



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, ✉ dmorc@esic.nic.in

File No.: e-U-25/12/NSQ/2022-MedV(E-12328) / 572 Dated: 19/12/2024

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/2024/06

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 Hospital, Pandeypur, Varanasi, UP -221002	Macleods Pharmaceuticals Limited	Thyroxine Sodium Tab/Cap- Each Tab/ Cap to contain: Thyroxine Sodium 25mcg/ Thyrox 25	145C 1688 12	1624014 8D 05-2024 04-2026	Central Drugs Laboratory, Kolkata KOL/LSGS/2024-25/27 Dated.- 02.12.2024	The sample does not conform to I.P. with respect to the test for "Dissolution" Category 'B'

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. Initiate action as per clause for 'Testing of Drugs-Quality Control' of Terms & Conditions of respective DG-ESIC RC.
3. Replacement of supplies or cost of the material is to be recovered along with testing charges (if any) from the firm.

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,

Signed by Neeta Garbiyal
Date: 19-12-2024 12:58:12

Dy. Medical Commissioner
(Rate Contract)

Copy for information to:

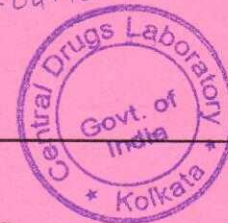
1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi-110002 (dci@nic.in).
2. Office of Assistant Commissioner, Food & Drugs Control Administration , C/o Food & Drugs Laboratory, Near Polytechnic, Vadodra-390002 with the request to take appropriate action on NSQ reported for the above said batch under information to this office .
3. Office of Assistant Commissioner (Drug) , Food Safety & Administration Sector-C, Aliganj, Lucknow,Uttar Pradesh. (Email: upfdadrug@gmail.com).
4. M/s Macleods Pharmaceuticals Limited , Plot no. 2209, GIDC, Sarigam, Dist. Valsad-396155.
5. M/s Macleods Pharmaceuticals Limited,Atlanta Arcade,Marol Church road,Opposite Leela Hotel, Andheri,(East), Mumbai-400059. (Email: pshukla@macleodspharma.com, tenders@macleodspharma.com).
6. Website Content Manager with request for uploading on ESIC website.
7. 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. 2142

Date. 04.12.24



FORM 13
(See rule 46)
CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

- Name of Inspector from whom received** : Mr. Ravendra Verma
Varanasi Sub Zone 1st Floor, Mata Anandamayee Hospital, Shivala, Varanasi-221001, Uttar Pradesh (India) - 0
- Serial No. and date of Inspector's memorandum** : LS/VNS/RV/2024/098/338 , 29-OCT-2024
- Number of Sample** : LS/VNS/RV/2024/098
- Date of receipt** : 06-NOV-2024
- Names of drugs purporting to be contained in the sample** : Thyroxine Sodium Tablets IP.. (THYROX- 25)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSGSD/KOL/2024-25/0036	KOL/LSGS/2024-25/27	16240148D	05/2024	04/2026	Macleods Pharmaceuticals Ltd., Plot No. 2209, GIDC, Sarigam, Dist. Valsad 396155.

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

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

Date of Testing : From 22-Nov-2024 To 29-Nov-2024

COMPOSITION : Thyroxine Sodium IP eq. to anhydrous Thyroxine Sodium 25 mcg.

Protocol Applied : IP 2022

Sr No.	Test Name	Result	Limits
1	Description	Light blue colored, elongated, flat, bi-elliptical, one side scored uncoated tablets having engraved '25' on the other side, in sealed amber colored glass bottle, in paper carton.	NA
2	Identification	Gives positive test for Thyroxine Sodium.	NA
3	Dissolution	Does not pass the test (Found: Average drugs release : 49.97% of claim; Limit: NLT 70% of claim).	NA
4	Liothyronine sodium	Passes the test.	NA
5	Uniformity of content	Passes the test.	NA

Assay

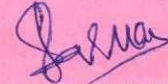
Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method

1	Thyroxine Sodium equivalent to anhydrous Thyroxine Sodium	26.64 mcg/tablet	25 mcg/tablet	106.56	90 % to 110 %	HPLC (Ref.: IP 2022)
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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 IP with respect to test for 'Dissolution'.

Date: 02-DEC-2024



GOVERNMENT ANALYST
DR. PRODIPTA SARKAR
ASSOCIATE BIOCHEMIST
Central Drugs Laboratory
Govt. of India
3, Kyd Street, Kolkata - 16

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

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