



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 : B.LALZAMLIANA Drug Inspector (F&D)
CMO West Office
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO(W)/DRUGS/50 , 25-FEB-2025
- Number of Sample : SMP/MZ/TMT/2024-2025/045
- Date of receipt : 06-MAR-2025
- Names of drugs purporting to be contained in the sample : Ambroxol HCl, Salbutamol Sulphate & Guaiphenesin Liquid (RESPIRA)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
SD/GUW/2025-GUW/LS/2025-26/0745	26/737	RSP3041	May-2023 Apr-2026	NA	Naxpar Pharma Pvt. Ltd., 182, Village- Gurumajra, Kishanpura, Baddi, Dist- Solan Himachal Pradesh -174101.

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 23-Jun-2025 To 10-Sep-2025

COMPOSITION : Each 5ml contains:
Ambroxol Hydrochloride IP 15 mg
Salbutamol Sulphate IP eq. to Salbutamol 1mg
Guaiphenesin IP 50 mg

Protocol Applied : Manufacturer Specification

Sr No.	Test Name	Result	Limits
1	Description	Light orange colored liquid filled in amber colored 100 ml plastic bottles.	NA
2	Identification	Gives positive test for Ambroxol HCl, Salbutamol Sulphate & Guaiphenesin.	NA
3	Weight per ml	1.303 g/ml	NA
4	pH	3.98	3.0 to 4.5 .

say

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

1	Ambroxol Hydrochloride	11.287 mg/ 5 ml	15 mg/ 5 ml	75.246	90 % to 115 %	Manufacturer Specification
2	Salbutamol Sulphate eq. to Salbutamol	0.8111 mg/ 5 ml	1 mg/ 5 ml	81.11	90 % to 117.5 %	Manufacturer Specification
3	Guaiphenesin	48.09 mg/ 5 ml	50 mg/ 5 ml	96.18	90 % to 110 %	Manufacturer Specification

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 claim as per Manufacturer Specification with respect to the test for "Assay" of Ambroxol Hydrochloride and Salbutamol.

Date: 29-SEP-2025

GOVERNMENT ANALYST

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

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

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