सत्यमेव जयते

सीमा शुल्क (अपील) आयुक्त का कार्यालय,
OFFICE OF THE COMMISSIONER OF CUSTOMS (APPEALS), अहमदाबाद AHMEDABAD,
चौथी मंज़िल 4th Floor, हुडको बिल्डिंग HUDCO Building, ईश्वर भुवन रोड़ Ishwar Bhuvan Road,
नवरंगपुरा Navrangpura, अहमदाबाद Ahmedabad – 380 009
दूरभाष क्रमांक Tel. No. 079-26589281
DIN- 20251171MN0000333680

क	फ़ाइलसंख्या FILE NO.	S/49-456/CUS/AHD/ 2023-24
ख	अपील आदेश संख्या ORDER-IN-APPEAL No. (सीमा शुल्क अधिनियम, 1962 की धारा 128 क के अंतर्गत) (UNDER SECTION 128A OF THE CUSTOMS ACT, 1962):	AHD-CUSTM-000-APP-463-25-26
ग	पारितकर्ता PASSED BY	SHRI AMIT GUPTA Commissioner of Customs (Appeals), AHMEDABAD
घ	दिनांक DATE	28.11.2025
ङ	उदभूत अपील आदेश की सं. व दिनांक ARISING OUT OF ORDER-IN-ORIGINAL NO.	OIO No.: 46/DC/ACC/Speaking Order/Troikaa/23-24 dt. 22.01.2024 passed by the DC, Customs, Air Cargo Complex, Ahmedabad.
च	अपील आदेश जारी करने की दिनांक ORDER- IN-APPEAL ISSUED ON:	28.11.2025
छ	अपीलकर्ता का नाम व पता NAME AND ADDRESS OF THE APPELLANT:	M/s Troikka Pharmaceuticals Ltd, C-1, Sara Industrial Estate Ltd., Chota Rampur, Beyond Selaqui, Dehradun- 248197. **Regd. Office:** M/s Troikka Pharmaceuticals Ltd, "Commerce House-1", Satya Marg, Bodakdev, Ahmedabad-380 054.

.1	**यह प्रति उस व्यक्ति के निजी उपयोग के लिए मुफ्त में दी जाती है जिनके नाम यह जारी किया गया है .**

	This copy is granted free of cost for the private use of the person to whom it is issued.
2.	सीमाशुल्क अधिनियम 1962 की धारा 129 डी डी) (1) यथा संशोधित (के अधीन निम्नलिखित श्रेणियों के मामलों के सम्बन्ध में कोई व्यक्ति इस आदेश से अपने को आहत महसूस करता हो तो इस आदेश की प्राप्ति की तारीख से 3 महीने के अंदर अपर सचिव/संयुक्त सचिव) आवेदन संशोधन(, वित्त मंत्रालय,)राजस्व विभाग (संसद मार्ग, नई दिल्ली को पुनरीक्षण आवेदन प्रस्तुत कर सकते है.
	Under Section 129 DD(1) of the Customs Act, 1962 (as amended), in respect of the following categories of cases, any person aggrieved by this order can prefer a Revision Application to The Additional Secretary/Joint Secretary (Revision Application), Ministry of Finance, (Department of Revenue) Parliament Street, New Delhi within 3 months from the date of communication of the order.
	लिखित सम्बन्धित आदेश/Order relating to :
(क(	बैगेज़ के रूप में आयातित कोई माल .
(a)	any goods imported on baggage.
(ख(	भारत में आयात करने हेतु किसी वाहन में लादा गया लेकिन भारत में उनके गन्तव्य स्थान पर उतारे न गए माल या उस गन्तव्य स्थान पर उतारे जाने के लिए अपेक्षित माल उतारे न जाने पर या उस गन्तव्य स्थान पर उतारे गए माल की मात्रा में अपेक्षित माल से कमी हो .
(b)	any goods loaded in a conveyance for importation into India, but which are not unloaded at their place of destination in India or so much of the quantity of such goods as has not been unloaded at any such destination if goods unloaded at such destination are short of the quantity required to be unloaded at that destination.
(ग (	सीमाशुल्क अधिनियम, 1962 के अध्याय X तथा उसके अधीन बनाए गए नियमों के तहत शुल्क वापसी की अदायगी .
(c)	Payment of drawback as provided in Chapter X of Customs Act, 1962 and the rules made thereunder.
.3	पुनरीक्षण आवेदन पत्र संगत नियमावली में विनिर्दिष्ट प्रारूप में प्रस्तुत करना होगा जिसके अन्तर्गत उसकी जांच की जाएगी और उस के साथ निम्नलिखित कागजात संलग्न होने चाहिए :
	The revision application should be in such form and shall be verified in such manner as may be specified in the relevant rules and should be accompanied by :
)क (	कोर्ट फी एक्ट,1870 के मद सं 6.अनुसूची 1 के अधीन निर्धारित किए गए अनुसार इस आदेश की 4 प्रतियां, जिसकी एक प्रति में पचास पैसे की न्यायालय शुल्क टिकट लगा होना चाहिए .
(a)	4 copies of this order, bearing Court Fee Stamp of paise fifty only in one copy as prescribed under Schedule 1 item 6 of the Court Fee Act, 1870.
)ख(	सम्बद्ध दस्तावेज़ों के अलावा साथ मूल आदेश की 4 प्रतियां, यदि हो
(b)	4 copies of the Order-in-Original, in addition to relevant documents, if any
)ग(	पुनरीक्षण के लिए आवेदन की 4 प्रतियां
(c)	4 copies of the Application for Revision.
)घ(	पुनरीक्षण आवेदन दायर करने के लिए सीमाशुल्क अधिनियम,) 1962 यथासंशोधित (में निर्धारित फीस जोअन्य रसीद,फीस,दण्ड,जब्तीऔर विविध मदों के शीर्षके अधीन आता है में रु)-/200 .रूपए दो सौ मात्र (या रु)-/1000.रूपए एक हज़ार मात्र(,जैसा भी मामला हो,से सम्बन्धित भुगतान के प्रमाणिक चलान टी.आर 6.की दोप्रतियां .यदि शुल्क,मांगा गया ब्याज,लगाया गया दंड की राशिऔर रूपए एक लाख या उससे कम हो तो ऐसे फीस के रूप में रु -/200.और यदि एक लाख से अधिक हो तो फीस के रूप में रु-/1000.
(d)	The duplicate copy of the T.R.6 challan evidencing payment of Rs.200/- (Rupees two Hundred only) or Rs.1,000/- (Rupees one thousand only) as the case may be, under the Head of other receipts, fees, fines, forfeitures and Miscellaneous Items being the fee prescribed in the Customs Act, 1962 (as amended) for filing a Revision Application. If the amount of duty and interest demanded, fine or penalty levied is one lakh rupees or less, fees as Rs.200/- and if it is more than one lakh rupees, the fee is Rs.1000/-.

4.	**मद सं 2 .के अधीन सूचित मामलों के अलावा अन्य मामलों के सम्बंन्ध में यदि कोई व्यक्ति इस आदेश से आहत महसूस करता हो तो वे सीमाशुल्क अधिनियम 1962 की धारा 129 ए (1) के अधीन फॉर्म सी.ए 3-.में सीमाशुल्क, केन्द्रीय उत्पाद शुल्क और सेवा कर अपील अधिकरण के समक्ष निम्नलिखित पते पर अपील कर सकते हैं**	
	In respect of cases other than these mentioned under item 2 above, any person aggrieved by this order can file an appeal under Section 129 A(1) of the Customs Act, 1962 in form C.A.-3 before the Customs, Excise and Service Tax Appellate Tribunal at the following address :	
	सीमाशुल्क, केंद्रीय उत्पाद शुल्क व सेवा कर अपीलियअधिकरण, पश्चिमी क्षेत्रीय पीठ	**Customs, Excise & Service Tax Appellate Tribunal, West Zonal Bench**
	दूसरी मंज़िल,बहुमाली भवन, निकट गिरधरनगर पुल, असारवा, अहमदाबाद380016-	2nd Floor, Bahumali Bhavan, Nr.Girdhar Nagar Bridge, Asarwa, Ahmedabad-380 016
5.	**सीमाशुल्क अधिनियम, 1962 की धारा 129 ए (6) के अधीन, सीमाशुल्क अधिनियम, 1962 की धारा 129ए (1) के अधीन अपील के साथ निम्नलिखित शुल्क संलग्न होने चाहिए-**	
	Under Section 129 A (6) of the Customs Act, 1962 an appeal under Section 129 A (1) of the Customs Act, 1962 shall be accompanied by a fee of -	
)क(	**अपील से सम्बन्धित मामले में जहां किसी सीमाशुल्क अधिकारी द्वारा मांगा गया शुल्क और व्याज तथा लगाया गया दंड की रकम पाँच लाख रूपए या उससे कम हो तो एक हज़ार रुपए .**	
(a)	where the amount of duty and interest demanded and penalty levied by any officer of Customs in the case to which the appeal relates is five lakh rupees or less, one thousand rupees;	
)ख(	**अपील से सम्बन्धित मामले में जहां किसी सीमाशुल्क अधिकारी द्वारा मांगा गया शुल्क और व्याज तथा लगाया गया दंड की रकम पाँच लाख रूपए से अधिक हो लेकिन रुपये पचास लाख से अधिक न हो तो; पांच हज़ार रुपए**	
(b)	where the amount of duty and interest demanded and penalty levied by any officer of Customs in the case to which the appeal relates is more than five lakh rupees but not exceeding fifty lakh rupees, five thousand rupees ;	
)ग(	**अपील से सम्बन्धित मामले में जहां किसी सीमाशुल्क अधिकारी द्वारा मांगा गया शुल्क और व्याज तथा लगाया गया दंड की रकम पचास लाख रूपए से अधिक हो तो; दस हज़ार रुपए.**	
(c)	where the amount of duty and interest demanded and penalty levied by any officer of Customs in the case to which the appeal relates is more than fifty lakh rupees, ten thousand rupees	
)घ(	इस आदेश के विरुद्ध अधिकरण के सामने,मांगे गए शुल्क के % 10 अदा करने पर,जहां शुल्क या शुल्क एवं दंड विवाद में हैं,या दंड के % 10 अदा करने पर,जहां केवल दंड विवाद में है,अपील रखा जाएगा।	
(d)	An appeal against this order shall lie before the Tribunal on payment of 10% of the duty demanded where duty or duty and penalty are in dispute, or penalty, where penalty alone is in dispute.	
6.	**उक्त अधिनियम की धारा) 129 ए (के अन्तर्गत अपील प्राधिकरण के समक्ष दायर प्रत्येक आवेदन पत्र) -क (रोक आदेश के लिए या गलतियों को सुधारने के लिए या किसी अन्य प्रयोजन के लिए किए गए अपील - : अथवा)ख (अपील या आवेदन पत्र का प्रत्यावर्तन के लिए दायर आवेदन के साथ रुपये पाँच सौ का शुल्क भी संलग्न होने चाहिए.**	
	Under section 129 (a) of the said Act, every application made before the Appellate Tribunal- (a) in an appeal for grant of stay or for rectification of mistake or for any other purpose; or (b) for restoration of an appeal or an application shall be accompanied by a fee of five Hundred rupees.	

ORDER IN APPEAL

M/s Troikka Pharmaceuticals Ltd, C-1, Sara Industrial Estate Ltd., Chota Rampur, Beyond Selaqui, Dehradun- 248197 having regd. Office : M/s Troikka Pharmaceuticals Ltd, "Commerce House-1", Satya Marg, Bodakdev, Ahmedabad-380 054 (herein after referred as the appellant) filed appeal against the OIO No.: 46/DC/ACC/Speaking Order/Troikaa/23-24 dt. 22.01.2024 (hereinafter referred to as the impugned OIO) passed the DC, Customs, ACC, Old Airport, Ahmedabad (hereinafter referred to as the adjudicating authority).

2. Brief facts of the case are that the appellant filed the Bill of Entry No.: 9237640 dated 15.12.2023 for the import and clearances of 90.10 grams "Dexmedetomidine Hydrochloride" classifying under CTI 2933 2990 vide Invoice No.: N2023-12/00124 dated 13.12.2023 under Section 17(1) of the Customs Act, 1962. This CTI 2933 2990 attracts Basic Customs Duty @7.5%, SWS and IGST under the First Schedule to the Customs Tariff Act, 1975.

2.1 Where as, the adjudicating authority, on the basis of Note 01 & 03 of Chapter 98 of the First Schedule to the Customs Tariff Act, 1975, conditions of License No.: TL/RKZ/23/000021 in Form No.: 11 under Rule 33 of the Drugs and Cosmetics Rules, 1945 to import the drugs i.e. "Dexmedetomidine Hydrochloride USP" , MSDS (Material Safety Data Sheet), definitions, literature, characteristics and its intended use, classified the imported goods under CTI 9802 0000. This CTI attracts Basic Customs Duty @10%, SWS and IGST under the First Schedule to the Customs Tariff Act, 1975.

2.2 The adjudicating authority through impugned order classified the imported goods i.e. "Dexmedetomidine Hydrochloride" CTI 9802 0000 attracts Basic Customs Duty @10%, SWS and IGST under the Customs Tariff instead of appellant's declared classification under CTI 2933 2990 which attracts Basic Customs Duty @7.5%, SWS and IGST under the Customs Tariff. While passing above impugned order, the adjudicating authority recorded his findings as under:

> *5. I have gone through the details of Bill of Entry No. 9237640 dated 15.12.2023 available on the ICES and import documents e-Sanchit by the Importer seeking clearance of goods namely "Dexmedetomidine Hydrochloride USP" under CTH 2933. The Bill of Entry is self-assessed by the Importer under Section 17 of Customs Act 1962 in final assessment mode. I have also gone*

through the contentions put forth by the Importer in their letter dated 24.12.2023. Further vide letter dated 08.01.2024 the Importer has requested for waiver of SCN and Personal Hearing and for issuance of speaking order.

6. I find that the Importer has been licensed under Rule 33 of Drugs and Cosmetics Rules 1945 to import the drug I.e. "Dexmedetomidine Hydrochloride USP" for the purpose of examination, test or analysis at M/s. Troikaa Pharmaceuticals Limited, C-1, Sara Ind. Estate Ltd., Chota Rampur, Beyond Selaqui, Dehradun, 248197-Uttarakhand -248197. The classification of any goods is decided by going sequentially through General Rules for the Interpretation of Import Tariff. As per Rule 1, the titles of Sections, Chapters and sub-chapters are provided for ease of reference only; for legal purpose classification is to be determined according to the terms of the headings and any relative Section or Chapter Notes. Going by the terms of Rule 1, the classification of goods under Customs Tariff has to be decided by Section and Chapter Notes. Chapter Note 3 to Chapter 98, provides that "Heading 9802 covers all chemicals, organic or inorganic, whether or not chemically defined, imported in packing not exceeding 500 gms or 500 milliliters and which can be identified with reference to the purity, markings or other features to show them to be meant for use solely as laboratory chemicals." Note 1 to the same chapter provides that the chapter 98 is to be taken to apply to all goods which satisfy the conditions prescribed therein, even though they may be covered by a more specific heading elsewhere in the Schedule. Reading Note 1 in combination with Note 3 implies that, in the present case, if the import goods satisfy condition of Note 3, the goods would be classified under Chapter 98 even if said goods are more specifically classifiable under any heading of other chapters including CTH 2933.

7. (a) Therefore, there would be no need to visit any other chapter heading seeking classification of import goods, if the goods satisfy conditions of Chapter Note 3, as per which, all inorganic and organic chemicals imported in packings not exceeding 500gms would be classifiable under CTH 9802, if they can be identified with reference to the purity, markings or other features to show them to be meant for use solely as laboratory chemicals.

(b) As per Wikipedia, "a laboratory is a facility that provides controlled conditions in which scientific or technological research, experiments, and measurement may be performed. Laboratories are found in a variety of settings

such as schools, universities privately owned research institutions, corporate research and testing facilities, government regulatory and forensic Investigation centers, physicians' offices, clinics, hospitals, regional and national referral centers, and even occasionally personal residences." Collins dictionary defines, a laboratory as "a building or a room where scientific experiments, analyses, and research are carried out". Therefore, any facility which provides controlled conditions to perform scientific or technological research, experiments, and measurement is a laboratory.

(c) US National Regulatory commissioner defines a chemical as "a substance that has a defined composition". Similarly as per Wikipedia a chemical substance is "a unique form of matter with constant chemical composition and characteristic properties"

(d) Guided by the definitions of Laboratory and Chemicals at Sub Para (b) and (c) above, it can be said that any substance having defined chemical composition and the same is meant to be used in a facility for performing analysis, scientific and technological research or experiments would be Laboratory Chemicals. Note 3 even does relaxes the requirement of the substance being chemically defined to be classified under CTH 9802.

(e) The MSDS of the import goods attached in E-sanchit with the Bill of Entry, the chemical formula of import goods as C13H16N2,HCl. As per condition No. 1, the licence allows import of the goods exclusively for the purpose of examination, test or analysis and that too only at the place (i.e. testing facility) allowed by the Licensing Authority. Therefore, in terms of definitions mentioned above, the import item is a Chemical having specified chemical composition and is meant to be used at a place i.e. a laboratory having facility for performing test, examination and analysis on the imported product. Therefore the imported product i.e. "Dexmedetomidine Hydrochloride USP" is chemical and imported as a laboratory chemical i.e. for test, examination and analysis.

(f) The license in form 11 has allowed import of goods namely "Dexmedetomidine Hydrochloride USP" indicating that the product conforms to US compendial standards for strength, quality, or purity, Further, the MSDS (at point 1.2) attached in the E-sanchit mentions identified uses of the imported goods as "Laboratory Chemical, manufacture of substances". In the present case, the goods have been allowed to be imported for the purpose of examination, test and analysis therefore the identified use is laboratory chemical. If these characteristics of the imported product are seen in light of the Note 3 to

Chapter 98 then it becomes clear that the imported goods can be identified with respect to purity and other features and the same is meant to be used as laboratory chemical. The quantity of the goods is also within limits prescribed in Note 3.

(g) The contention of Importer that the items covered under Chapter 29 are restricted for import has no bearing on tariff classification of the goods. The importer has put up some definition of the laboratory chemical but neither backed the definition with its source nor explained as to how the import goods are not laboratory chemicals. Lastly, the importer has stated that the import goods can't be identified with respect to purity, markings or other features to be meant for use solely as laboratory chemicals. However, as put forth in Sub Para (a) to (f), the MSDS reveals the product conforms to US compendial standards for strength, quality, or purity. Licence in form 11 reveals that that import goods are meant to be used for test, examination and analysis at place having such facility, the MSDS mentions the identified uses as Laboratory chemical.

(h) In view of the definitions, literature, characteristics and intended use of the imported product described at Sub Para (a) to (f), it is easy to conclude that the imported goods would merit classification under CTI 9802 0000 and there is no need to visit Chapter 29 or any other chapter for the purpose of Customs Tariff Classification of the imported goods in terms of Note 1 and Note 3 of Chapter 98."

3 Being aggrieved with the impugned order passed by the adjudicating authority, the Appellant have filed the present appeal. The Appellant have, inter-alia, raised various contentions and filed detailed submissions in their Appeal memorandum dt. 21.03.2024 and further additional submission dt. 24.11.2025, as given below in support of their claims:

- *The standalone Chapter 98 under the First Schedule to the Customs Tariff Act, 1975 is special and unique to India and has no support from the HSN to which India is a signatory from Chapters 1 to 97. It is an India specific special classification introduced by India in its the CTA, 1975 for the sake of convenience so that diverse goods imported together as project imports, as baggage, as medicines, as postal imports etc. are classified under one heading and one Tariff Entry all subject to duty at a uniform rate to facilitate assessment and ensure faster clearance since the alternative would be to classify each*

item distinctly and subject each to duty as applicable to each such goods. However such grouped assessments are subject to conditions stipulated under the Chapter 98 Notes 1 to 7.

- *However, vide the Chapter Notes 4, 5, 6, and 7 the Heading 98.03 or 98.04 is not to be taken to apply in respect of certain specified items or those articles which are subject to clearance under an import licence or a custom clearance permit. Apart from the restrictive Chapter Notes 4 to 7, it is also correspondingly clarified in the CBIC Customs Manual 2023 Chapter 5 Paras 1.1, 6.1 and 7.1. (Exhibits-G)*
- *Similarly by analogy heading 98.02 may not be taken to apply to those chemicals which are drug substances allowed clearance only on the basis of drug import licence subject to end use medicament drug manufacture licence and NOC from the ADC stationed at the import port.*
- *Even otherwise vide the Chapter 98 Note 3 has restrictive application by virtue of the Note 3 conditions that: (1)The quantity imported not to exceed in packing 500g/500 ml, and (2) Such chemicals should be identified with reference to purity, markings and other features to show them to be meant for use solely as a laboratory chemical.*
- *In the import under dispute the first limb of the Note 3 is satisfied as the packing does not exceed 500g. However, the said goods have for a variety of reasons claimed to be identified as laboratory chemicals but in essence the Adjudicating Authority has still treated the import as a drug import requiring a valid drug licence which has been produced for clearance and the Adjudicating Authority has referred the Bill of Entry to the ADC located at the port for NOC as a permitted drug import and also debited the quantity 90.1 grams in 2 such licences one permitting 90 grams and the second having balance more than 0.10 grams.*
- *Thus it has been claimed by the Adjudicating Authority to be a laboratory chemical for duty purposes only but still in fact been otherwise identified as a drug item. The import of Dexmedetomidine Hydrochloride USP in sealed vials (45.10 g + 45.00 g) under a test analyses licence both for the import and end use as manufacture of an approved medicament is to be processed not in a laboratory set up but a sophisticated set of production equipments in batches of 25 liter water for injection infusion solutions each ML. with a concentration of 100 mcg of the drug for testing and analyses of all such future batches of sedative-hypnotics 1ML/2ML/4ML/10ML injections for validation of the*

medicament not for commercial sale but for preparation of dossiers for international medicament approval and registration. A copy each of the import and manufacturing licences, product permission and the elaborate controlled manufacturing processes flow chart is enclosed. Each 25 liter drug production batch will involve 2.95 grams of the API resulting in eg. 11682 2 ML. Infusion vials cach ML. having a concentration of 100 mcg of the API and the filled quantity will be 2.14ML.. (Exhibit-H)

- *A copy of the self-assessed Bill of Entry showing TE 2933 2900 and the description Dexmedetomidine Hydrochloride is enclosed and also the copy of the re-assessed Bill of entry showing TE 9802 0000 still showing the description as Dexmedetomidine Hydrochloride is enclosed. Only the TE and duty rate has been changed in the re-assessed BE without changing the description to Laboratory Chemicals. Thus the TE has been changed only for duty purposes but for all other purposes including that of prohibitions and permissibility the import has been treated as a drug import under a valid drug licence for end use under a valid medicament manufacturing licence. (Exhibits D and I).*
- *Laboratory Chemicals do not find place in the Drugs and Cosmetics Act, 1940 and do not require import and manufacturing drug licences in Form 11 and 29, respectively. The manufacturer-supplier in the exporting country in the Material Data Safety Sheet has shown therein the substance/mixture une an Anesthetic for Injection. Further in the said MSDS identified uses has been stated as Laboratory Chemicals, Manufacture of substances. This indicative uses is not binding on the Drug Authority, Customs and the Appellants in India as for Indian provisions under the Import Policy, the Drug Act and the Customs Act it is a prohibited item subject to a valid drug import and drug manufacturing item even if the import is of only 90.1 grams meant for testing and analyses of the manufactured anesthetics viz. sedative-hypnosis drug in fixed dosage injectible infivials. (Exhibit J).*
- *It is a fact that the authority competent, the Drug Controlling and Licensing Authority, has for the purpose of the Drug Act identified the import and the end use both as controlled and licensed items and not a chemical to be used for testing of samples of eg blood, food and the like and the Adjudicating Authority has in fact for the permitted import and clearance purposes also treated the import as drug controlled and licensed nem even when import permitted of 90.10 grams and the end use manufacture also permitted is of a tent and*

analyses batches.

- *Thus the identity of the substance imported irrespective of the quantity 90.1 grams (valued around Rs.1.18 Crs) has been treated as a specific chemically defined controlled drug substance for the purpose of import validation and not as a generic chemical meant to be used solely as a laboratory chemical. The Adjudicating Authority has identified for import validation purposes the import as a controlled and licensed drug item contra to which only for duty purposes it has been attempted to be identified not as a most specific drug category item but more general as a laboratory chemical. The most specific description as a drug category item shall prevail over a more general laboratory chemical category item as the Adjudicating Authority has not ruled out the import and end use as a drug category item/product, but on the contrary accepted the import as a drug category item for the purpose of import clearance and allowed the import as a valid import only on the basis of drug import and manufacture licences in Form 11 and 29, respectively and the ADC has also confirmed so by granting an NOC under the provisions of the Drug Act and the Rules made there under.*
- *That note 3 of Chapter 98 (as existing at the time of import), which prescribes the conditions to classify a product as a laboratory chemical. The relevant extract of the aforesaid note is reproduced hereinbelow:*

  "Heading 9802 covers all chemicals, organic or inorganic, whether or not chemically defined, imported in packings not exceeding 500 gms or 500 millilitres and which can be identified with reference to the purity, markings or other features to show them to be meant for use solely as laboratory chemicals"
- *Upon a perusal of the aforesaid chapter note, the following conditions to classify a product as a laboratory chemical emerge (i) The product should be an organic or inorganic chemical, whether or not chemically defined; (ii) The product should be imported in packings not exceeding 500 gm or 500 ml; and From the purity, markings or other features of the product, it should be discerned that the product is meant to be used solely for laboratory chemicals.*
- *That the aforesaid conditions are not met for the imported goods to be indicated as solely for use as laboratory chemicals, as the said goods are also used for manufacturing another product named Dexmedetomidine 100 mg concentrate solution for infusion ("manufactured product"), for which a separate license in Form 29 (under Rule 89 of the Narcotics and Psychotropic*

substances rules, 1985) dated 22.10.2021 has been procured by the Appellant. It is pertinent to note that in the said license, the imported product is mentioned as an active ingredient in the manufacturing composition of the manufactured product. A copy of the manufacturing license under Form 29 dated 22.10.2021 is enclosed herewith as Exhibit-'A' to this submission.

- *That, the material data safety sheet submitted by the exporter of the imported goods mentions two uses: namely, laboratory chemicals and manufacture. This itself clearly establishes that the imported goods are not meant to be used, solely as laboratory chemicals. A copy of the material data safety sheet as provided by the exporter of the imported goods, is enclosed herewith as Exhibit-'B' to this submission.*

PERSONAL HEARING:

4. Personal hearing in the matter was held on 12.11.2025 in virtual mode. Shri Mukul Sharda, Associate Director and Shri Varenayam Shastri, Assistant Manager appeared for hearing on behalf of the Appellant. They reiterated the submissions made in the appeal memorandum. They submitted additional submissions in the matter also.

DISCUSSION & FINDINGS:

5. The Appellant has filed the present appeal on 26.03.2024. In the Form C.A.-1, the date of communication of the Order-In-Original dated 22.01.2024 has been shown as 03.02.2024. Therefore, as per the appellant submission, the appeal has been filed within normal period of 60 days, as stipulated under Section 128 (1) of the Customs Act, 1962.

5.1 The Appellant has submitted copy of the E Payment receipt dt. 10.01.2024 for Rs. 36,84,223/- towards payment of re-assessed duty liability alongwith interest. Since the entire duty amount together with interest has already been paid, such payment shall be treated as sufficient compliance with the mandatory pre-deposit requirement under Section 129E of the Customs Act, 1962. As the appeal has been filed within the stipulated time-limit and complies with the requirement of Section 129E of the Customs Act, 1962, the appeals has been admitted and being taken up for disposal on merits.

5.2 Copy of appeal memorandum and its enclosures received from the appellant have been forwarded to the adjudicating authority i.e the Deputy Commissioner, Customs, Air Cargo Complex, Ahmedabad vide letter dt. 01.07.2024 calling comments

and necessary information/ details. However, till date no reply have been received in the matter.

6. I have carefully gone through the appeal memorandum as well as records of the case and the submissions made on behalf of the Appellant during the course of hearing. The issue to be decided in the present appeal is whether the impugned order passed by the adjudicating authority classifying the imported goods under CTH 9802 0000 of the Custom Tariff instead of CTH 2933 2990 of the Custom Tariff as claimed by the appellant, in the facts and circumstances of the case, is legal and proper or otherwise.

6.1 It is observed that the appellant filed Bill of Entry No. 9237640 dated 15.12.2023 for the import and clearance of 90.10 grams of Dexmedetomidine Hydrochloride, classifying the product under CTI 2933 2990, vide Invoice No. N2023-12/00124 dated 13.12.2023, in terms of Section 17(1) of the Customs Act, 1962. The tariff entry CTI 2933 2990 attracts Basic Customs Duty @ 7.5%, SWS and IGST as per the Customs Tariff Act, 1975. The adjudicating authority, relying upon Note 1 and Note 3 of Chapter 98 of the Customs Tariff Act, 1975, the conditions attached to Licence No. TL/RKZ/23/000021 issued in Form No. 11 under Rule 33 of the Drugs and Cosmetics Rules, 1945 for import of the drug "Dexmedetomidine Hydrochloride USP", as well as the MSDS, definitions, literature, product characteristics and its intended use, reclassified the imported goods under CTI 9802 0000. The said tariff entry attracts Basic Customs Duty @ 10%, along with SWS and IGST. Through the impugned order, the adjudicating authority has thus classified the imported goods, namely Dexmedetomidine Hydrochloride, under CTH 9802 0000, which attracts Basic Customs Duty @ 10%, in place of the appellant's declared classification under CTH 2933 2990, which attracts Basic Customs Duty @ 7.5%, along with SWS and IGST, under the Customs Tariff Act, 1975.

6.2 I find that the appellant, in his appeal memorandum and additional submission, submitted that the imported goods i.e. Dexmedetomidine Hydrochloride USP are used for manufacturing another product named Dexmedetomidine 100 mg concentrate solution for infusion ("manufactured product"), for which a separate License No.: 1492/UA/TEST/2021 dated 22/10/2021 vide F.No.: 26/1/Drug/73/2019-18694 issued by the Drug Controlling & Licensing Authority (mfg.), Uttrakhand to the appellant. Copy of this License submitted by the appellant is produced herein under for better understanding subject matter :

19

OFFICE OF THE DRUGS CONTROLLING & LICENSING AUTHORITY
DIRECTORATE GENERAL OF MEDICAL HEALTH & FAMILY WELFARE,
SAHASTRADHARA ROAD, DEHRADUN (UTTARAKHAND)

File No. 26/1/DRUG/73/2019 | 18694 Date: 22/10/2021

License No. 1492/UA/TEST/2021

FORM - 29
[See Rule 89]

License to manufacture drugs for purposes of examination, test or Analysis.

1. **M/s Troikaa Pharmaceuticals Ltd.,** is hereby licensed to manufacture the drugs specified Below for purposes of examination, test and analysis at **C-1, Sara Industrial Estate, Selaqui, Dehradun-248197, Uttarakhand, India.**
2. This License is subject to the conditions prescribed in part VIII of the Drugs and Cosmetics Rules, 1945.
3. This License shall be in force for three year from the date specified below.

Sr. No.	Name of Drug	COMPOSITION
01	**DEXMEDETOMIDINE 100 MICROGRAMS/ML CONCENTRATE FOR SOLUTION FOR INFUSION**	Each ml contains Dexmedetomidine Hydrochloride Eq. to Dexmedetomidine .....100 mcg Water for injections .....q. s.

22.10.2021

Drug Licensing & Controlling Authority (m/g.)
Uttarakhand

(Hemant Singh Negi)
Drug Controlling & Licensing Authority
(Mfg.) Garhwal Mandal
Uttarakhand

In view of Licence No. 1492/UA/TEST/2021 dated 22.10.2021, it is clearly established that the appellant holds a valid manufacturing licence to manufacture the drug 'Dexmedetomidine 100 mg/ml Concentrate for Solution for Infusion', the formulation of which contains Dexmedetomidine Hydrochloride, which is the imported goods in question. Accordingly, the adjudicating authority's conclusion that the imported goods are intended solely for use as laboratory chemicals for examination, testing, and analysis is factually and legally unsustainable. The said licence unequivocally demonstrates that the imported goods are used for manufacturing a finished drug product, and not merely as laboratory

chemicals.

6.3 I further find that the appellant has submitted copies material data safety sheet (MSDS) for the imported goods i.e. Dexmedetomidine Hydrochloride issued by the NORCHIM. The appellant emphasized that imported goods mentions two uses first laboratory chemicals and manufacture of substance and this manufacture itself clearly establishes that the imported goods are not meant to be used, solely as laboratory chemicals. Copy of this MSDS dt. 24.02.2023 submitted by the appellant is produced herein under :

Exhibit : B

J 36

NORCHIM

☎ 33 (0)3 44.56.09.20
Fax 33 (0)3 44.56.66.75

MATERIAL SAFETY DATA SHEET

ACCORDING TO REGULATION (EC) 1907/2006
Version 4 – February 24th 2023
Print date: February 24th 2023
GENERIC EU MSDS - NO COUNTRY SPECIFIC DATA - NO OEL DATA

- Product name: Dexmedetomidine Hydrochloride
- Product number: PF452410
- Substance / Mixture use: Anesthetic for injection
- REACH No.: A registration number is not available for this substance as the substance or its uses are exempted from registration.
- CAS-No: 145108-58-3

Identified uses: Laboratory chemicals, Manufacture of substances

Company:	NORCHIM 33, quai d'Arnont 60340 SAINT LEU D'ESSERENT
Telephone:	33 (0)3 44 56 09 20
Fax:	33 (0)3 44 56 66 75
E-mail adresse:	contact@norchim.com
Service in charge of information:	Safety Department

Emergency information: ORFILA Phone: +33(0)1.45.42.59.59

In view of the Material Safety Data Sheet (MSDS) placed on record, it

stands conclusively established that the imported product, Dexmedetomidine Hydrochloride, is not confined to use as a laboratory chemical, but in fact a key active pharmaceutical ingredient (API) employed in the manufacture of other finished pharmaceutical formulations. Therefore, the finding of the adjudicating authority that the said goods are "laboratory chemicals" meant only for testing, examination, or analytical purposes is contrary to the material evidence and hence legally unsustainable. The impugned conclusion suffers from non-consideration of vital documents and amounts to a misclassification of the nature and end-use of the imported goods. Accordingly, the observations of the adjudicating authority cannot be upheld and merit interference in appeal.

6.4 It is further observed that the appellant in his reply submitted that the Note 3 of Chapter 98 (as existing at the time of import), which prescribes the conditions to classify a product as a laboratory chemical.

> *The relevant extract of the aforesaid note is reproduced hereinbelow:*
> *"Heading 9802 covers all chemicals, organic or inorganic, whether or not chemically defined, imported in packings not exceeding 500 gms or 500 millilitres and which can be identified with reference to the purity, markings or other features to show them to be meant for use solely as laboratory chemicals"*

The appellant further submitted that *the aforesaid chapter note no.: 03 contains the following conditions to classify a product as a laboratory chemical :*

(i) The product should be an organic or inorganic chemical, whether or not chemically defined;

(ii) The product should be imported in packings not exceeding 500 gm or 500 ml; and

(iii) From the purity, markings or other features of the product, it should be discerned that the product is meant to be used ***solely*** *for laboratory chemicals.*

6.4.1 The appellant argued that the imported goods cannot be treated as "solely for use as laboratory chemicals" because they are also used to manufacture another product, *Dexmedetomidine 100 mg Concentrate for Infusion*. For making this product, the appellant has a separate Form 29 license dated 22.10.2021 under Rule 89 of the NDPS

Rules, 1985. This license clearly mentions that the imported item is used as an active ingredient in the manufacturing process.

6.4.2 I find from the Form 29 licence dated 22.10.2021, it is evident that the appellant was specifically authorised to manufacture the drug *Dexmedetomidine*, in which *Dexmedetomidine Hydrochloride*—the imported item—functions as the active pharmaceutical ingredient. When read together with the MSDS (Material Safety Data Sheet), which clearly indicates that the product has recognized pharmaceutical and manufacturing applications, it becomes abundantly clear that the imported goods cannot be regarded as "laboratory chemicals" meant solely for testing, examination, or analysis. Consequently, the finding of the adjudicating authority classifying the goods under CTH 9802 0000 is contrary to the material evidence, factually incorrect, and legally unsustainable. The impugned conclusion therefore cannot be upheld and merits interference in appeal.

6.5 To ascertain the classification practices followed at other airports and seaports in India, the import data pertaining to *Dexmedetomidine Hydrochloride* was searched through online sources. The results available on the websites (i) SEAIR Exim Solutions and (ii) ZAUBA indicate that the said goods are being classified under Chapter Heading 2933 9900 at both Ahmedabad and Hyderabad Air Cargo complexes.

(i) SEAIR Exim Solutions :

SEAIR EXIM SOLUTIONS

USA Data | Global Trade Data | HS Code | Pricing | Subscribe | Login

Total Product

View Export data of dexmedetomidine hydrochloride | Subscribe Now | Downloads

DATE	INDIAN PORT	CTH	ITEM DESCRIPTION	QUANTITY	UQC	U.P.USD	ASSESS USD	COO	DUTY
30-Jun-2016	ahmedabad	29339900	chemical : dexmedetomidine hydrochloride usp	14	GMS	5454.00	76356.00	united states	
26-Jan-2016	hyderabad air cargo	29339900	hisy-dxmd-1005-n dexmedetomidine hydrochloride (c1187340) (30 grams x 5500 usd)	0.03	KGS	5555000.00	166650.00	united states	
26-Jan-2016	hyderabad air cargo	29339900	hisy-dxmd-1005-n dexmedetomidine hydrochloride (c1187340) (30 grams x 5500 usd)	0.03	KGS	5555000.00	166650.00	united states	

(ii) ZAUBA :

zauba.com/import-dexmedetomidine+hcl/hs-code-29/fp-united-states/ip-INAMD4-hs-code.html

Dexmedetomidine Hcl Import Data

29 United-states Ahmedabad dexmedetomidine hcl

Date	HS Code	Description	Origin Country	Port of Discharge	Unit	Quantity	Total Value (USD)	Price Per Unit (USD)
May 06 2016	29339900	CHEMICAL : DEXMEDETOMIDINE HCL	United States	Ahmedabad	KGS	0	66,977	6,088,851.82
May 06 2016	29339900	CHEMICAL : DEXMEDETOMIDINE HCL	United States	Ahmedabad	KGS	0	142,479	5,479,966.15
Oct 06 2015	29339900	CHEMICAL : DEXMEDETOMIDINE HCL USP	United States	Ahmedabad	KGS	0	36,527	6,641,220.91

From the import data relating to the chemical Dexmedetomidine Hydrochloride, it is observed that consignments imported through Ahmedabad and Hyderabad Air Cargo complexes have consistently been classified under Chapter Heading 2933 9900. This evidences that the said goods are regularly imported into India and are uniformly assessed under the same tariff heading. Accordingly, even on this basis, it can be reasonably inferred and established that the correct classification of the imported goods is under Chapter Heading 2933 9900.

7. From the foregoing facts, discussion, and material on record, it is evident that the adjudicating authority failed to properly appreciate the material evidence establishing that the imported goods, *Dexmedetomidine Hydrochloride*, cannot be treated as "laboratory chemicals" used solely for testing, examination, or analysis and classified under CTH 9802 0000. On the contrary, it is demonstrably clear that the imported goods are utilised in the manufacture of other products, as conclusively established by the Form 29 licence dated 22.10.2021 issued under Rule 89 of the NDPS Rules, 1985, and corroborated by the Material Safety Data Sheet (MSDS). In view of these incontrovertible facts, the classification and findings of the adjudicating authority are factually incorrect, legally unsustainable, and cannot be upheld in the eyes of law.

8. In view of the findings and conclusions recorded hereinabove, I hereby pass the following order:

1. The classification of the imported goods i.e. Dexmedetomidine Hydrochloride, under CTH 9802 0000 as held by the adjudicating authority is set aside.
2. The imported goods are hereby reclassified under CTH 2933 2990, in accordance with the evidence on record, including the Form 29 licence dated 22.10.2021 issued under Rule 89 of the NDPS Rules, 1985 and the Material Safety Data Sheet (MSDS).
3. The appeal filed by the appellant is allowed, with consequential relief, if any, in accordance with law.

(Amit Gupta)
Commissioner (Appeals),
Customs, Ahmedabad

F. No. S/49-456/CUS/AHD/2023-24 Date: 28.11.2025

By Speed Post.

M/s Troikka Pharmaceuticals Ltd,
C-1, Sara Industrial Estate Ltd.,
Chota Rampur, Beyond Selaqui,
Dehradun- 248197.

Regd. Office:

M/s Troikka Pharmaceuticals Ltd,
"Commerce House-1", Satya Marg, Bodakdev,
Ahmedabad-380 054.

prakashgirigosai@troikaapharma.com / jigneshpandit-exim@troikaapharma.com

Copy to:
1.The Chief Commissioner of Customs Gujarat, Custom House, Ahmedabad. (email: ccoahm-guj@nic.in)
2.The Principal Commissioner of Customs, Custom House, Ahmedabad. (email: cus-ahmd-guj@nic.in rra-customsahd@gov.in)
3. The Deputy Commissioner of Customs, Air Cargo Complex, Ahmedabad. (email: aircargo-amd@gov.in)
4. Shri Mukul Sharda , Associate Director and Shri Varenayam Shastri, Assistant Manager (MukulSharda@bdo.in VarenyamShastri@bdo.in)
5. Guard File.