



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, ☎011-23604773, ✉gmo-rc@esic.nic.in

U-25/12/NSQ/2023-MedV(E-178406) / 549

Dated: 29/11/2024
31/12/2024

To

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/05/2024

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/ Brand Name	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. Bengal Chemicals and Pharmaceuticals Ltd.	Amoxycillin and Potassium clavulanate Injection IP 1.2g	GeM item	P292301 07/2023 06/2025	Sample no-1708/24 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/1708 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. Bengal Chemicals & Pharmaceuticals Limited 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: 29-11-2024 18:59:27

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 (Kerala 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. Bengal Chemicals & Pharmaceuticals Limited, 6 Ganesh Chunder Avenue, Calcutta - 700 013 (e-mail: bcplmdsecretariat@gmail.com).
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/09/NV/10/24-ESIC
Dated :25/10/2024
3. Number of sample. : 1708/24
4. Date of Receipt. : 26/10/2024
5. Name of drugs purporting to be contained in the sample : Amoxycillin and Potassium Clavulanate
Injection IP 1.2g
Batch No : P292301
Mfd.by: Bengal Chemicals & Pharmaceuticals Ltd
(A Govt of India Enterprises) at 11 W.E.A,
Faridabad- 121 001(Haryana)
R.O: 6, Ganesh Chunder Avenue, Kolkata- 700013

GOVT/HOSPITAL 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 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.1051178/24/RDTL
1708/24



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
24/11/24
ANUSHA.K.V
SENIOR PHARMACIST

K. L.
28/11/24
Pharmacy Store
Incharge

LABORATORY PROTOCOL

Protocol Number : 1708/24
Received from : Nisha Vincent
Drugs Inspector
Office of the Assistant Drugs Controller,
Civil Station, Ernakulam - 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 and Potassium Clavulanate Injection IP 1.2g
1 vial + 1 Diluent Ampoule
Composition : Each vial contains Amoxicillin Sodium IP (Sterile) equivalent to
Amoxicillin 1000mg, Potassium Clavulanate (Anhydrous Basis) IP (Sterile)
equivalent to Clavulanic Acid 200 mg

Batch No : P292301
Date of Manufacture : 07/2023
Date of Expiry : 06/2025
Mfg./Rpg. Lic.No. : 676-L-B(H)

Manufactured /Repacked-by

Bengal Chemicals & Pharmaceuticals Ltd,
(A Govt of India Enterprise) at 11 W.E.A,
Faridabad- 121 001(Haryana)
R.O: 6, Ganesh Chunder Avenue, Kolkata- 700013

GOVT/HOSPITAL SUPPLY

Results / Calculations
Description : Off white powder.
Identification : Gives positive results for the presence of Amoxicillin and
Clavulanic acid.
pH : Complies with IP.
Bacterial Endotoxins : Complies with IP
Water : Complies with IP
Sterility : Complies with IP
Particulate Matter : Complies with IP
Clarity of solution : Complies with IP
Assay : Each vial of average net weight contains Amoxicillin 989.53 mg against the label claim
of Amoxicillin Sodium IP (Sterile) equivalent to Amoxicillin 1000 mg ie, 99.0% of the stated
amount and Clavulanic acid 151.74 mg against the label claim of Potassium Clavulanate
(Anhydrous Basis) IP (Sterile) equivalent to Clavulanic Acid, 200 mg
ie, 75.9% 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
27/11/24

ANUSHA.K.U
SENIOR PHARMACIST

Anusha
28/11/24
Pharmacy Store
message

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