



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,
 Drugs Inspector (F & D)
 CMO West Office,
 Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum :B.11012/5/2024-CMO (W)/DRUGS/19
 Dated Aizawl, the 12th December, 2024
- Number of Sample :SMP/MZ/TMT/2024-2025/024
- Date of receipt :06-JAN-2025
- Names of drugs purporting to be contained in the sample: Betamethasone Sodium Phosphate Injection IP
 (BETAGLOW); 1ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024-25/1744	GUW/LS/2024-25/1769	AL4E111	05/2024	04/2026	ANROSE PHARMA 147, Mauza Sansiwala, Post-Barotiwala, Tehsil- Kasauli, Distt. SOLAN (H.P.)

- 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

- Result of test or analysis with protocols or test or analysis applied :Please see below

Date of Testing : From 20-Jan-2025 To 20-Feb-2025

COMPOSITION : Each ml contains:
 Betamethasone Sodium Phosphate IP
 eq. to Betamethasone 4mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Colorless solution in sealed transparent glass ampoule with blue dot mark on the neck in blister pack.	NA
2	Identification	Gives positive test for Betamethasone.	NA
3	Sterility	Complies.	NA
4	Bacterial Endotoxin	Complies.	NA
5	Extractable volume	Complies.	NA
6	Particulate matter	Complies.	NA
7.	pH	Complies (Found: 8.34).	8.0 to 9.0.

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Betamethasone Sodium Phosphate eq. to Betamethasone	3.76 mg/ml	4 mg/ml	94	92.5 % to 107.5%	I.P. 2022

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

The sample conforms to I.P. with respect to the above tests only.

Date: 25-FEB-2025


GOVERNMENT ANALYST
Dilip Kr. Sarkar
Government Analyst
R.D.T.L., Guwahati-22

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

