GOVERNMENT OF PAKISTAN
COLLECTORATE OF CUSTOMS APPRAISEMENT (EAST)
CUSTOM HOUSE, KARACHI.

C-38/KAPE/DC/PCT/2025 Dated.15.12. 2025

PUBLIC NOTICE NO.17 /2025

SUBJECT: **CLASSFICATION OF '6-AMINO PENICILLANIC ACID (6-APA)'**

The Collectorate of Customs Appraisement (West), Karachi has forwarded a reference Si/Misc/130/2025 Group-II dated 07.08.2025 for determination of correct classification of "**6-AMINO PENICILLANIC ACID (6-APA)**".

(A). Background of the Dispute:

2. Brief facts as reported by the referring Collectorate are that M/s Pharmagen Limited imported consignment vide GD KAPW-HC-210989-30-06-2025 declared to contain "**6-AMINO PENICILLANIC ACID (6-APA)**" under PCT heading 2934.9990. The Collectorate of Customs (Enforcement), Karachi on receipt of credible information blocked the consignment which was examined and goods were referred to Custom House Laboratory for test and analysis. The Custom House Laboratory vide letter No.CF/R/27/25 dated 08.07.2025 reported the goods to be '6-Amino Penicillanic Acid (6-APA) (*An active derivative of Penicillin*)'. Therefore in view of lab report, and Explanatory Notes to HS 29.41, the Collectorate classified the imported item 6-Amino Pencillanic Acid (6-APA) under PCT heading 2941.1000 being Penicillin and its derivatives. Similarly, another GD No.KAPW-HC-4875-09-07-2025 imported by M/s.Zafa Pharmaceutical Laboratories (Pvt) Limited said to contain 6-APA under PCT heading 2934.9990 was blocked by Collectorate of Customs (Enforcement), Karachi and being identical case, the matter along with earlier reference was again forwarded vide letter No. Si/Misc/149/2025 dated 08.08.2025 to Classification Committee to determine appropriate PCT heading after clubbing both the cases.

(B). Importer's Point of View:

3. The importer's contention is that the subject goods are classifiable under PCT heading 2934.9990 on the following grounds:-

a) *The product under reference, 6-Aminopenicillanic Acid (commonly known as 6-APA), is an intermediate complexity molecule. The complexity of chemical compounds is determined by their functional groups and basic structure (chain or ring). The*

Usman Asghar
Chief (TPS)

addition or absence of such groups fundamentally changes their physical and chemical properties.

b) *6-APA constitutes the core B-lactam nucleus, which is the chemical skeleton and building block for many antibiotics such as amoxicillin, ampicillin, oxacillin, and carbenicillin. The expert opinion of HEJ also confirms this position."*

c) *However, 6-APA lacks the necessary functional groups that impart antibiotic properties. It serves only as an intermediate and precursor.*

d) *Beta-lactam antibiotics (penicillins, cephalosporins, penems, carbacephems, monobactams) share a beta-lactam ring structure with variable side chains that confer antibacterial activity. As of date, the FDA has approved over 34 such compounds as active ingredients.*

e) *Effective antibiotics must destroy bacteria or inhibit their growth at microgram concentrations in blood. 6-APA, having weak antibacterial activity, cannot be used as an antibiotic in its present form. Only after molecular modification with functional side groups does it transform into an active antibiotic.*

f) *The Exclusion Clause (b) to HS 2941 [EN, Page VI-2941-2] states:*
"Chemically defined organic compounds with very low antibiotic activity, used as intermediates in the manufacture of antibiotics". Thus 6-APA stands excluded from HS code 2941 because

- *It lacks essential functional groups for anti-bacterial efficacy.*
- *It has only weak activity and cannot serve as an antibiotic.*
- *It is an intermediate not a finished anti-biotic.*

Accordingly, 6-APA is rightly classifiable under PCT 2934.9990. Cross Ruling NY864585 specifically classifies 6-APA (CAS 551-16-6) under Subheading 2934.90.5000.

g) *The Explanatory Notes (VI-2941-1) define anti-biotics as substance secreted by living organism that*

(i) Kill or inhibit microorganisms.
(ii) Have powerful inhibitory effects on pathogens.
(iii) Are effective at microgram concentration in blood. Test reports establish that
(i) 6-APA shows weak anti-bacterial activity.
(ii) It has no powerful inhibitory effect on pathogens.

(iii) If used it would require KG quantities instead of microgram levels rendering it in effective as antibiotic. Therefore, it remains classifiable under HS 2934.9990 as a beta lactum intermediate compound.

(C) Department Point of View:

(i) The Department is of the view that imported item i.e. 6-Amino Pencillianic Acid (6-APA) is rightly classifiable under PCT heading 2941.1000 being Penicillin and their derivative. The Custom House laboratory mentions that 6-APA is an active derivative of penicillin. Further, the relevant portion of the Explanatory Notes to heading 29.41 is reproduced as under:

"*In this heading the term "derivatives" refer to active antibiotic compounds which could be obtained from a compound of this heading and which retains the essential characteristics of the parent compound including its basic structure.*"

(ii) The Explanatory notes to subheading 2941.10 further clarify the inclusion of 6-APA (6-Amino Penicillanic Acid) which is re-produced as under:-

This sub-heading includes all Pencillans, that is, all active antibiotic compounds whose molecules contain the penin or 6-aminopenteillunie acid skeleton of a beta lactam of amino (J-carboxy-5, 5-dimethylblazolidin-2-yI (t) acetic acid, In which amine group of the lactam ring attached to organics acids by amide bond neither the structure of these organic acids nor the salt formation or other substitution on the carboxyl group of the thlazolldine ring, effect the classification. However, the basic structure of the penin (skeleton) should remain unmodified.

(iii) The Explanatory Notes to heading 29.34 provides that nucleic acids and their salts are complex compounds which when combined with proteins, form the nucleon-proteins found in the nuclei of animal and vegetable cells. They are combination of phosphoric acids with sugar and pyrimidine or purine compounds, generally in the form of white powder, soluble in water, however, a the custom house lab report says the imported goods are "insoluble in water". In addition, the EN also provides that they heterocyclic compound covered under heading 29.34 are compounds containing an unfused thiazole ring (whether or not hydrogenated) in the structure. Whereas the Custom House lab has provided the chemical structure which shows that the imported item has

fused thiazole ring. In light of this explanation, the imported product do not tall under HS 29.34.

(iv) On the basis of the test report and Explanatory Notes to the heading 2941 has thus interpreted that 6-APA being active derivative of natural penicillin having a penicillanic acid structure, a chemical structure that is specified in the heading 2941.1000 and does not fall in any earlier headings, therefore, the said item does not fall in the declared heading i.e. 2934.9990.
Since 6-APA has a pencillianic acid structure, as confirmed by the Custom House laboratory, which is specified in PCT heading 2941.1000, the said item does not qualify for any exclusion to the PCT heading 2941.1000 based on the level of antibiotic activity.

(v) The report further confirms the identity and structure on further clarification sought from Incharge Lab HEJ vide letter No.SI/MISC/130/2025 dated 12.08.2025 as below:-

(i) Antibiotic activity: Antibacterial susceptibility test of 6-Aminopenicillanic acid was performed, against a specific bacterial strain i.e. Staphylococcus aureus and Excherichia coli. The antibiotics Amoxicillin and Ampicillin are used as reference standards. The results showed that the 6-Aminopenicillanic acid (G-APA) has significant low minimum inhibit concentration (antibacterial activity) as compared to Amoxicillin and Ampicillin antibiotics. Chemical name of the given sample is 6-Aminopenicillanic Acid, commonly known as G-APA. It is a bicycle molecule consisting of a thiazolidine ring fused to a lactam ring, and free amino group at 6 position.

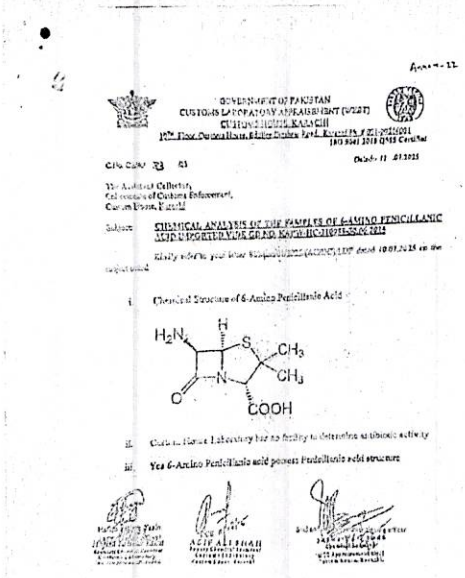
(ii) 6-APA is a key intermediate in the production of many semi-synthetic antibiotics. The addition of different acyl groups to the 6-amino group of 6-APA results in the formation of various penicillin. It is not finished product, it is intermediate of many antibiotics, such as amoxicillin, ampicillin, oxacillin, and carbenicillin.

(iii) 6-APA, or 6-aminopenicillanie acid, is a crucial intermediate in the production of various semi-synthetic penicillin and serves as the active nucleus for all penicillin. It's a key building block for synthesizing antibiotics like amoxicillin, ampicillin, oxacillin, and carbenicillin. It's produced from penicillin G, a natural penicillin, and is then modified to create a wide range of antibacterial drugs.

(iv) Yes, 6-aminopenicillanic acid (6-APA) is an important intermediate in the production of semi-synthetic antibiotics. It serves as a building block for various penicillin-based drugs, like amoxicillin, ampicillin, oxacillin & carbenicillian.

(D) Product Analysis:-

The lab reports are presented as below:-



GOVERNMENT OF PAKISTAN
CUSTOMS LABORATORY APPRAISEMENT (WEST)
CUSTOMS HOUSE, KARACHI

Subject: CHEMICAL ANALYSIS OF THE SAMPLES OF 6-AMINO PENICILLANIC ACID IMPORTED VIDE GD NO. KAPW-IIC-110987-30.06.2025

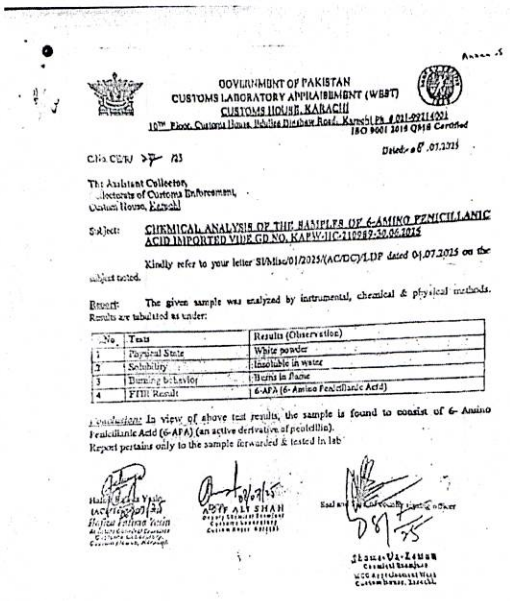
Kindly refer to your letter SUMisc/01/2025/(AC/DC)/LDP dated 10.07.2025 on the subject noted.

i. Chemical Structure of 6-Amino Penicillanic Acid

ii. Customs House Laboratory has no facility to determine antibiotic activity

iii. Yes 6-Amino Penicillanic acid possess Penicillanic acid structure

ACIP ALI SHAH



GOVERNMENT OF PAKISTAN
CUSTOMS LABORATORY APPRAISEMENT (WEST)
CUSTOMS HOUSE, KARACHI
10th Floor, Customs House, Polaris Darbar Road, Karachi PA # 021-99214021
ISO 9001 2015 QMS Certified

Dated: 08.07.2025

To: The Assistant Collector,
Directorate of Customs Enforcement,
Custom House, Karachi

Subject: CHEMICAL ANALYSIS OF THE SAMPLES OF 6-AMINO PENICILLANIC ACID IMPORTED VIDE GD NO. KAPW-IIC-110987-30.06.2025

Kindly refer to your letter SUMisc/01/2025/(AC/DC)/LDP dated 04.07.2025 on the subject noted.

Report: The given sample was analyzed by instrumental, chemical & physical methods. Results are tabulated as under:

No.	Tests	Results (Observation)
1	Physical State	White powder
2	Solubility	Insoluble in water
3	Burning behavior	Burns in flame
4	FTIR Result	6-APA (6- Amino Penicillanic Acid)

Conclusion: In view of above test results, the sample is found to consist of 6- Amino Penicillanic Acid (6-APA) (an active derivative of penicillin).
Report pertains only to the sample forwarded & tested in lab

ACIP ALI SHAH

Shams-Uz-Zaman

(E) Law and Analysis:

5. The Classification Committee considered the arguments and stance of both sides and examined the documents put forth and the relevant provisions of law dealing with the HS Classification. Classification of any imported goods under Pakistan Customs Tariff is determined under the General Rules for interpretation (GIR) of the First Schedule to the Customs Act, 1969. The Committee considered the PCT headings relied upon by the importers and the referring Collectorate which are reproduced for ease of reference:

PCT Heading	Terms of Heading
2934.9990	- - - Other
2941.1000	- Penicillin and their derivatives with a penicillanic acid structure; salts thereof
...	Any other relevant PCT Heading

6. The Classification Committee examined the proposed classifications in light of the Explanatory Notes to headings and the GIR and the following observations were made: -

a.) The Explanatory Notes to sub heading 2941.10 explains the criteria for inclusion by defining the penicillin in following words:

"This subheading includes all penicillins, that is, ***all active antibiotic compounds*** *whose molecules contain* ***the penin*** *or* ***6-aminopenicillanic acid skeleton of a ß-lactam of amino-(4-carboxy-5,5-dimethylthiazolidin-2-yl)acetic acid, in which the amine group of the lactam ring is attached to organic acids by an amide bond.*** *Neither the structure of these organic acids, nor the salt formation or other substitutions on the carboxyl group of the thiazolidine ring, affect the classification. However, the basic structure of penin (skeleton) should remain unmodified."*

This elaborates the structure of penicillin (all active antibiotic compounds) included in the heading 2941, which does not match with the structure of the subject good i.e. 6-APA.

The 6-APA is a pre-cursor which is used in industrial synthesis of various semi-synthetic antibiotics and it requires specific side chain attached to its **6-amino position** to confer the potent antibiotic properties as on its own it has **very low or negligible antibiotic activity**. It can qualify as penicillin **only with a specific acyl side chain** that would render it equivalent to natural penicillin. This position has also been further substantiated by the **HEJ Research Institute of Chemistry** in its report No.Nil dated 13.08.2025 (**Annex-A**) in response to Collectorate Letter No.SI/Misc/130/2025-Group-II dated 12.08.2025 which is reproduced as under: -

> **"Antibiotic activity: Antibacterial susceptibility test of 6-APA was performed against a specific bacterial strain i.e.*Staphyloccus and Escherichia coli.* The antibiotic Amoxicillin and Ampicillin are used as reference standards. The results showed that the 6-APA has significant *low minimum inhibit concentration (Antibacterial activity)* as compared to Amoxicillin and Ampicillin Antibiotics."**

This differentiation can be verified by the exclusion in General Explanatory notes of Heading 2941 which is reproduced as follows:

This heading does not cover:

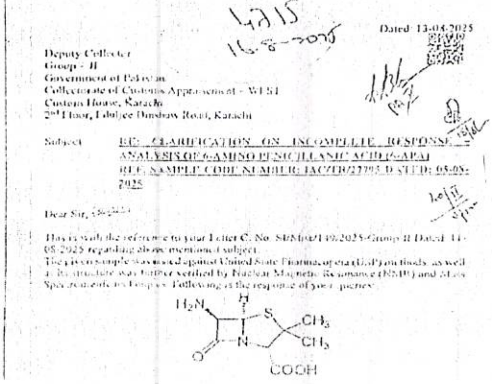
(b) Chemically defined organic compound with a very low antibiotic activity, used as intermediates in manufacture of antibiotics (earlier heading of this chapter according to structure).

b) Further references were obtained from *Dictionary of Organic Compound* that describes 6-APA as use in chemical synthesis of semi synthetic penicillin's lacking an acyl side chain therefore confirming its minimal intrinsic bioactivity compared to final penicillin products (*The attachment of a variable acyl group at the 6-amino position is necessary to create effective anti biotic compound*). The well-known encyclopedia of chemicals, drugs and biology "*The Merck Index*" refers 6-APA as the starting material for their synthesis distinguishing the pre-cursor from active drug. The *Ullmann Encyclopedia of Industrial Chemistry* 6-APA as a key raw material for semi-synthetic modifications for preparing antibiotics.

Therefore, inferring from a) and b) and getting strength from relevant Explanatory Notes to heading 2941, the classification committee is of the view that

a) As per above exclusion mentioned in Explanatory Notes to heading 2941, the **<u>chemically defined organic compounds with low antibiotic activity are excluded</u>** from this heading and are classifiable in earlier heading of this chapter according to structure i.e. in subject case 2934.9990 (Nucleic acid and their salts). Since the 6-APA lacks necessary specific side chain (acyl group) as confirmed from above lab reports, therefore in its present state, it cannot confer antibacterial characteristics. However, by adding different chemical side chains to the 6-APA nucleus, pharmacists can create variety of semi-synthetic antibiotics with improved antibacterial effects. Therefore, the classification committee is of the considered view that 6-APA is excluded from purview of heading 2941, as **<u>a unique chemical group</u>** must be attached to amino position (C-6) of the 6-APA nucleus **<u>to make it active antibiotic compound.</u>**

b) Furthermore, the heading notes for heading 2941 mentions that for 6-APA to be included in heading 2941, the free amine group of **<u>B-lactam ring has to be attached to organic acids by an amide bond</u>** which is absent in our case as confirmed from HEJ Lab reports 4546 dated 06.08.2025 and Number Nil dated 13.08.2025,**<u>as the amine group NH2 is free in subject 6-APA</u>**. The structural elaboration is as below: -


University of Karachi, Karachi 75270, Pakistan

4215
16-8-2025

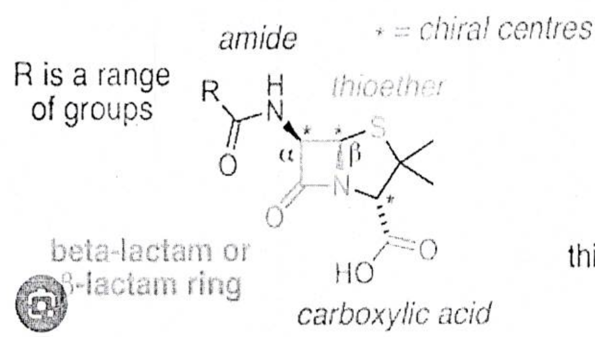
Dated: 13-08-2025

Deputy Collector
Group - II
Government of Pakistan
Collectorate of Customs Appraisement - WEST
Custom House, Karachi
2nd Floor, Eduljee Dinshaw Road, Karachi

Subject: RE: CLARIFICATION ON INCOMPLETE RESPONSE - ANALYSIS OF 6-AMINO PENICILLANIC ACID (6-APA) REF. SAMPLE CODE NUMBER: [illegible] DATED: 05-08-2025

Dear Sir,

This is with the reference to your Letter C. No. [illegible]/2025-Group II Dated 11-08-2025 regarding above mentioned subject.
The given sample was tested against United State Pharmacopeia (USP) methods as well as its structure was further verified by Nuclear Magnetic Resonance (NMR) and Mass Spectrometric techniques. Following is the response of your queries:



Therefore, R is free in subject 6-APA.Accordingly, the committee is of the view that "6-AMINO PENICILLANIC ACID (6-APA)" is classifiable under PCT heading 2934.9990.

Conclusion:

7. After thorough examination, the Classification Committee has determined in terms of GIR Rule 1 and Pakistan Rule 1, that "**6-AMINO PENICILLANIC ACID (6-APA)**" is classifiable under PCT heading 2934.9990.

8. The above classification determination is specific to the product whose details/ specifications have been given above. Further, the ruling is based on the documents and information provided by the referring Collectorate and shall be treated as annulled if it is found at any subsequent stage that the same was obtained by providing incorrect, false, misleading or incomplete information.

9. This Public Notice is issued in terms of Chapter-II (Classification) of CGO 02/2025 dated 24.03.2025 and any appeal against this determination/decision shall lie with the Board in terms of Rule 2 of the Pakistan Rules provided in the preamble of the First Schedule to the Customs Act, 1969.

-Sd-
(Ammara Durrani)
Additional Collector/
Secretary to the Classification Committee

Copy for information to:

1. Member (Customs-Policy), Federal Board of Revenue, Islamabad.
2. Member (Customs-Operations), Federal Board of Revenue, Islamabad.
3. Member (Customs-Legal & Accounting), Federal Board of Revenue, Islamabad.
4. Member (FATE), Federal Board of Revenue, Islamabad.
5. The Chief (Tariff & Trade), Federal Board of Revenue, Islamabad.
6. The Chief Collector of Customs (Appraisement) South, Custom House, Karachi.
7. The Chief Collector of Customs (Enforcement) Islamabad.
8. The Chief Collector of Customs (Exports / IOCO), Custom House, Karachi.
9. The Chief Collector of Customs (Appraisement) Central, Custom House, Lahore.
10. The Chief Collector of Customs (North), Custom House, Islamabad.
11. The Chief Collector of Customs (Khyber Pakhtunkhwa), Custom House, Peshawar.
12. The Chief Collector of Customs (Baluchistan), Custom House, Quetta.
13. The Secretary (Tariff -I), Federal Board of Revenue, Islamabad
14. All Collectors / Directors of Customs.

15. The Karachi Chamber of Commerce & Industry, Karachi.
16. The Federation of Pakistan Chambers of Commerce and Industry, Karachi.
17. The Karachi Customs Agents Association, Karachi.
18. Rizwan Ali Kaim,M/s Pharmagen Ltd,Business Arcade Suit 107,Ist Floor, Plot 27, Block-6 PECHS, Karachi.
19. ZAFA Pharmaceutical Laboratories (Private) Ltd. L/1 B, Sohrab Goth Flyover, Federal-B Area Block 21 Industrial Area, Karachi, 75950
20. The Collector, Collectorate of Customs (Enforcement), Karachi.
21. Notice Board.

(Ammara Durrani)
Additional Collector/
Secretary to the Classification Committee