कर्मचारी राज्य बीमा निगम
(श्रम एवं रोज़गार मन्त्रालय,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, dmc-rc@esic.nic.in

File No.:e-U-25/12/NSQ/2022-MedV(E-12328)/302 Dated: /05/2025

To,
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/05/2025

Subject: Declaration of Drug "Not of Standard Quality" on Testing - reg

Sir/Madam

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

NSQ Reported by	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No./ DOM/ DOE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
ESIC Model Hospital, Baddi, H.P	Zuventus Healthcare Limited,	Amoxycillin+ Clavulanate+ lactic Acid Bacillus Tab/Cap- Each Tab/Cap to contain: Amoxycillin Trihydrate Eqv. to Amoxycillin 500 mg, Clavulanate Potassium Eqv. to Clavulanic Acid 125mg, lactic Acid Bacillus - 60 Million Spores **Augpen LB 625**	157 1551a 22	ZO5AF24052 08/2024 01/2026	Government Analyst, Drug Testing Laboratory, Baddi, Distt. Solan (H.P)-173205 DHSR/DTL/Report/25-26-0887 Dated:13.05.2025	The sample does not conforms **to claim as per Patent & Proprietary in respect to the assay of Amoxycillin.**

In context to above, it is directed that:

1. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality" (copy enclosed).
2. Replacement of supplies or cost of the materials is to be recovered along with testing charges (if any) from the firm.
3. Initiate action as per clause for 'Testing of Drugs-Quality Control" of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC.
4. Maintain record of action taken at respective user units.

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Contd. to pre page:

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

Yours Faithfully,

Enclosures: As above

Digitally signed by
Sanjiv Kochhar
Date: 27-05-2025
12:09:58

Dy. Medical Commissioner (RC)

Copy to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi-110002 (dci@nic.in).
2. The State Drug Controller,Food and Drug Administration , Survey No. 341, 2nd Floor, Bandra Kurla Complex , Opposite RBI, Kala Nagar, Bandra East, Mumbai-400051 (whogmp.mahafda@gmail.com) with the request to take appropriate action on NSQ reported for the above said batch under information to this office (copy of test report enclosed) .
3. State Drug Controller,Controlling cum Licensing Authority, Baddi, Himachal Pradesh-173205 (Email:sdc4hp@gmail.com).
4. Food & Drug Administration,Gangtok,Sikkim-737101 (Email:-sikkimdrugcontrol@gmail.com)
5. M/s Zuventus Healthcare Limited,Zuventus House, Plot Y2,CTS No.358/A2, Near Nahur Railway Station, Nahar (West), Mumbai-400078 (Email-sheetal.khanvilkar@zuventus.com,Nilesh.Nabar@zuventus.com.in
6. M/s Zuventus Healthcare Limited, Kamerey bhasmay, elaka, pakyong Rangpo, East Sikkim-737131 (Email id:enquiry@zuventus.com)
7. Website Content Manager with request for uploading on ESIC website.
8. Guard file.

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 : Akshay Kumar, Drugs Inspector HQ Baddi

2. Serial No. and date of Inspectors memorandum : FDA/Sales-2024-480, Dated: 15/01/2025

3. Number of Sample : ESI/01

4. Date of receipt : 16/01/2025

5. Name of drugs purporting to be contained in the sample :

Sample Name	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
Amoxycillin, Potassium Clavulanate and Lactic Acid Bacillus Tablets **(AUGPEN-LB® 625)**	ZO5AF24052	08/2024	01/2026	Zuventus Healthcare Limited Kamerey Bhasmay, Elaka, Pakyong Rangpo, East Sikkim 737132, India.

6.Condition of seals on (The packet or on portion of sample or container) : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector.

7. Result of test or analysis with protocols of test or analysis applied for the Sample No LSD/DTL/0206/24-25

Composition: **Each Filmcoated tablet is purported to contains:**

Amoxycillin Trihydrate IP
Eq to Amoxycillin 500 mg
Potassium Clavulanate Diluted IP
Eq to Clavulanic Acid 125 mg
Lactic Acid Bacillus 60 million spores

Protocol Applied : Patent & Proprietary

Sr.No	Test Name	Result	Limits
1.	Description	Light Yellow coloured , Oval, biconvex, film coated tablet plain on both sides. Packed in alu-alu blister pack.	NA
2.	Identification		
(a)	By HPLC	Positive for Amoxycillin Trihydrate & Potassium Clavulanate.	NA
(b)	By Microscopically	Positive for Lactic acid Bacillus	
3.	Average Weight	1094.795 mg	NA
4.	Uniformity of weight	Complies	± 5.0%
5.	Disintegration Test	Complies	NMT 30 Minutes

Contd.....

Assay:

S. No	Ingredient Name	Found	Claim	% of Claim	Limits	Procedure/ Method
1.	Amoxycillin Trihydrate calculated as Amoxycillin	388.43 mg	500 mg	77.69 %	90% - 120%	DTL/STP/QC/081
2	Potassium Clavulanate Diluted calculated as Clavulanic Acid	126.45 mg	125 mg	101.16 %	90% - 120%	DTL/STP/QC/081
3.	Lactic acid Bacillus	67.52 million spores	60 million spores	112.53%	NLT 90%	DTL/STP/QC/081

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 reason given below:

The Sample does not conforms to claim as per Patent & Proprietary in respect to the Assay of Amoxycillin.

Date: 13/05/2025

Government Analyst:

Deepika Banyal
Government Analyst
Drugs Testing Laboratory, Baddi
Distt. Solan(H.P.) 173205

No. DHSR/DTL/Report/25-26- 0887

Dated: 13/05/2025

.....END OF REPORT.....