



कर्मचारी राज्य बीमा निगम  
(श्रम एवं रोजगार मंत्रालय, भारत सरकार)  
EMPLOYEES' STATE INSURANCE CORPORATION  
(Ministry of Labour & Employment, Govt. of India)



मुख्यालय/HEADQUARTERS  
पंचदीप भवन, सी.आई.जी. मार्ग, नई दिल्ली -110 002  
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002  
[www.esic.gov.in](http://www.esic.gov.in), ☎011-23604773, ✉gmc-rc@esic.nic.in

U-25/12/NSQ/2023-MedV(E-178406) / 140

दिनांक: 08.04.2025

सेवा में,

**Director (Medical) Delhi / Director (Medical) Noida,  
Dean, All ESIC PGIMSR's, Medical & Dental Colleges  
Medical Superintendents - All ESIC Hospitals,  
Directors, ESI Scheme, All States**

**NSQ/02/2025**

**Subject: "Not of Standard Quality" on Testing - reg**

विषय: "परीक्षण पर "मानक गुणवत्ता का नहीं" - संबंध में।

महोदय/महोदया,

It is hereby informed that the Drug/item, procured through GeM Portal, has been reported as "Not of Standard Quality" on testing analysis as detailed below:

NSQ Reported by	Name of the Pharmaceutical Firm	Item Name/ Brand Name	RC No/ Item No	Batch No./ DOM/ DOE	Date of sampling/ Name of the Laboratory/ Report No. & Date/	Reason of NSQ
ESIC Hospital Tirunelveli, Tamil Nadu	M/s. Hindustan Antibiotics Ltd.	Amoxycillin and Potassium Clavulanate Tablets IP 625 mg	Procured through GeM	BT240491 01/05/2024 30/04/2026	Sample no- SJ/91/PK/24 dt. 19.11.2024 /Drug Testing Laboratory- Madurai, Govt. of Tamilnadu /R.No.- 3992/2024 dt. 13.01.2025	The Sample does not conform to IP Specification for <b>Amoxycillin and Potassium Clavulanate Tablets with respect to the content of Clavulanic Acid in Potassium Clavulante.</b>

**Contd to pre-page:**

In context to above, it is directed to:

1. Stop use of the reported batch of the above mentioned item immediately which has been reported as "Not of Standard Quality"(copy enclosed).
2. Stop the payment for the above said batch of the respective item.
3. Incident to be raised on GeM Portal and penal action w.r.t. replacement/recovery/testing charges etc. to be taken as per Terms & Conditions of GeM.

This issues with the approval of Medical Commissioner (Procurement).

भवदीय,

संलग्न: उपरोक्तानुसार

Digitally signed by

Sanjiv Kochhar

Date: 16-04-2025

15:37:10  
उप चिकित्सा आयुक्त (दर संविदा)

**Government of Tamilnadu**  
**Drugs Testing Laboratory – Madurai.**

REPORT NO: 3992 /2024

Form 13

[ See Rule 46]

Certificate of test or analysis by Government Analyst Under Section 25(1) of the Drugs and  
Cosmetics Act , 1940


- |  |   |                  |
|--|---|------------------|
| 1. Name of the inspector from whom received  | S.Jesin,<br>Drugs Inspector, Palayamkottai Range, Kanyakumari Zone,<br>O/o the Assistant Director of Drugs Control,<br>Kanyakumari Zone, Nagercoil-629001 |                  |
| 2. Serial No and Date of Inspectors Memorandum                                       | SJ/91/PK/24   | Date: 13-11-2024 |
| 3. Sample Number   | SJ/91/PK/24   |                  |
| 4. Date of Receipt   | 19-11-2024  |                  |
| 5. Name of Drug(s) purpoting to be contained<br>In the sample                        | Amoxycillin and Potassium Clavulanate Tablets IP 625 mg   |                  |
| 6. Composition :   | 1x10x10 Tablets   |                  |
| Each film coated tablet contains:  | B.No: BT240491  | M/D: 05/2024     |
| Amoxycillin Trihydrate IP  |   | E/D : 04/2026    |
| equivalent to Amoxycillin 500 mg   | Manufactured by:  |                  |
| Potassium Clavulanate Diluted IP   | Hindustan Antibiotics Ltd.,   |                  |
| equivalent to Clavulanic Acid 125 mg   | at: Village Saini Majra, Tehsil Nalagarh  |                  |
| Excipients q.s   | Dist. Solan (HP)- 174101  |                  |
| Colour: Titanium Dioxide IP  |   |                  |
| 7. Condition of seal on the package (packet or on portion<br>of Sample or container) | Seal intact and identical with the specimen impression<br>of the seal received from the Drug Inspector  |                  |
| 8. Result of test or analysis with protocols of test or analysis applied             |   |                  |

ANALYSIS DONE	RESULT OF ANALYSIS	LABEL CLAIM /
Nature of packing and Quantity of the sample received	Received 10 Aluminium foil Strips containing 10 tablets each with label claim printed on it and kept in an original carton	IP Specification 1x10x10 Tablets
Description	White coated tablets	Film coated tablets
Identification	Answers the identification test for Amoxycillin Trihydrate and Potassium Clavulanate	
Assay		
Estimation of	Each tablet is found to contain	Each tablet purports to contain
Amoxycillin (in Amoxycillin Trihydrate)	541.95 mg ( 108.4% )	500 mg
Clavulanic Acid (in Potassium Clavulanate)	102.96 mg ( 82.4% )	125 mg (IP Limit: 90% to 120% of label claim)

In the opinion of the undersigned , the sample referred to above is **Not of Standard Quality** as defined in the  
Drugs and Cosmetics Act, 1940 and rules there under.

**The Sample does not conform to IP Specification for Amoxycillin and Potassium Clavulanate Tablets  
with respect to the content of Clavulanic Acid in Potassium Clavulanate.**

Protocol of Analysis : IP (2022)Method  
Date: 13-01-2025

  
K. Alageswari  
Government Analyst

By Registered Post

Office of the Government Analyst,  
Drugs Testing Laboratory, Madurai-19.

Report No: 3992 /2024

Dated: 13-01-2025

Sub: Drugs - Drugs and Cosmetics Act 1940 and rules there under - sample of  
Drugs received for analysis and Report - Regarding.

Ref: Your Memorandum No.  
Sample Number

SJ/91/PK/24  
SJ/91/PK/24

Dt: 13-Nov-2024

Amoxycillin and Potassium Clavulanate Tablets IP 625 mg

1x10x10 Tablets

B.No: BT240491 M/D: 05/2024 E/D: 04/2026

Manufactured by:  
Hindustan Antibiotics Ltd.,  
at: Village Saini Majra, Tehsil Nalagarh  
Dist. Solan (HP)- 174101

is " NOT OF STANDARD QUALITY".

A certificate of analysis in triplicate is enclosed herewith for further action.



K. Alageswari  
Government Analyst

To  
S. Jesin,  
Drugs Inspector, Palayamkottai Range, Kanyakumari Zone,  
O/o the Assistant Director of Drugs Control,  
Kanyakumari Zone, Nagercoil-629001

Copy to:  
The Drugs Controller (India), New Delhi with a copy of the Report of Analysis.

Copy to:  
The Director of Drugs Control, Chennai-6 with a copy of the Report of Analysis.