



मृख्यालय/HEADQUARTERS' पँचदीप 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) | 403

Dated:

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/10/2025

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:

Sample	Name of the	Item Name/ Brand	RC No/	Batch No./	Name of the	Reason of
taken Premises	Firm (M/s)	Name	Item No/ Page No	DOM/ DOE	Laboratory/ Report No. & Date	NSQ
		Clotrimazole + Lignocaine Ear Drop- Each Bottle to contain: Clotrimazole 1%, Lignocaine Hydrochloride 2% Candid	149 551 42	Batch No. 11231684 DOM:09-23 DOE:08-26	Government Analyst, Karnataka MR No. 1577-BLR- 25-26/PS- 7459 Dated 19-07- 2025	The sample has been declared as Not of Standard Quality as it does not conform to the label claim with respect to "Assay for Clotrimazole" Category-"B" (copy enclosed)

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. Initiate action as per clause for 'Testing of Drugs-Quality Control" of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC.

Contd. to pre page:
4. Maintained record of action taken at in respective user units.

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

Enclosures: As above

Yours Faithfully,

Digitally signed by Sanjiv Kochhar Date: 26-07-2025 10:39:26 Dy. Medical Commissioner (Rate Contract)

Copy to:

 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).

3. The State Drug Controller, Food & Drug Administration, Survey No. 341, 2nd Floor, Bandra Kurla Complex, Opposite RBI, Kala Nagar, Bandra East Mumbai-400051 (whogmp.mahafda@gmail.com)

4. State Drug Controller, Controlling cum Licensing Authority, Baddi, himachal Pradesh-173205 (Email-sdc4hp@gmail.com) with request to take appropriate action on NSQ reported for the above said batch (copy of test report enclosed).

5. M/s Glenmark Pharmaceuticals Limited, Glenmark House, B.D. Sawant Marg, Chakala, Andheri East, Mumbai - 400099 (Emall:

govt.tenders@glenmarkpharma.com).

6. M/s Glenmark Pharmaceuticals Limited(Unit-III, Village- nattanwara, P.O.-Rajpura, Nalagarh, Distt. Solan (H.P.)-174101 (Email- complianceofficer@glenmarkpharma.com)

7. Website Content Manager with request for uploading on ESIC website.

8. Guard file.