



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 : K.Lalngilneia, Assistant Director (F and D)
Asst. Director (F&D), CMO Office,
Mamit Distric: Mamit, Mizoram- 796441.
- Serial No. and date of Inspector's memorandum : B.17011/12/09-CMO (M)/DRUGS/9 , 14-MAY-2024
- Number of Sample : NIL
- Date of receipt : 20-MAY-2024
- Names of drugs purporting to be contained in the sample : Ambroxol Hcl, Guaiphenesin, Terbutaline Sulphate and
Menthol Syrup (Cofar-A Syrup)

| Lab. Sample No. | Report No. | Batch No. | Date of Mfg. | Date of Exp. | Mfg. By |
|----------------------|---------------------|-----------|--------------|--------------|--|
| LSD/GUW/2024-25/1026 | GUW/LS/2024-25/1055 | PNL3242A | Mar-2023 | Feb-2025 | Plena Remedies., Plot No. -17, Industrial Area (Himuda) Bhatoli Kalan, Baddi, Distt. Solan (H.P.)-173205 |

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 24-Jul-2024 To 15-Oct-2024

COMPOSITION : Each 5 ml contains:
 Ambroxol HCL IP 15 mg
 Guaiphenesin IP 50 mg
 Menthol IP 2.5 mg
 Terbutaline Sulphate IP 1.25 mg

Protocol Applied : Manufacturer's Specification

| Sr No. | Test Name | Result | Limits |
|--------|----------------|--|----------------|
| 1 | Description | Pink color liquid filled in plastic bottles. | NA |
| 2 | Identification | Gives positive test for Ambroxol Hcl, Guaiphenesin and Terbutaline Sulphate. | NA |
| 3 | Weight per ml | 1.1019 g/ml | NA |
| 4 | pH | Found 5.34 | 4.00 to 6.00 . |

Assay

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

Standard
ADEFPD
12/12/24
ddpau
slrta
Km

| | | | | | | |
|---|------------------------|--------------|-------------|---------|---------------|------------------------------|
| 1 | Ambroxol Hydrochloride | 16.1 mg/5ml | 15 mg/5ml | 107.333 | 90 % to 110 % | Manufacturer's Specification |
| 2 | Terbutaline Sulphate | 1.35 mg/5ml | 1.25 mg/5ml | 108 | 90 % to 110 % | Manufacturer's Specification |
| 3 | Guaiphenesin | 54.15 mg/5ml | 50 mg/5ml | 108.3 | 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 claim as per Manufacturer's Specification in respect of test performed.

Date: 21-OCT-2024

Rinku Kalita
GOVERNMENT ANALYST

✓ Rinku Kalita
Government Analyst
R.D.T.L., Guwahati-22

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