



कर्मचारी राज्य बीमा निगम
(श्रम एवं रोज़गार 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
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U-25/12/NSQ/2023-MedV(E-178406) / 548
To

Date: 3/12/2024

Director (Medical) Delhi/Director (Medical) NOIDA

Dean, All ESIC PGIMSR's, Medical & Dental Colleges

Medical Superintendents-All ESIC Hospitals

Director, ESI Scheme-All States

NSQ/04/2024

विषय: "Not of Standard Quality" on Testing procured through GeM Portal-reg.

Sir/Madam,

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

NSQ Reported by	Name of the Pharmaceutical Firm	Item Name BrandName	RC No.	Batch no. DOM/ DOE	Date of sampling/ Name of the Laboratory/ Report No. & Date/	Reason of NSQ
MS, ESIC Hosp. Udyogamandal, Ernakulam, Kerala-683501	M/s. Hindustan Antibiotics Ltd	Amoxycillin and Potassium clavulanate Injection IP 1.2g	GeM item	D0092333B 07/2023 06/2025	Sample no-1707/24 dt. 26.10.2024 Test Dt - 05.11.2024 Office of the Asstt. Drugs Controller, Civil Station, Ernakulam- 682030 R.No.- SW.1051178/24/RDTL/1707 dt. 22.11.2024	Sample does not conform to IP 2022. This particular batch of sample fails the test Assay of Clavulanic Acid.

In context to the above, user units which have procured the above said item, Mfg. by M/s. Hindustan Antibiotics Ltd. through GeM Portal, are hereby directed to:

1. Immediately stop use of the reported batch of the "Not of Standard Quality" item (as above)
2. Stop the payment for the above said batches of the respective item immediately.
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.

यह पत्र, चिकित्सा आयुक्त (Procurement), क.रा.बी.निगम के अनुमोदन से जारी किया जाता है।

शुभेच्छु

Encl: As above

Signed by Neeta Garbiyal
Date: 03-12-2024 10:15:48
उप चिकित्सा आयुक्त (दर संविदा)

Copy for information to:

1. The Central Drugs Standard Control Organisation, DGHS, FDA Bhawan, ITO, Kotla Road-110002 (e-mail: dci@nic.in). (copies of Test Reports enclosed).
2. Office of Drug Controller (Kerela State), Red Cross Road, Vanchiyoor.P.O. Triruvananthapuram-695035 (e-mail: dc.drugs@kerala.gov.in) with the request to take appropriate action on 'NSQ' reported for the above said batches under intimation to this office (copies of Test Reports enclosed).
3. Chief Executive Officer (CEO), Government e-Marketplace, Jeevan Tara Building, 2nd Floor, Parliament Street, New Delhi-110001, (e-mail: ceo-gem@gov.in) (copies of Test Reports enclosed).
4. M/s. Hindustan Antibiotics Ltd, Reg. Office Pimpri, Pune - 411018 (e-mail md@halpune.in)
5. Website Content Manager with request for uploading on ESIC Website.
6. Guard File.

उप चिकित्सा आयुक्त (दर संविदा)

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 Inspector from whom received : Nisha Vincent
Drugs Inspector,
Office of the Asst. Drugs Controller,
Civil station, Ernakulam - 682030.
2. Serial No. and date of Inspector's memorandum : TOP PRIORITY/08/NV/10/24-ESIC
Dated :25/10/2024
3. Number of sample. : 1707/24
4. Date of Receipt. : 26/10/2024
5. Name of drugs purporting to be contained in the sample : Amoxicillin & Potassium Clavulanate
Injection IP 1200 mg
Batch No : D0092333B
Mfd. by: Hindustan Antibiotics Ltd,
(A Govt of India Enterprise) at Mauza Ogli,
Suketi Road, Kala - Amb, Distt. Sirmour-173030.

GOVT. SUPPLY
6. Condition of seals on the package. : Intact. compared with the specimen impression
of the seal sent separately and found to be identical.
7. Result of Test or analysis with protocols of test or analysis applied. : IP 2022

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 for the reasons given below:

NOT OF STANDARD QUALITY

Sample does not conform to IP 2022. This particular batch of sample fails the test Assay of Clavulanic Acid, hence declared as Not of Standard Quality.

Date : 22/11/2024
No : SW.1051162/24/RDTL
1707/24



Binu
Binu.KK
Government Analyst

- Copy to:- 1. The Drugs Controller, Kerala State, Thiruvananthapuram for information
2. The Drugs Controller, India, Directorate General of Health Services, New Delhi for Information.
3. Stock file

ANUSHA
27/10/24

ANUSHA.K.V
SENIOR PHARMACIST

Pharmacy
28/11/24
Pharmacy & State
Incharge

LABORATORY PROTOCOL

Protocol Number : 1707/24
Received from : Nisha Vincent
Drugs Inspector
Office of the Assistant Drugs Controller,
Civil Station, Eriakulam - 682030.

Date of Receipt : 26/10/2024
Date of Test : 05/11/2024
Completed on : 22/11/2024
Date of Report : 22/11/2024

Details of the Sample : Amoxicillin & Potassium Clavulanate Injection IP 1200 mg
Composition : Each vial contains Amoxicillin Sodium (Sterile) IP eq. to
Anhydrous Amoxicillin 1.00gm, Potassium Clavulanate (Sterile) IP
eq. to Clavulanic Acid 0.2 gm

Batch No : D0092333B
Date of Manufacture : 07/2023
Date of Expiry : 06/2025
Mfg./Rpg. Lic.No. : NL-MB/2021/291

Manufactured /Repacked by

Hindustan Antibiotics Ltd,
(A Govt of India Enterprise) at Mauza Ogli,
Suketi Road, Kala - Amb, Distt.Sirmour-173030.

GOVT. SUPPLY

Results / Calculations

Description : Off white powder.

Identification : Gives positive results for the presence of Amoxicillin Sodium and
Clavulanic acid.

pH : Complies with IP

Bacterial Endotoxins : Complies with IP

Water : Complies with IP

Particulate Matter : Complies with IP

Clarity of solution : Complies with IP

Sterility : Complies with IP

Assay : Each vial of average net weight contains Amoxicillin 1.007gm against the label claim
Amoxicillin Sodium (Sterile) IP eq. to Anhydrous Amoxicillin 1.00 g ie, 100.7% of
the stated amount and Clavulanic Acid 0.1509gm against the label claim Potassium
Clavulanate (Sterile) IP eq. to Clavulanic Acid 0.2gm ie, 75.5% of the stated amount.

IP Limit: Not less than 90.0 percent and not more than 107.5 percent of the stated amount of
of Amoxicillin and Clavulanic acid.



Binu

Binu.KK
Government Analyst

Anusha
22/11/24

ANUSHA.K.V
SENIOR PHARMACIST

Anusha
22/11/24
Pharmacy
Incharge

Sheet1

ESIC HOSPITAL, UDYOGAMANDAL											
Sl. No.	RC No:	Name of Pharmaceutical Firm	Name of Item	Item No: & Page No: as per RC	Drug License number & Place of production	Batch number	D.O Mfg & D. O Expiry	Date of sampling	Name of Laboratory / Govt.agency reporting the NSQ	Report No.	Date of report
1		Hindustan Antibiotic Ltd	Amoxycillin & Potassium clavulanate Inj; IP. 1200Mg		NL-MB/2021/291, Pune	D0092333B	07/23, 06/25	25-10-24	Regional Drugs Testing Laboratory, Ernakulam	SW.1051162/24/RDTL 1707/24	22-11-24
2		Bengal chemicals & Pharmaceuticals Ltd.	Amoxycillin & Potassium clavulanate Inj; IP. 1.2Mg		676-L-B(H), Kolkata	P292301	07/23, 06/25	25-10-24	Regional Drugs Testing Laboratory, Ernakulam	SW.1051178/24/RDTL 1708/24	22-11-24