



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 : Mr. R. Vanlalruata, Assistant Director (F and D)
OFFICE OF CHIEF MEDICAL OFFICER,
AIZAWL, MIZORAM, PIN:-796017.
- Serial No. and date of Inspector's memorandum : 130/IPA-AZL E/III-2025 , 22-SEP-2025
- Number of Sample : NIL
- Date of receipt : 08-OCT-2025
- Names of drugs purporting to be contained in the sample : Betamethasone Sodium Phosphate Injection IP (Betjec)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/1161	GUW/LS/2025-26/1127	ULN-25161	Mar-2025 Feb-2027	NA	ULTRATECH PHARMACEUTICALS, Vill. Tipra, P.O. : Barotiwalla, Distt. Solan, (H.P.)

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 30-Dec-2025 To 31-Dec-2025

COMPOSITION : Each ml contains:
Betamethasone Sodium Phosphate 4 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Clear and colorless liquid filled in amber colored glass ampoules, in blister pack.	
2	Identification	Gives positive test for Betamethasone Sodium Phosphate.	
3	Sterility	Passes the test.	
4	Extractable Volume	Complies.	
5	Particulate matter	Passes the test.	
6	pH	8.12 .	8.0 to 9.0 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Betamethasone Sodium Phosphate equivalent to Betamethasone	3.81 mg/vial	4 mg/vial	95.25	92.5 % to 107.5 %	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 conform to claim as per I.P. 2022 in respect of test performed.

Date: 27-JAN-2026

Rinku Kalita
GOVERNMENT ANALYST

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

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

