

## Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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## **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/17,

Govt of Incia

Dated Aizawl, the 12-DEC-2024

3. Number of Sample

: SMP/MZ/TMT/2024-25/022

4. Date of receipt

: 06-JAN-2025

5. Names of drugs purporting to be contained in the sample : Salbutamol Sulphate Tablets IP 2 mg (Asthalin-2)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1917	GUW/LS/2024- 25/1936	C131636	Dec-2023	Nov-2026	CIPLA LTD,Plot No. 27, Jharmajari, Baddi (H.P.) 173 205 India.

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: 24-Mar-2025, 25-Mar-2025

COMPOSITION

Each uncoated tablet contains:

Salbutamol Sulphate IP

equivalent to Salbutamol 2 mg

## Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1 Description		White, round, flat, uncoated tablet having scored on one side in blister strip.	NA	
2	Identification	Gives positive test for Salbutamol.	NA .	
3	Average weight	0.1106 g	NA	
4	Disintegration	Passes the test. (Time taken for disintegration 01 minute 28 seconds)	NMT 15 minutes	

## say

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Salbutamol Sulphate IP equivalent to Salbutamol	1.93 mg/Tablet	2 mg/Tablet	96.5	90 % to 110 %	I.P. 2022

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 I.P. with respect to the above tests only.

Date: 25-MAR-2025

Amar Jyofi Chamuah Government Analyst R.D.T.L., Guwahati-22

END OF REPORT