# 203

## Form-13



(See Rule-46)

## MR No.1577-BLR-25-26/PS -7459

## 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: Karunadevi, Assistant Drugs Controller OFFICE OF THE ASST DRUGS CONTROLLER, CA:4/1 SyNo:17, Ground Floor, MSK Compound, Kalaburgi Circle-ADC2, Kalaburgi-585103

2. Serial No of Inspectors Memorandum: GL2/REG/CMS/106830/KA-B01 and Date 06-04-2025

3. Number of Sample: 106830 4. Date of Receipt: 23-05-2025

5. Name of drugs purporting to be contained in the sample: Candid Ear Drops (Clotrimazole+Lignocaine hydrochloride Ear Drops {1.0+2.0}% w/v)

Batch No: 11231684 Date Of Mfg.:09-2023 Date of Exp: 08-2026

Quantity: 01 x 10 x 10 ml. Mfg Lic. no. MNB/09/732

Mfg. by: Glenmark Pharmaceuticals Ltd. ,(Unit-II), Village Bhattanwala, P.O.Rajpura,

Nalagarh, Distt. Solan (H.P)-174101

6. Condition of seals on the package: Intact & Tally with Specimen Seal

7. Result of test or analysis with protocols of test or analysis applied:Inhouse Method and IP 2022
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 thereunder for the reasons given below

## **RESULTS**

**DESCRIPTION:** Clear, colourless liquid contained in sealed plastic dropper bottles packed in sealed carton

boxes.

IDENTIFICATION: Answers to the test for Clotrimazole and Lignocaine hydrochloride.

Assay For	<u>Found</u>	Label Claim
Clotrimazole	0.496 % w/v	1 % w/v
Lignocaine hydrochloride	2.05 % w/v	2 % w/v

## Reason for declaring Sample as Not of Standard Quality:

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".

(CE. Rajendra(I/C))

Dated:19/07/2025 CC: DC Karnataka

Government Analyst, Karnataka

Signature Not Verified
Digitally signed by
Date: 2025.07 19 13:24:52
+05:30

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