

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India) - 781022

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Govt. of India

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

: K. Lalngilneia, Asst. Director (F and D) Asst. Director (F&D), CMO Office,

Mamit Distric: Mamit, Mizoram- 796441.

2. Serial No. and date of Inspector's memorandum

: B.17011/12/09-CMO (M)/DRUGS/7, 16-JAN-2024

Number of Sample

: NIL

4. Date of receipt

: 18-APR-2024

Names of drugs purporting to be contained in the sample : Ambroxol Hydrochloride Syrup (AMBRODIL SYRUP)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By	
LSD/GUW/2024- 25/0869	GUW/LS/2024- 25/898	MPC230759	Mar-2023	A 0005	M/s. ARISTO Pharmaceuticals Pvt. Ltd., Plot No.:208, New	
6 Condition of as				140	Industrial Area No.:2, Mandideep, Dist.:Raisen (M.P.)	

ondition 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: From 17-Sep-2024 To 18-Sep-2024

COMPOSITION

Each 5 ml contains:

Ambroxol Hydrochloride IP 30 mg

Protocol Applied: Reference I.P.

Sr No.	Test Name	Result			
1	Description	Yeliow colored clear liquid in amber colored 100 ml plastic bottles.	NA Limits		
2	Identification	Gives positive test for Ambroxol Hydrochloride.	NA		
3	Weight per ml	1.2528 gm/ml	NA		

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ambroxol Hydrochloride	31.1 mg/5ml	30 mg/5ml	103.666	90 % to 110 %	Reference I.P.

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:-

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The sample conforms to claim as per Reference I.P. in respect of test performed. Date: 19-SEP-2024 **GOVERNMENT ANALYST** Rinku Kalita Government Analyst R.D.T.L., Guwahati-22 - END OF REPORT -Page 2 of 2