



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



महान्यालय/HEADQUARTERS
पंचदीप भवन, सी.आई.ए. मार्ग, नई दिल्ली -110 002
Panchdeep Bhawan, C.I.G. Marg, New Delhi-110002
www.esic.gov.in ☎ 011-23604773 ✉ gmrc@esic.in

File No. U-25/12/NSQ/2023-MedV(E-178406) 1/38

Dated: 16-04-2026

✓ 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-08/2026

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". The details of the drug reported NSQ is given below:

Sample taken Premises	Name of the Firm (M/s)	Item Name/ Brand Name	RC No/ Item No/ Page No	Batch No. / DO M/ D OE	Name of the Laboratory/ Report No. & Date	Reason of NSQ
ESIC Medical college & Hospital, Sanathnagar, Hyderabad	Vivimed Labs Ltd.	Wax Softner Ear Drops Each Vial to contain: Para Dichlorobenzene 2% wlv, Benzocaine 2.7% wlv, Chlorbutol 5%, Turpentine Oil 15% wlv	142C 1234	Batch No. - 5C U01 DOM: 03/25 DOE: 02/27	The Government Analyst, Central Drug Testing Laboratory, Hyderabad CDTLH/2126/F-1547/2025-26 Dated-26/03/2026	The sample received does not conform to Manufacturers specification with respect to the test for assay for the contents of Para Dichlorobenzene, Chlorbutol, Turpentine Oil only (copy enclosed).

In context to above, it is directed to:

1. Medical Store to immediately withdrawn stock from respective sub-stores/Dispensaries/patient care area.
2. Medical Store to immediately write a letter to vendor for replacement of stock with another batch, within 15 days or to pick up stock and return the payment made other process of risk purchase to be initiated and recover cost of

- testing (if any) from the vendor.
3. Stop use of the batch of the above-mentioned item immediately which has been reported as "Not of Standard Quality".
 4. Initiate action as per relevant clause of Terms & Conditions of respective DG-ESIC Tender Enquiry/RC.
 5. Maintained record of action taken at in respective user units.

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

Yours Sincerely,

Enclosures: As above

Digitally signed by
Sanjiv Kochhar
Date: 16-04-2026
09:21:45
Dy. Medical Commissioner
(Rate Contract)

Copy to:

1. The Drug Controller General of India, CDSCO, CIG Road, New Delhi- 110002 (dci@nic.in).
2. Office of Deputy Drug Controller (I), Central Drug Standard Control Organization, Zonal office, Hyderabad, CDSCO Bhavan, Beside T.B & Demonstration Centre, S.R. Nagar, Hyderabad – 500038, AP. (E-mail: hyderabad@cdsco.nic.in)
- 3 Vivimed Labs Ltd., 3rd floor, North End Building, Road No. 2, Banjara Hills, Hyderabad, Telangana – 500055, (E-mail: vivek.am@vivimedlabs.com)
4. Website Content Manager with request for uploading on ESIC website.
5. 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 : Mr. Rahul Singh, (Drugs Inspector)
Hyderabad Zone CDSCO, Zonal office, Hyderabad ,
CDSCO BHAVAN, Beside T.B. & Demonstration
Centre, S.R. Nagar, Hyderabad - 500038, AP (India) -
2. Serial No. and date of Inspector's memorandum : 6-2/HZ/RS/2025-2026/1956 , 24-JAN-2026
3. Number of Sample : LS/RS/HZ/2026/010
4. Date of receipt : 27-JAN-2026
5. Names of drugs purporting to be contained in the sample : EAR WAX SOFTENING DROPS, (CERUMINOLYTIC
DROPS)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/HYD/2025-26/1404	HYD/LS/2025-26/1658	5CU01	03/2025 02/2027	NA	M/s. Vivimed Labs Limited., Plot NO.:8, Phase V, IDA, Jeedimetla, Medchal- Malkajgiri Dist. Telangana State - 500 055

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 04-Mar-2026 To 23-Mar-2026

COMPOSITION : Paradichlorobenzene 2 % w/v, Benzocaine IP 2.7 % w/v, Chlorbutol IP 5 %
w/v, Turpentine Oil IP 15 % w/v

Protocol Applied : Manufacturers Specification

Sr No.	Test Name	Result	Limits
1	Description	Pale yellow, viscous liquid, packed in plastic container with dispensing nozzle and screw cap, enclosed in paper carton box.	NA
2	Identification	Positive for Paradichlorobenzene, Benzocaine, Chlorbutol and Turpentine oil.	NA
3	Extractable Volume	10.08 ml	NLT 10 ml

Assay

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

1	Paradichlorobenzene	0.611 % w/v	2 % w/v	30.55	90 % to 110 %	Manufacturers Specification
2	Benzocaine	2.506 % w/v	2.7 % w/v	92.814	90 % to 110 %	Manufacturers Specification
3	Chlorbutol	3.243 % w/v	5 % w/v	64.86	90 % to 110 %	Manufacturers Specification
4	Turpentine Oil	6.59 % w/v	15 % w/v	43.933	90 % to 110 %	Manufacturers Specification

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 RECEIVED DOES NOT CONFORM TO MANUFACTURERS SPECIFICATION WITH RESPECT TO THE TEST FOR ASSAY FOR THE CONTENTS OF PARADICHLOROBENZENE, CHLORBUTOL AND TURPENTINE OIL ONLY.

CDTLH REPORT NO.: CDTLH/2126/F-1547/2025-26

Date: 26-MAR-2026



GOVERNMENT ANALYST

डा. ए. रघुराम रेड्डी / Dr. A. Raghuram Reddy, M.Pharm, Ph.D.,
सरकारी विश्लेषक / Government Analyst

केन्द्रीय औषधि परीक्षण प्रयोगशाला / Central Drugs Testing Laboratory
केन्द्रीय औषधि मानक नियंत्रण संगठन / Central Drugs Standard Control Organisation
स्वास्थ्य सेवा निदेशकालय / Directorate General of Health Services
स्वास्थ्य एवं परिवार कल्याण विभाग / Ministry of Health & Family Welfare
एन.आर.नगर, हैदराबाद-500026 / S.R. Nagar, Hyderabad - 500 036

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

END OF REPORT

