THE AUTHORITY FOR ADVANCE RULINGS
IN KARNATAKA
GOODS AND SERVICES TAX
VANIJYA THERIGE KARYALAYA, KALIDASA ROAD
GANDHINAGAR, BENGALURU – 560 009

Advance Ruling No. KAR ADRG 24 / 2021
Date : 16-04-2021

Present:

1. Dr.M.P.Ravi Prasad
   Additional Commissioner of Commercial Taxes . . . . Member (State)

2. Sri.Mashhood Ur Rehman Farooqui,
   Joint Commissioner of Customs & Indirect Taxes, ... Member (Central)

1.	Name and address of the Applicant	M/s.Kaustubha Scientific Research Laboratory Private Ltd., No. 142, 3rd Floor, 5th Cross, RMV Extension, Bengaluru (Urban), Karnataka- 560080
2.	GSTIN or User ID	29AABCP0825A1ZX
3.	Date of filing of Form GST ARA-01	16-12-2020
4.	Represented by	Sri. Dayananda, CA & Authorised Representative
5	Jurisdictional Authority – Centre	The Commissioner of Indirect Taxes, Bangalore North West Commissionerate, Bengaluru.
6	**Jurisdictional Authority – State**	LGSTO-130, Bengaluru.
7.	Whether the payment of fees discharged and if yes, the amount and CIN	Yes, discharged fee of Rs.5,000/- under CGST Act and Rs.5,000/- under KGST Act vide reference number DC2912200121203 dated 16-12-2020 by way of debit from Electronic Cash Ledger

ORDER UNDER SECTION 98(4) OF CGST ACT, 2017
& UNDER SECTION 98(4) OF KGST ACT, 2017

M/s Kaustubha Scientific Research Laboratory Private Ltd., (herein after referred to as 'the applicant'), #142, 3rd Floor, 5th Cross, RMV Extension, Bengaluru (Urban), Karnataka- 560080 having GSTIN number- 29AABCP0825A1ZX have filed an application for Advance Ruling under Section 97 of CGST Act, 2017, read with Rule 104 of the CGST Rules and Section 97 of the KGST Act, 2017 read with Rule 104 of KGST Rules 2017, in FORM GST ARA-01 discharging the fee of Rs.5,000/- each under the CGST Act and the KGST Act..

Authority For Advance Ruling Karnataka, Bengaluru

2. The applicant is a registered person under the provisions of the Central Goods and Services Tax Act, 2017 as well as the Karnataka Goods and Services Tax Act, 2017 (hereinafter referred to as the "CGST Act" and the "KGST Act/SGST Act" respectively) engaged in the distribution of Pharmaceutical Reference Standards from Pharmacopoeias like European Pharmacopoeia (EP), British Pharmacopeia (BP), Indian Pharmacopeia (IP), Japanese Pharmacopoeia (JP). The applicant is seeking advance ruling on the applicability of entry in Notification No. 01/2017-IT (R) for their product prepared laboratory reagents/ Pharmaceutical Reference Standards.

3. The applicant has sought advance ruling in respect of the following question:

> *Whether the applicable entry for prepared laboratory reagents/ Pharmaceutical Reference Standards in the Notification No. 01/2017-IT (R) is Sr. No. 80 of Schedule II, attracting a levy of 12% or Sr. No. 453 of Schedule III attracting a levy of 18 %?*

4. **Admissibility of the application**: The question is about "*applicability of a notification issued under the provisions of this Act*" and hence is admissible under Section 97(2)(b) of the CGST Act 2017.

5. The applicant furnishes some facts relevant to the issue:

5.1. The applicant plans to import and supply Prepared Laboratory Reagents/PRS. The applicant is a science-based organization conceptualized to cater to the growing analytical and regulatory requirement of the pharmaceutical industries and to provide solutions to the new challenges in separations and purifications faced in the Pharmaceutical and Research Institutions worldwide. They intend to import Pharmaceutical Reference Standards (hereinafter also referred to as 'PRS') from various official pharmacopoeias like US Pharmacopoeia (USP), European Pharmacopeia (EDQM), British Pharmacopoeia (BP) or any other suitable pharmacopoeia and to further supply them to pharmaceutical companies in India.

5.2 PRS is in the nature of Prepared Laboratory Reagent and is a substance of known purity which is intended to be used exclusively for a specified analytical calibrating and referencing purposes. PRS is not used for detection or diagnosis and is not to be used as a drug as clearly stated on the label or accompanying certificate or literature. PRS is a reference analytical sample provided by the official global pharmacopoeias required to be used by the pharmaceutical manufacturers to confirm their product quality standards in conformity with the respective monographs prescribed. These official reference standards are global in nature and are required to be used by drug manufacturers to ensure that the quality of the medicines produced by them are in conformity with the respective monographs prescribed by these official pharmacopoeias. The drug manufacturing companies use these PRS in their laboratory tests on all drug substances for determining the purity of medicine and identification and quantification of pharmaceutical

impurities. PRS is classifiable as 'Prepared Laboratory Reagent' and is covered under Tariff Entry 3822 00 90 of the Customs Tariff Act. This classification is supported by the decision of Hon'ble CESTAT, Bangalore in the matter which is reported as **LGC Promochem India Pvt. Ltd. v. Commissioner of Customs & Service Tax, Bangalore [2016 (340) E.L.T. 406 (Tri. - Bang.)]**. This decision has been upheld by Hon'ble Supreme Court of India and reported in **2018 (360) E.L.T. A173 (S.C.)**.

5.3 The applicant submits that the classification of PRS under Tariff Item 3822 00 90 is undisputed and the present application has not been filed for clarification with regard to the classification of PRS. In the facts of the present case, the issue under consideration is the applicability of rate of tax on import and supply of the Prepared Laboratory Reagent classifiable under Tariff Item 3822 00 90, in terms of in terms of the Rate Notification No. 01/2017-CT (R) dated 28.06.2017.

5.4 The applicant submits that the only entry in the Rate Notification which covers the goods falling under Chapter Heading 3822 being 'Diagnostic Kits and Reagents' is Entry No. 80 of Schedule-II, which provides for the rate of GST at 12%. The relevant entry reads as follows:

Schedule-II –12%		
S. No.	**Chapter/ Heading/ Sub-heading/ Tariff item**	**Description of Goods**
80	3822	All diagnostic kits and reagents

In the alternative, Entry No. 453 to Schedule-III, a residuary entry, provides applicable rate of GST @ 18% on all goods that are not specified in Schedule I, II, IV, V or VI. The relevant entry reads as follows:

Schedule-III –18%		
S. No.	**Chapter/ Heading/ Sub-heading/ Tariff item**	**Description of Goods**
453	Any Chapter	Goods which are not specified in Schedule I, II, IV, V or VI

5.5 In the above factual matrix, the applicant seeks clarity on whether the PRS classifiable under Tariff Item 3822 00 90 shall be covered under Entry No. 80 of Schedule II to Notification No.1/2017-Integrated Tax (Rate) dated 28.06.2017 (as amended) which covers 'All diagnostic kits and reagents' falling under Chapter Heading 3822, and thus subject to 12% rate of Integrated Tax. This application is being filed under the apprehension that the PRS intended to be imported and intended to be supplied by the applicant could be treated by the department as falling under Entry No. 453 of Schedule III to Notification No.1/2017-Integrated Tax (Rate) dated 28.06.2017 (as amended) which covers goods of any Chapter which are not specified in Schedule I, II, IV, V or VI and consequentially subject to higher rate of tax at 18%.

5.6 Chapter 38 of the Customs Tariff Act, 1975 *(hereinafter referred to as 'CTA')* provides for classification of *"Miscellaneous chemical products"*.Chapter Heading 3822 covers *"Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 3002 or 3006; certified reference materials"*. The relevant portion of the Customs Tariff Act is extracted hereunder:

Tariff Item	Description of goods
3822	**Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 3002 or 3006; certified reference materials**
3822 00	- *Diagnostic or laboratory reagents on a backing, prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading 3002 or 3006; certified reference materials:*
	--- *For medical diagnosis:*
3822 00 11	---- Pregnancy confirmation reagents
3822 00 12	---- Reagents for diagnosing AIDS
3822 00 19	---- Other
3822 00 90	--- Other

5.7 It is submitted that Sub-heading 3822 00 covers the following goods:

- Diagnostic reagents on a backing;
- Laboratory reagents on a backing;
- Prepared diagnostic reagents on a backing, other than those of heading 3002 or 3006;
- Prepared diagnostic reagents without a backing, other than those of heading 3002 or 3006;
- Prepared laboratory reagents on a backing, other than those of heading 3002 or 3006;
- **Prepared laboratory reagents without a backing, other than those of heading 3002 or 3006**; and
- Certified reference materials.

5.8 The Harmonised System of Nomenclature (hereinafter referred to as 'HSN') Explanatory Notes at Page No. VI-3822-1 [Explanatory Notes – Sixth Edition (2017) Volume 2 – Sections VI – VIII – Chapters 29 -43] relates to Chapter Heading 38.22. Relevant portions of the HSN Explanatory Notes are extracted hereunder for ease of reference –

"This heading covers diagnostic or laboratory reagents on a backing, ***prepared diagnostic or laboratory reagents****, other than diagnostic reagents of heading 30.02 or diagnostic reagents designed to be administered to the patient and blood grouping reagents of heading 30.06. It also covers certified reference materials. Diagnostic reagents are used in the evaluation of physical, biophysical or biochemical processes and states in animals and humans; their functions based upon a measurable or observable change in the biological or chemical substances constituting the reagent. Prepared diagnostic reagents of this heading may be similar in function to those designed to be administered to patients (subheading 3006.30), with the exception that they are used for in vitro, rather than for in vivo, applications.* ***Prepared laboratory reagents include not only diagnostic reagents, but also other analytical reagents used for purposes other than detection or diagnosis.*** *Prepared diagnostic and laboratory reagents may be used in medical, veterinary, scientific or industrial laboratories, in hospitals, in industry, in the field or, in some cases, in the home.....*

The reagents of this heading should be clearly identifiable as being for use only as diagnostic or laboratory reagents. This must be clear from their composition, labelling, instructions for in vitro or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support).

[Emphasis supplied]

5.9 In the instant case, the goods intended to be imported *viz.* Pharmaceutical Reference Standards('PRS') is a *'prepared laboratory reagent without a backing'* with a label and proper instructions for its use.

5.10 Classification of goods covered under the First Schedule to the CTA is done as per the General Rules for Interpretation *(hereinafter referred to as 'GI Rules').* Rule 1 to GI Rules gives precedence to the Section or Chapter Notes while classifying a product. For the legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require. As per Rule 1 of the GI Rules, classification is to be determined only on the basis of description of the heading, read with relevant Section or Chapter Notes. Further, in terms of Rule 3(a) of the GI Rules, the heading which provides the most specific description shall be preferred to headings providing a more general description. Therefore, in terms of Rule 1 read with Rule 3(a) of the GI Rules, the Pharmaceutical Reference Standards ('PRS') is appropriately classifiable under Chapter Heading 3822 of the CTA.

5.11 The applicant intends to classify PRS as a *'prepared laboratory reagent without a backing'*, under Tariff Entry 3822 00 90, in line with the decision of the Hon'ble CESTAT Bangalore in the matter of **LGC Promochem India Pvt. Ltd. v. Commissioner of Customs & Service Tax, Bangalore [2016 (340) E.L.T. 406 (Tri. - Bang.)]** has held the following:

> ***"7.7*** *In our considered view, the Pharmaceutical Reference Standard are required for analytical measurement which depend on many variable to provide data needed to make informed decisions. The quality of this data is as good as the Reference material used and high-quality Reference material are available only from the organizations with robust quality system viz. US Pharmacopoeia, British Pharmacopoeia, etc. The Reference Standard of the Organizations like United Standard Pharmacopoeia and British Pharmacopoeia instill confidence, as to that the products which are tested against the standard as laid down by these pharmacopeias would qualify to be used safely. On this background the goods imported by the main appellant are to be considered whether they are Pharmaceutical Reference Standards or otherwise. The phrase "Reference Standards" is not defined or described in Customs Act, 1962 or Customs Tariff Act that appeared to establish appropriate product description as early as in the year 2004, a particular reference seeking clarification on the description of "Pharmaceutical Reference Standards" was made to appropriate and competent authority in this matter, i.e., Drugs Controller General (India) under Directorate General of Health Services (Drug Division)who vide his letter reference No. X19014/10/04-D, dated 17-11-2004 stated as under :-*
>
> .....
>
> ***7.8*** *Plain reading of the above letter from the Drugs Controller General (India) would clearly indicate that the Reference Standards are substances required for analytical calibrating or referencing purpose which would be required to estimate the standard of the product manufactured or consumed by the clients of the main appellants. It is to be noted that based upon the above clarification, the Central Drug Testing Laboratory Mumbai vide letter No. 80/CDTL-M/2004-05/1469, dated 13-8-2004 clarified as under :-*
>
> .....
>
> ***7.9*** *Plain reading of both the communications from the competent authority to comment upon the issue seems to establish that intended use of Pharmaceutical Reference Standards, are Chemicals (Reagents) substance of known purity which are intended to be used exclusively for a specified analytical, calibrating or referencing purpose and the same should be stated on the label and or accompanying certificate or literature.*
>
> ***7.10*** *On perusal of the records, we find that the appellant had shown that the imported products, which had label and certificate of analysis from United State Pharmacopoeia convention indicating that Pharmaceutical Reference Standards is as per the standard laid down by them. It has to be noted that Pharmaceutical Reference Standards which are accompanied by the certificate issued by US*

Pharmacopoeia are distinctive product and gets classified under laboratory chemical or under Chapter Heading 3822 read with Chapter Notes of Chapter 38 as reproduced hereinabove. The conclusion that can be reached is that Pharmaceutical Reference Standard cannot be classified as certified Reference Materials and consequently not extending the scope of applicability of notification to products other than covered under Chapter Heading 28 and Chapter 29 is also not applicable.

[Emphasis supplied]

5.12 The Hon'ble CESTAT Bangalore in the above Final Order has held that the imported product *i.e.* 'Pharmaceutical Reference Standards', cannot be classified as Certified Reference Materials but the same are Chemicals (Reagents) substance of known purity which are intended to be used exclusively for a specified analytical, calibrating or referencing purpose and the same gets classified under laboratory chemical under the Chapter Heading 3822 of the CTH. Further the Hon'ble Supreme Court has affirmed the decision of the Hon'ble CESTAT Bangalore in the matter of **Commissioner of Customs & Service Tax, Bangalore v. LGC Promochem India Pvt. Ltd.** reported in **2018 (360) E.L.T. A173 (S.C.).**

5.13 The description under Entry No. 80 of Schedule II of the Rate Notification reads as *"All diagnostic kits and reagents"*. It is submitted that Entry No. 80 covers two types of goods: all diagnostic kits; **and** reagents.

5.14 The applicant submits that the meaning of the term ***'reagent'*** is wide enough to encompass both the diagnostic reagents as well as prepared laboratory reagent. As per the HSN Explanatory Notes to Chapter Heading 38.22, the term 'reagent' under Chapter Heading 3822 should be clearly identifiable as being for use only as diagnostic or laboratory reagents. It further provides that prepared laboratory reagents include not only diagnostic reagents, but also other analytical reagents used for purposes other than detection or diagnosis. Further, the HSN Explanatory Notes provides that reagents of this heading should be clearly identifiable as being for use only as diagnostic reagents or laboratory reagents which must be clear from their composition, labelling, instructions for in vitro or laboratory use, indication of the specific diagnostic test to be performed or physical form (e.g., presented on a backing or support). On a reading of the HSN Explanatory Notes with terms or words used in Entry 80 of Schedule II of the Rate Notification, the applicant states that the description - *"All diagnostic kits and reagents"* includes the following types of reagents-

(a) Diagnostic reagents on a backing;

(b) Laboratory reagents on a backing;

(c) Prepared diagnostic reagents on a backing, other than those of heading 3002 or 3006;

(d) Prepared diagnostic reagents without a backing, other than those of heading 3002 or 3006;

(e) Prepared laboratory reagents on a backing, other than those of heading 3002 or 3006; and

(f) **Prepared laboratory reagents without a backing, other than those of heading 3002 or 3006.**

As mentioned in ground A supra, the Pharmaceutical Reference Standards intended to be imported by the Applicant is 'Prepared laboratory reagents without a backing, other than those of heading 3002 or 3006' with a proper labelling and appropriate instructions for its use and iscovered under (f) *supra.* . and thus consequentially covered under the term 'reagent' in Entry No. 80 of Schedule II of the Rate Notification which read as *"All diagnostic kits and reagents"*. Accordingly, the intended import andsupply of *'Pharmaceutical Reference Standard'* would attract a levy of Integrated Tax at the rate of 12 per cent.

5.15 The applicant submits that the Entry No. 80 to Schedule-II of the Rate Notification reads as *"All diagnostic kits **and** reagents"*. It is submitted that as the term 'and' has used in the Entry No. 80, it has been used conjunctively to separate the words, 'All diagnostic kits' and 'Reagents'. Therefore, the term 'reagents' has to be treated as a separate word whose identity shall be separate from the words preceding it. The applicant submits that upon perusal of the description under Entry No. 80 to Schedule-II of the Rate Notification, it leads to a clear conclusion that the Entry covers reagents which may be either used in laboratory or for diagnosis. The applicant submits that there is no specific exclusion or qualification which has been used before the word 'reagent' in the Entry to evidence the exclusion of any particular type of 'reagent'. It is therefore submitted that in the absence of a specific exclusion or qualification to the term 'reagent', both laboratory reagents and diagnostic reagents shall be covered under Entry 80 of Schedule II of the Rate Notification.

5.16 The applicant further relies on the ruling of the Appellate Authority for the Advance Rulings in the case of **CHROMACHEMIE LABORATORY PVT. LTD. 2020 (34) G.S.T.L. 182 (App. A.A.R. - GST - Kar.)**

5.17 Therefore, the applicant submits that due to the reasons cited above, the goods in issue i.e., 'Pharmaceutical Reference Standard' classified under Tariff Item 3822 00 90 to CTA is covered under the specific Entry No. 80 to Schedule-II of the Rate Notification which reads as *"All diagnostic kits and reagents"*. Hence, vide this Entry, the intended import and supply of *'Pharmaceutical Reference Standard'* would attract a levy of Integrated Tax at the rate of 12 per cent.

VIRTUAL HEARING: / PROCEEDINGS HELD ON 28-01-2021

6. Sri. Dayananda, Chartered Accountant and Duly Authorized Representative of the applicant appeared for personal hearing proceedings held on 28.01.2021 and reiterated the facts narrated in their application

FINDINGS & DISCUSSION

7. At the outset we would like to make it clear that the provisions of CGST Act, 2017 and the KGST Act, 2017 are in *pari-materia* and have the same provisions in like matter and differ from each other only on a few specific provisions. Therefore, unless a mention is particularly made to such dissimilar provisions, a reference to the CGST Act would also mean reference to the corresponding similar provisions in the KGST Act.

8. We have considered the submissions made by the applicant in their application for advance ruling as well as the submissions made by applicant and his authorized representatives during the hearing.

9. We observe that the facts of the case are identical to the ruling passed by this authority in the case of M/s. Chromachemie Laboratory Pvt. Ltd., vide Order No. KAR ADRG 71/2019 dated 23.09.2019, wherein it was ruled that Entry. No. 80 of Schedule II to Notification No. 01/2017-Central Tax (Rate) dated 28.06.2017 is not applicable to prepared laboratory reagents. The Karnataka Appellate Authority of Advance Ruling, while disposing the appeal filed by M/s. Chromachemie Laboratory Pvt. Ltd., has set aside the aforesaid ruling vide order No. KAR/AAAR-08/2019-20 dated 14.01.2020. The relevant portion of the order is quoted below:

> ***18.*** *The interpretation given by the Authority for Advance Ruling that the entry Sl. No. 80 covers only diagnostic kits and diagnostic reagents is not correct. The principle of ejusdem generis applied by the Authority in interpreting the entry Sl. No. 80 is misconstrued. The rule of ejusdem generis applies when (1) the statute contains an enumeration of specific words; (2) the subjects of enumeration constitute a class or category; (3) that class or category is not exhausted by the enumeration; (4) the general terms follow the enumeration; and (5) there is no indication of a different legislative intent. In the instant case, the words used in the entry Sl. No. 80 of Schedule II "diagnostic kits and reagents" are of one class of goods falling under Chapter Heading 3822 of the Customs Tariff. However, the general word "All" is preceding the enumeration and does not follow the enumeration. The rule of ejusdem generis has no inverse application. General words preceding the enumeration are not governed by this rule. Further, the phrase "All diagnostic kits and reagents" brings within its fold the entire range of diagnostic and laboratory reagents which have been listed in (a) to (f) of Para 16 above. There is no scope for bringing within its ambit other goods since the phrase is exhaustive in its enumeration. We also find that the Fitment Committee which was mandated to recommend suitable GST rates for goods, have, after taking into consideration the indirect tax rates which were in existence, recommended a rate of 12% for "Diagnostic or laboratory reagents". This recommendation has been implemented by entry Sl. No. 80 of Schedule II of Notification No. 1/2017-C.T./I.T. (R), dated 28-6-2017. It is evident from the recommendations of the Fitment Committee that the legislative intent was to reduce the GST rate on all reagents from the rate which was prevalent in the earlier tax regime. Therefore, we are of the view that the principle of ejusdem generis has no application in this case and all reagents which are covered under Heading 3822 would be covered under Sl. No. 80 of Schedule II of the rate Notification.*

Authority For Advance Ruling ★ Karnataka, Bengaluru ★

Kaustubha