



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, ✉: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 conform 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.

e-U-25/12/NSQ/2022-MedV I(12328)**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
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@zuentus.com, Nilesh.Nabar@zuentus.com.in)
6. M/s Zuventus Healthcare Limited, Kamerey bhasmay, elaka, pakyong Rangpo, East Sikkim-737131 (Email id: enquiry@zuentus.com)
7. Website Content Manager with request for uploading on ESIC website.
8. Guard file.

Email**RCCell**

Fwd: Regarding Tab amoxicillin pottasium clavulanate and lactic acid bacillus tablet (Augpen LB 625) BATCH Z05AF 24052 MFG 8/26 AND EXP 1/26 " NOT OF STANDARD QUALITY

From : DMC RC <dmc-rc@esic.nic.in>

Wed, May 21, 2025 12:46 PM

Subject : Fwd: Regarding Tab amoxicillin pottasium clavulanate and lactic acid bacillus tablet (Augpen LB 625) BATCH Z05AF 24052 MFG 8/26 AND EXP 1/26 " NOT OF STANDARD QUALITY 2 attachments**To :** RCCell <rc-hqrs@esic.gov.in>**Reply To :** DMC RC <dmc-rc@esic.nic.in>

महोदय/महोदया,

उपरोक्त विषयांतर्गत आपके सादर सूचनार्थ एवं आवश्यक कार्रवाई हेतु संलग्नक प्रेषित है।

Please find herein attachment for your kind information & necessary action.

धन्यवाद,

उप चिकित्सा आयुक्त (आर सी व पीसी, शाखा ५)

क रा बी निगम मुख्यालय

VOIP No. 10011026

From: "S S" <ms-baddi.hp@esic.nic.in>**To:** "DMC RC" <dmc-rc@esic.nic.in>, "DMC Procurement" <dmc-procurement.hq@esic.gov.in>**Sent:** Wednesday, May 21, 2025 12:04:09 PM**Subject:** Regarding Tab amoxicillin pottasium clavulanate and lactic acid bacillus tablet (Augpen LB 625) BATCH Z05AF 24052 MFG 8/26 AND EXP 1/26 " NOT OF STANDARD QUALITY

महोदय/महोदया,

Sir/Madam,

उपरोक्त विषयांतर्गत आपके सादर सूचनार्थ एवं आवश्यक कार्रवाई हेतु संलग्नक प्रेषित है।

Please find herein attachment for your kind information & necessary action.

1

सादर धन्यवाद/Thanks & regards.....

चिकित्सा अधीक्षक/Medical superintendent,
क.रा.बी.निगम आदर्श अस्पताल, बद्दी (हि. प्र.)
ESIC Model Hospital, Baddi (H.P)

From: "ROHIT KAUSHIK" <dr.rohit.kaushik@esic.nic.in>
To: "S S" <ms-baddi.hp@esic.nic.in>
Cc: "Dr. Sugeet Tandon" <dr.sugeet.tandon@esic.nic.in>
Sent: Wednesday, May 21, 2025 11:10:03 AM
Subject: Regarding Tab amoxicillin pottasium clavulanate and lactic acid bacillus tablet (Augpen LB 625) BATCH Z05AF 24052 MFG 8/26 AND EXP 1/26 " NOT OF STANDARD QUALITY

Respected Madam,

Kindly find attachment of Letter To Dy Medical Commissioner (RC) regarding Tab amoxicillin pottasium clavulanate and lactic acid bacillus tablet (Augpen LB 625) BATCH Z05AF 24052 MFG 8/26 AND EXP 1/26 " NOT OF STANDARD QUALITY" , Now MS may like to see and if agree and send this letter to ESIC HQ Dy Medical Commissioner (RC) for further necessary action .

With Regards
Dr Rohit Kaushik
CMS
ESIC MH BADDI
H.P

 **dy commisioner.pdf**
134 KB

 **sample report.pdf**
721 KB



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



सत्यमेव जयते

आदर्श अस्पताल / Model Hospital
गाँव काठा, बद्दी, जिला सोलन, हिमाचल प्रदेश- 173205
Village-Katha, Baddi, District:Solan, Himachal Pradesh- 173205
Phone: 01795-275105, 275106, E.mail: ms-baddi.hp@esic.nic.in
Website: www.esic.nic.in/ www.esichospitals.gov.in/ www.esic.in

EComp. No.:226898 226898 File No.:142/U-16/02/16/Testingofdrugs/Pharmacy ..

Date-19/05/2025

To
Dy. Medical Commissioner (rate contract)
ESIC Panchdeep Bhawan,
Comrade Inderjeet Gupta (CIG) Marg.
New Delhi-110002

Sub-Regarding Not Of Standard quality of the sample amoxycillin pottasium clavulanate and lactic acid bacillus tablet (Augpen LB 625 Tab).

Sir,

This is to inform you that the below-mentioned drug has been declared as " NOT OF STANDARD QUALITY" and it has been directed to stop use of the batch of the drug immediately by the drug inspector, Baddi, HP. vide letter Ref No.FDA/Sales-2025-56, mail received on Dated-19/05/25.

S . n o	Sam ple No .	Product (Name and content)	Batch No.	Mfg date, Expir y Date	RC No	Mfd. by	Report No. & Date	NSQ Re ported b y
1	ESI/01	(Augpen LB 625 Tab). Amoxycillin+Clavulanate +Lactic Acid Bacillus Tab /Cap- Each Tab/Cap to contain: Amoxycillin Trihydrate Eqv. to Amoxy cillin 500mg, Clavulanat e Potassium Eqv. to Clav ulanic Acid 125mg, lactic Acid Bacillus - 60 Million Spores-AUGPEN LB 625	Z05AF 24052	8/24, 01/26	157	Zuventus Healt hcare Limited, kemerey Bhas my, elka,Pakyo ng, Rangpo, Ea st Sikkim, 737132	No. DH SR/DTL / Report/ 25-26-0 887	Drug Insp ector O/o State Drug Cont roller Baddi, Dis tt. Solan Himachal Pradesh

Sample taken on Date-15/01/2025

The report is attached for your information and further necessary action.

This has also been intimated to the firm and O/o State Drug Controller, Baddi, HP.

This letter is Approved and Signed after Approval by Competent Authority.

Rohit Kaushik, IMO-CMS-RK, Central Medical Store
21-05-2025

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
Amoxicillin, 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 : Seals were intact & identical to the specimen
 (The packet or on portion of sample or container) 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:

Amoxicillin Trihydrate	IP	
Eq to Amoxicillin		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 Amoxicillin 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.	Amoxicillin Trihydrate calculated as Amoxicillin	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 conform to claim as per Patent & Proprietary in respect to the Assay of Amoxicillin.

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.....

Health and Family Welfare Department Himachal Pradesh

Ref.:-

ADA/Soln-2025-56

From

Drug Inspector,
HQ Baddi, Distt. Solan H.P.

TO

ESIC Model Hospital,
Katha Baddi, Distt. Solan H.P.

Subject: - Regarding Not of standard quality declaration of the sample of Amoxicillin Pottasium Clavulanate and Lactic Acid Bacillus Tablets, Batch No. ZO5AF24052, Mfg date 08/2024 & Exp. Date 01/2026 Manufacturing by M/s Zuventus Healthcare Limited Kamerey Bhasmay, Elaka, Pakyong Rangpo, East Sikkim 737132.

Memo,

A sample of Amoxicillin Pottasium Clavulanate and Lactic Acid Bacillus Tablets, Batch No. ZO5AF24052, Mfg date 08/2024 & Exp. Date 01/2026 Manufacturing by M/s Zuventus Healthcare Limited Kamerey Bhasmay, Elaka, Pakyong Rangpo, East Sikkim 737132 was taken by Drug Inspector Baddi for the purpose of testing and analysis on 15.01.2025 from a premises ESIC Model Hospital Situated at Katha Baddi, Distt. Solan H.P. . The sample was sent to the DTL Baddi who was declared it as not of standard quality vide his report no. DHSR/DTL/Report/25-26-0887 dated 13.05.2025 for the reason cited in the report (Annexure-A original). You are directed to provide attested copy of purchase invoices of total quantity above said product & further to stop the distribution of said product. You reply in this regard should be submitted to this office in Seven days of receipt of this letter positively.

Akshay Kumar
Drug Inspector
H.Q. Baddi, Distt. Solan (H.P.)
Akshay Kumar
Drugs Inspector,
O/o State Drugs Controller,
Baddi, Distt. Solan Himachal Pradesh,