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Tax alert: CAAR Ruling holds Active Pharmaceutical Ingredients imported for clinical trials, eligible for lower rate of IGST

20 April 2026

India's Customs and indirect tax framework governing the import of Active Pharmaceutical Ingredients ('APIs') has historically been affected by interpretational divergences, particularly where imports occur for non-commercial purposes such as clinical trials, bioavailability studies, or bioequivalence assessments. Against this backdrop, the Customs Authority for Advance Rulings ('CAAR'), Mumbai, in its ruling involving imports made by Cipla Limited (hereinafter referred to as "the applicant"), has examined the scope of Sl. No. 226 of Schedule I as per Notification No. 9/2025-Integrated Tax (Rate) dated 17th September 2025. the Authority ruled that the language of Sl. No. 226—extending to goods falling under "Chapter 30 or any Chapter"—clearly brings APIs within its scope irrespective of their tariff classification. So APIs attract IGST at the rate of 5%, including those imported for clinical trials, bioavailability or bioequivalence studies, unless they fall within a specifically NIL-rated entry.

In a nutshell

APIs/bulk drugs retain their statutory identity as "drugs" irrespective of whether they are imported for manufacture, clinical trials, bioavailability studies, or bioequivalence testing.

The definition of "drug" under Section 3(b) of the Drugs and Cosmetics Act, 1940 is inclusive and covers APIs as substances intended to be used in the diagnosis, treatment, mitigation, or prevention of disease.

APIs are usually classifiable under general tariffs of Chapter 28 or 29 are nevertheless covered under "any chapter" in Sl. No. 226 of Schedule I to Notification No. 9/2025-Integrated Tax (Rate) dated 17th September 2025.

SL. No. 226 is a specific entry for "all drugs and medicines" and therefore overrides general entries as under Chapter 28 and 29.

The CAAR held that APIs imported by the applicant qualify as "drugs" under Sl. No. 226 of Notification No. 9/2025-Integrated Tax (Rate), and accordingly attract IGST at 5%, unless specifically covered under the NIL-rated entry at Sl. No. 113 of Notification No. 10/2025 dated 17th September 2025.

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Facts in brief

The applicant imported bulk drugs/APIs for manufacture aswell as for use in clinical trials, bioavailability and bioequivalence studies. While the APIs are classifiable under Chapters 28 or 29 of the Customs Tariff Act, 1975 – the applicant took advantage of broader scope of Sl. No. 226 of Schedule I, availing a lower rate of tax as per NT No. 9/2025-Integrated Tax (Rate). The Revenue authorities disputed the benefit of availing lower rate of tax, particularly where the imports were intended for clinical research, and sought to treat such APIs as generic chemical products attracting a higher rate of IGST.

The applicant therefore approached the CAAR Mumbai, seeking a ruling on whether bulk drugs/APIs, including those imported for analytical testing, clinical trials, bioavailability or bioequivalence studies, would qualify as "drugs" under Sl. No. 226 as per Notification No. 9/2025, attracting a lower rate of tax.

Arguments by the Applicant

The applicant submitted that the bulk drugs imported being APIs, are statutorily recognised as "drugs" in terms of Section 3(b) of the Drugs and Cosmetics Act, 1940 read with New Drugs and Clinical Trials Rules, 2019 and it includes substances intended for use as components of a drug. The applicant contended that APIs are regulated as drugs under the Drugs (Price Control) Order, 2013. Such drugs are imported only upon obtaining requisite licences from the Central Drugs Standard Control Organization ('CDSCO'), including grant of license to import vide Form 10 and Form CT-17, which has been duly fulfilled. Further, the applicant argued that such regulatory recognition conclusively establishes the intrinsic statutory character of APIs as drugs, irrespective of whether they are imported for manufacture of formulations or for clinical trials, bioavailability or bioequivalence studies.

Considering the above, the applicant thus relied on Sl. No. 226 of Schedule I to Notification No. 9/2025-Integrated Tax (Rate), that broadly covers all drugs and medicines. The applicant stated that the entry is specific, description-based and shall prevail over SL. No 35 or 36 of Schedule II to the said Notification, charging a higher rate of tax. It was argued that the wording of the entry does not restrict its scope for finished formulations or drugs for final consumption, and any attempt to draw a distinction based on end-use would render parts of the entry redundant. Reliance was also placed on judicial precedents and on various advance rulings holding that, in the absence of restrictive language, the expression "drugs" includes bulk drugs, and that APIs do not lose their character as drugs merely because they are imported for testing or clinical research purposes.

CAAR's observations and findings

- Some of the important observations and findings of the Customs Authority for Advance Rulings (CAAR), Mumbai, as recorded in its ruling dated 17 March 2026, are as follows:
  - The Authority observed that the central issue for determination was not the tariff classification of the subject goods under Chapter 28 or 29, which was undisputed, but the applicable rate of IGST, specifically whether the imported APIs qualify as "drugs", as classifiable under Sl. No. 226 of Schedule I to Notification No. 9/2025-Integrated Tax (Rate).
  - The Authority noticed that the expression "drugs" is not defined either under Goods & Service Tax Act or Customs Tariff Act nor an explanation is brought in the notification. In such circumstances, it held that recourse must be made to the statute governing the goods, namely the Drugs and Cosmetics Act, 1940. On examining Section 3(b) of the said Act, the Authority found that the definition of "drug" is wide and inclusive, and expressly covers substances intended for use as components of a drug, thereby squarely encompassing APIs.
  - On a conjoint reading of the definition of "bulk drug / API" under the Drugs (Price Control) Order, 2013, with the definition of "drug" under the Drugs and Cosmetics Act, 1940, the Authority observed that APIs are pharmaceutical substances used either as such or as active ingredients in formulations and

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therefore retain their statutory character as drugs at all stages of use.

- The Authority observed that APIs imported for testing, bioavailability studies, bioequivalence studies or clinical trials do not lose their character as drugs, merely on account of such interim or developmental use. It noted that such activities are an integral and mandatory part of the drug development and approval process under the New Drugs and Clinical Trials Rules, 2019, and do not alter the essential nature of the goods.
- Significant reliance was placed on the fact that APIs are regulated and licensed as drugs by the Central Drugs Standard Control Organization (CDSCO), including imports effected under Forms 10 and CT-17. The Authority held that such regulatory recognition reinforces the statutory identity of APIs as drugs for tax purposes as well.
- Interpreting Sl. No. 226, the Authority observed that the entry is description-based and not chapter-based. The deliberate use of the expression "or any Chapter" was held to demonstrate legislative intent to extend the benefit beyond finished formulations classifiable under Chapter 30, and to cover drug substances classifiable under other chapters, including Chapters 28 and 29.
- The Authority further emphasised the principle that a specific entry prevails over a general one (*generalia specialibus non derogant*), holding that Sl. No. 226, being a specific entry classifying goods by their essential character as drugs, must override the general entries pertaining to organic and inorganic chemicals under Chapters 28 and 29.
- Relying on judicial precedents and advance rulings, authorities have consistently held that in the absence of restrictive language in the notification, no artificial distinction can be drawn between bulk drugs and finished drugs. Thus, the expression "drugs" is wide enough to include bulk drugs.
- The Authority rejected the department's argument that APIs imported for clinical trials or research purposes fall outside the scope of Sl. No. 226, holding that end-use at a particular stage cannot override the statutory definition and essential character of the goods.

Ratio of the Ruling

The CAAR held that bulk drugs and APIs qualify as "drugs" and are appropriately classified under Sl. No. 226 of Schedule I to Notification No. 9/2025–Integrated Tax (Rate). Invoking the principle of generalia specialibus non derogant, the Authority ruled that the specific entry covering "all drugs and medicines" would prevail over the general tariff entries relating to organic and inorganic chemicals under Chapter 28 or 29. It further noted that the language of Sl. No. 226—extending to goods falling under "Chapter 30 or any Chapter"—clearly brings APIs within its scope irrespective of their tariff classification. Consequently, APIs attract IGST at the rate of 5%, including those imported for clinical trials, bioavailability or bioequivalence studies, unless they fall within a specifically NIL-rated entry.

Way Forward

The CAAR ruling provides meaningful certainty for the pharmaceutical sector, particularly for entities involved in drug research, clinical development and regulatory approvals. By affirming that bulk drugs / APIs retain their character as "drugs" irrespective of their stage of use, the ruling significantly mitigates the risk of beneficial rate denial on APIs imported for clinical trials, bioavailability or bioequivalence studies.

Although this ruling is binding on the parties involved, it however strengthens the industry's position to legitimately avail lower rate of IGST at 5% on API imports under Sl. No. 226, even where such imports are intended for non-commercial research purposes. It is advisable that importers may consider seeking advance rulings to secure binding certainty for future imports, opting for provisional assessment where disputes remain live, and evaluating refund opportunities for past imports where higher IGST may have been paid due to restrictive departmental interpretations.

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