Regional Drugs Testing Laboratory
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Regional Drugs Testing Laboratory Govt of India Guwahati-22

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** : B.LALZAMLIANA,
   Drugs Inspector (F&D)
   CMO West Office
   Kulikawn, Aizawl- 796005
2. **Serial No. and date of Inspector's memorandum** : B.11012/5/2024-CMO(W)/DRUGS/14 ,
   Dated Aizawl, the 18th October, 2024
3. **Number of Sample** : SMP/MZ/TMT/2024-2025/019
4. **Date of receipt** : 28-OCT-2024
5. **Names of drugs purporting to be contained in the sample** : Dextromethorphan Hydrobromide, Cetirizine Di-Hydrochloride, Phenylephrine Hydrochloride, Guaiphenesin & Menthol Syrup (Fodep-RFSYRUP)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Dateof Exp.	Mfg. By
LSD/GUW/2024-25/1468	GUW/LS/2024-25/1494	FDRL601	Apr-2024	Mar-2026	M/S Tulbros Formulations., Plot No. 91, Sector IIDC, IIE Pantnagar, SIDCUL, Dist. U.S. Nagar- 263153 (Uttrakhand).

6. **Condition of seals on** [the packet or on portion of sample or container] : Seals were intact & identical to the 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 : 02-Jan-2025, 03-Jan-2025

COMPOSITION :
Each 5 ml contains:
Dextromethorphan Hydrobromide IP 10mg.
Cetirizine Di-Hydrochloride IP 5 mg.
Phenylephrine Hcl IP 5mg.
Guaiphenesin IP 100 mg.
Menthol IP 0.5 mg

Protocol Applied : Manufacturer's Specification

Sr No.	Test Name	Result	Limits
1	Description	Pink colour syrupy liquid in amber coloured plastic bottle.	NA
2	Identification	Gives positive test for Cetirizine Di-Hydrochloride, Phenylephrine Hydrochloride and Guaiphenesin.	NA
3	Weight per ml	1.0667 g	NA

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Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Cetirizine Dihydrochloride	4.88 mg/5ml	5 mg/5ml	97.6	90 % to 110 %	Manufacturer's Specification
2	Phenylephrine Hydrochloride	4.52 mg/5ml	5 mg/5ml	90.4	90 % to 110 %	Manufacturer's Specification
3	Guaiphenesin	90.16 mg/5ml	100 mg/5ml	90.16	90 % to 110 %	Manufacturer's Specification

In the opinion of the undersigned the sample referred to above **is of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample conforms to Manufacturer's Specification with respect to the above tests only.

Date: 06-JAN-2025

GOVERNMENT ANALYST
Amar Jyoti Chamuah
Government Analyst
R.D.T.L., Guwahati-22

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