

WEB - UPLOAD



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) / 26

Dated:

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/2025/01**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 Report & NSQ
ESIC MC, PGIMSR & MH, Rajajinagar, Bangalore	M/s Overseas Healthcare Pvt Ltd	Azithromycin Syrup- Each 5 ml to contain Azithromycin 100 mg Azysafe	145C :1379 8	AZ1-206 10-2023 03-2025	Central Drugs Laboratory, Kolkata KOL/LS/2024- 25/1711 Dated.- 24.02.2025	The sample does not conform to I.P. with respect to the test of "Uniformity of Volume"

In context to above, it is directed to:

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. No order should be placed to the approved pharmaceutical firm for above mentioned drug, which have been found to be "Not of Standard Quality" on test analysis in the currency of Rate Contract 145C.
4. Initiate action as per clause for 'Testing of Drugs-Quality Control' of Terms & Conditions of respective DG-ESIC RC.
5. Maintained record of action taken at in 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
Neeta Garbiyal
Date: 06-03-2025
15:52:59**

Dy. Medical Commissioner
(Rate Contract)

Copy to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi-110002 (dci@nic.in).
2. State Drug Controller(Karnataka) , Drug Control Department, Palace Road, Bengaluru-560001 (Email: dc.dcd-ka@nic.in) 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. Office of Drug Controller, Punjab, Sector-34A, Chandigarh 160016 (Email:punjabdrugscontrolorg@gmail.com)
4. M/s Overseas Healthcare Pvt Ltd ,335Km Milestone, National Highway No.1, P.O. Box 25, Phillaur, District-Jalandhar, Punjab State-844410 (Email:info@overseashealthcare.co.in,dmohcpl@gmail.co).
5. Website Content Manager with request for uploading on ESIC website.
6. Guard file.



Central Drugs Laboratory, Kolkata
3, Kyd Street Kolkata (India) - 700016
Phone No. 033-22299380.
Email:cdlkol@cdsco.nic.in, cdlkol@gmail.com

No. 2751

Date-25-02-25



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 : Mrs. Sunita Joshi ,Drugs Inspector
Mrs. Sunita Joshi
SUBZONAL OFFICE (Bangalore), Central Drugs
Standard Control Organization Sub zonal office,2nd
Floor, (O/o Drugs Controller for the State of Karnataka)
Palace Road, Bangalore-560001
2. Serial No. and date of Inspector's memorandum : DDC/BZ/SJ/7-3/2024-25/681 Dated 10.07.2024 , 10-
JUL-2024
3. Number of Sample : LS/SJ/BZ/2024/52
4. Date of receipt : 22-JUL-2024
5. Names of drugs purporting to be contained in the sample : Azithromycin Oral Suspension I.P. (Azysafe Liquid -100)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/KOL/2024-25/0558	KOL/LS/2024-25/1711	AZ1-206	10/2023	03/2025	M/s. Overseas Healthcare Pvt.Ltd., M/s. Overseas Healthcare Pvt.Ltd., 335Km Mllestone, National Highway No.1, P.O. Box No.25, Phillaur-144410 (Pb)

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

7. Result of test or analysis with protocols or test or analysis applied : Please see below

Date of Testing : From 07-Feb-2025 To 20-Feb-2025

COMPOSITION : Each 5 ml contains:
Azithromycin I.P. (as azithromycin Dihydrate) 100 mg
Flavoured Syrupy base

Protocol Applied : I.P

Sr No.	Test Name	Result	Limits
1	Description	Off-white viscous liquid supplied in sealed screw capped amber coloured plastic bottle	NA
2	Identification	Gives positive test for Azithromycin	NA
3	pH	8.27 pH	7.5 to 11 .
4	Related Substances	Test Not Done	NA
5	Uniformity Of Volume	Does not Complies	NA

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Azithromycin	94.95 mg/5ml	100 mg/5ml	94.95	90 % to 110 %	I.P

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:-

The sample does not conform to claim as per I.P in respect to the Test of Uniformity Of Volume

Date: 24-FEB-2025

DR. RAKESH KUMAR RISHI
Pharmacologist and Government Analyst
Govt. of India
Central Drugs Laboratory
3, KYD Street, Kol-16

GOVERNMENT ANALYST

6/24/25

Report in the red colored paper indicates the sample is not of standard quality.

----- END OF REPORT -----

