rea on the part of the assessee. Bona fide conduct on part of the assessee does not entail the goods liable for confiscation. In the instant case, the Noticees have neither done nor omitted to do any act which act or omission has rendered the imported goods liable to confiscation under Section 111(m) of the Customs Act. 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 as they did not abet the commission or omission of any act which rendered the subject goods liable for confiscation. In support of their submissions, the noticee relied upon various judgments viz. Shri Ram Vs. State of UP-1975 (3) SCC 495, Vaishali Developers & Builders Vs. CC Excise - 2016 (9) TMI 1543 - CESTAT N.D., Hindustan Steel Vs. State of Orissa - 1978 (2) ELT (J159), Akbar Badruddin Jiwani Vs. Collector of Customs - 1990 (47) ELT161, Harbhajan Kaur Vs. Collector of Customs - 1991 (56) E.L.T. 273 Tri Del etc.
- 2.27 They submitted that the customs department was always aware of the classification adopted and the exemption benefit availed under Sl. No. 167(A) of Notification No. 50/2017 by the Noticee. In fact, the consignments in dispute were examined and no queries were raised by the customs department. The present dispute can be one of legal interpretation and the Noticees have every right to believe that the classification adopted, and the exemption benefit availed by the Noticees is correct. 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. Duty demand is not sustainable in the present case since there has been no suppression or willful mis-statement of facts by the Noticee. The only allegation of classification and incorrect availment of Notification benefit is a matter of bona fide belief. The ingredients of Section 114A of the Customs Act are not satisfied in the instant case. The Noticees 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 and discharged IGST at a lower rate under bona fide belief and the imported goods were correctly declared by them in the bills of entry basis the import documents. In support of their submissions they relied upon the judgment in case of Anand Nishikawa Vs. CCE – (2005) 7 SCC 749, Pushpam Pharmaceuticals Company Vs. CCE – 1995 (78) ELT 401 (SC), Aban Lloyd Offshore Vs. CC – 2006 (200) ELT 370 (SC) etc.

- 2.28 The present SCN without providing any proper reasons or justification proposes to impose penalty in terms of Section 114AA of the Customs Act. As is evident, knowledge of any declaration, statement or document that is being made or signed or used must be possessed by the person against whom the Section is being invoked. They made bona fide declarations and accordingly, Section 114AA cannot be invoked against them. Penalty under Section 114AA is imposable only in those situations where exports benefits are claimed without exporting the goods and by presenting forged documents. In support of this argument, they placed reliance on the Twenty Seventh Report of the Standing Committee of Finance and reproduced relevant part of the report. The purpose was to punish those people who avail export benefits from the Indian Exchequer without exporting anything from India. Such cases involve serious criminal intent and it cannot be equated with the cases of duty evasion. However, the SCN has misconstrued the provisions to apply the same in case of declarations, statements and documents which are false and incorrect in material particulars in the business of import of goods for the purpose of the Act. Further, it is to be noted that Section 114AA covers cases of improper exportation from India and not a case where goods are imported into India. They relied upon the judgment in case of CC Vs. Sri Krishna Sounds & Lightings - 2018 (7) TMI 867-CESTAT Chennai, Bosch Chassis Esystems India Ltd. Vs. CC - 2015 (325) ELT 372 (Tri.-Del.). They further stated that no penalty can be imposed under Section 114AA of the Act in the absence of any mala fide on the part of the assessee. In support of their this view, they relied upon the judgment in case of Parag Domestic Appliances Vs. CC – 2017 (10) TMI 812-CESTAT Bangalore, Premax Logistics Vs. CC – 2017 (4) TMI 483-CESTAT Chennai.
- **2.29** Section 117 of the Customs Act, 1962 is a residuary section under the Customs Act and can be imposed in cases when where no express penalty is elsewhere provided. They submitted that they have never acted with a mala fide intent and the SCN does not give any reasoning or ground on the basis of which penalty has been imposed on the Noticees and that is why recourse to residuary Section 117 has been taken. Therefore, no penalty under section 117 of the Customs Act is imposable on the Noticees.
- 2.30 The SCN proposed to demand and recover Rs.64,92,31,496/- along with interest in terms of Section 28(4) and Section 28AA of the Customs Act and imposition of penalty under Section 112(a), Section 114A and Section 117 of the Customs Act. The present SCN has been improperly served to the Noticees without providing the details of the disputed period, disputed imports and the bifurcation of total differential duty and IGST demanded. 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, demand of IGST along with interest has been incorrectly proposed to be recovered. Also, penalty has been incorrectly proposed to be imposed on the Noticees so far as the IGST component of the demand is concerned and no interest can be recovered. They relied upon judgment in case of India Carbon Ltd. Vs. State of Assam -(1997) 6 SCC 479, wherein Hon'ble court relied upon the earlier five-judge bench decision in the case of J.K. Synthetics Ltd. Vs. CTO - (1994) 4 SCC 276 and held that interest can be levied and charged on delayed payment of tax only if the statute that levies and charges the tax makes a substantive provision in this behalf. They submitted that even post amendment to Section 3 of the Customs Tariff Act vide Finance Act, 2024, recovery provisions are borrowed from the Customs Act for the purpose of duty or tax or cess chargeable under this section.IGST cannot be recovered under Section 28 of the Customs Act since IGST is not a duty of customs and the mechanism for levy and recovery of IGST are prescribed under the Integrated Goods and Services Tax Act, 2017. Thus, recovery of IGST, the consequential interest and penalty are not leviable under the Customs Act. They relied upon judgment in case of Bajaj Health & Nutrition Pvt. Ltd. Vs. CC, Chennai - 2004 (166) ELT 189, Tonira Pharma Ltd. Vs. Commissioner - 2009 (237) ELT 65 (Tribunal), Siddeshwar Textile Mills Pvt. Ltd. Vs. Commissioner - 2009 (248) ELT 290 (Tri) etc.

2.31 The goods imported by the Noticees 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. 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), Jairath International Vs. UOI – 2019 (10) TMI 642 etc.

# PERSONAL HEARING

3.1 Opportunity for personal hearing in the matter was granted to the importer on 10.09.2025 and accordingly, the noticee attended the hearing on the said date through virtual mode. Akhilesh Kangsia, Madhura Khandekar- representative of M/s. J B Chemicals and Pharmaceuticals Ltd. appeared on behalf of the Noticee. They reiterated the written submissions dated 08.08.25 made by them as detailed in paras above and also referred upon various case laws. They further relied and submitted Drug Price Control Order (DPCO) wherein Bulk Drugs are also covered under the definition of Drugs. They submitted that NSPU, R&I initiated investigation against them in the identical matter, however, after investigation, NSPU found that they have availed the notification correctly and accordingly, issued closure letter dated 15.03.2024. They requested to drop the proceedings initiated against them.

#### **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 I find that on the basis of the Post Clearance Audit, it was noticed that M/s.J B Chemicals And Pharmaceuticals Limited 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 not imported as finished product and 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. 64,92,31,496/- was raised on the importer along with consequential penalties. They 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 that the goods are specifically covered under List 4 to the impugned Notification and therefore, are covered by Serial no. 167A of the notification.
- 4.3 Chief Commissioner of Customs, Mumbai Zone-II on 09.10.2025, granted extension of time limit to adjudicate the case up to 14.01.2026 as provided under Section 28 (9) of the Customs Act, 1962. 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. 64,92,31,496/- is recoverable from the importer under Section 28(4) along with applicable interest as per Section 28AA of the Customs Act, 1962 or otherwise?
- (C) Whether the goods imported vide Bills of Entry as detailed in Annexure-A to the notice are liable for confiscation under Section 111(m) of the Customs Act, 192 or otherwise?
- (D) Whether the penalty is imposable on the importer under Section 112(a) and/or 114A, 114AA and 117 of the Customs Act, 1962 or otherwise?

- (E) Whether the IGST rate 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?
- 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. J B Chemicals And Pharmaceuticals Limited 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 and are not finished product, 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:

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

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 thereunder. 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;

- 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 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. 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.
- **5.6** 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 are 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. 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 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 even if considered under Chapter 29 of the notification, the same stands eligible for the benefits under the said notification.

- 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 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. 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. J B Chemicals And Pharmaceuticals Limited 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 the notice has mentioned that the items of List 4 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 4 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 4 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 IOHEXOL, 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. 167A clearly states that "drugs/medicines" mentioned in List 4 are eligible for the duty exemption benefit. I find that the goods under import are specifically mentioned in List 4 of the notification and the presence of the goods in List 4 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.
- 5.9 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.

- I find that the notice had mentioned that the imported goods are used for the manufacture of injectable drug (CONTRAPAQUE INJ 240 mg/ml, 300 mg/ml, and 350 mg/ml) by adding Tromethamine USP, Edetate Calcium Disodium USP, and adjusting pH with Hydrochloric Acid, followed by filtration, nitrogen purging, and filling into vials. However, it is noted that such operations are routine pharmaceutical processes like dilution, pH adjustment, and sterile filling, which do not bring about any chemical or structural change in the imported product. These steps are only preparatory and do not result in emergence of a new product with distinct name, character, and use. It is evident from the manufacturing process submitted by M/s. Unique Chemicals (A Division of J.B. Chemicals & Pharmaceuticals Ltd.), that Iohexol itself is the end product and pharmaceutical substance, and not a raw material or intermediate. Finished products CONTRAPAQUE INJ 240MG, 300MG, and 350MG and imported goods share the same chemical identity — *Iohexol* — and only differ in concentration or presentation and do not undergo any major manufacturing process after import. Based on the submissions, it is found that there is no transformation resulting in a new product with a distinct name or character. The imported goods and the injectable drug are chemically identical pharmaceutical products, namely Iohexol. Most importantly, IOHEXOL i.e. the goods imported by the noticee are specifically and clearly listed at Sl. No. 55 of List 4 of Notification No. 50/2017 and the said notification grants duty exemption benefits to "Lifesaving drugs /medicines including their salts and esters and diagnostic test kits specified in List 4". Also, the exemption under Serial no. 167A of said notification is product-specific. In the instant case imported goods match the description in the List 4 exactly and are clearly mentioned at Sl. No. 55 (Iohexol) of List 4 of Notification No. 50/2017. Therefore, I am of the considered opinion that the imported goods are eligible for the benefits of Serial no. 167A of the exemption notification no. 50/2017-Customss.
- 5.11 I find that serial no. 167B 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. Therefore, I am of the considered opinion that the goods imported by M/s. J B Chemicals And Pharmaceuticals Limited i.e. Iohexol bulk quantity have 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.
- **5.12** 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."

5.13 I find that after implementation of GST in the identical matter one of the importers had filed an application before the jurisdictional Customs Officer, Nagpur to comply with Customs (Import of goods at Concessional Rate of Duty) Rules with respect to the identical products viz. IOHEXOL USP. However, Assistant Commissioner of Customs, Nagpur Customs vide their letter dated 24.04.2018 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)/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.)".

5.14 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 said importer i.e. M/s. JB Chemicals & Pharmaceuticals Limited. In that case, the investigating agency found that the importer had correctly availed the notification benefit and issued a letter vide F.No. MISC./NSPU/112/2023-24/R&I dated 15.03.2024 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. In view of above, this office is closing the investigation undertaken against the importer M/s. JB Chemicals & Pharmaceuticals Limited (IEC- 0388063262)."

- 5.15 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:
- 5.16 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 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:

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......"
- 5.17 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............."
- **5.18** 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."

- 5.19 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 and are imported as bulk drug. I find that goods imported by M/s. JB Chemicals & Pharmaceuticals Limited are governed by IGST Notification no. 01/2017-IGST 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). 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.
- 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. However, I find that the noticee in the instant case is different from the applicant in 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. JB Chemicals & Pharmaceuticals Limited as the same are squarely covered in List 1 to Schedule-I of the IGST Notification 01/2017-IGST.
- **5.21** In view of the above, I am of the considered opinion that the demand of differential duty amounting to Rs. 64,92,31,496/- 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 and has correctly paid IGST under Schedule I of the IGST notification. As the demand of differential duty is not sustainable, therefore, the interest on duty also cannot be demanded.
- **5.22** In view of the aforesaid discussions and findings, as the noticee has rightly availed serial no. 167A of the notification no. 50/2017-Customs and Serial no. 180 of IGST notification no. 01/2017-IGST. 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.

- **5.23** I find that the importer has rightly availed the notifications benefit and there has been no shortfall of duty and accordingly, the goods are also not liable for confiscation. Therefore, the penalty under Section 112(a), 114A, 114AA 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 order that the demand for differential duty amounting to Rs. 64,92,31,496/- (Rupees Sixty Four Crore Ninety Two Lakh Thirty One Thousand Four Hundred Ninety Six only) from the importer M/s. JB Chemicals & Pharmaceuticals Limited under Section 28(4) of the Customs Act, 1962, is not sustainable and is hereby dropped.
- **6.2** 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.
- 6.3 I order that the proposal to confiscate the goods covered under the Bills of Entry listed in Annexure-A of the SCN having a total assessable value of Rs. 297,95,85,444/- (Rupees Two Hundred Ninety Seven Crore Ninety Five Lacs Eighty Five Thousand Four Hundred Forty Four only) under Section 111(m) of the Customs Act, 1962, is not maintainable and is hereby dropped.
- **6.4** I order that the proposal to impose penalties on M/s JB Chemicals & Pharmaceuticals Limited under Sections 112(a), 114A, 114AA and /or 117 of the Customs Act, 1962, is not warranted and is hereby dropped.
- **6.5** I order that the Show Cause Notice No.1256/2024-25/COMMR/GRII(A-B)/NS-I/CAC/JNCH dated 15.10.2024 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-I, जेएनसीएच / NS-I, JNCH To,

1. M/s. J B Chemicals and Pharmaceuticals Limited (IEC 0388063262) Neelam Centre, B Wing, 4Th Floor Hind Cycle Road, Worli, Mumbai, Maharashtra, 400 030

# 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.