

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 32 SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

Name of Inspector from whom received

: Mr. R. Vanlalruata, Asst. Director (F and D)

ASSISTANT DIRECTOR(F&D)

OFFICE OF CHIEF MEDICAL OFFICER, AIZAWL,

al Druge

MIZORAM, PIN-769017

Serial No. and date of Inspector's memorandum

: MZ/24/A E/17/IPA, 17-DEC-2024

Number of Sample

: NIL

Date of receipt

: 02-JAN-2025

5. Names of drugs purporting to be contained in the sample : Dextrose Injection IP (5% w/v) (D5)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1689	GUW/LS/2024- 25/1719	(N)243113	Jun-2024	May-2026	M/s Klokter Lifesciences Pvt. Ltd.,, Samora, Indri Road, Karnal -132041.

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: From 17-Jan-2025 To 07-Feb-2025

COMPOSITION

Each 100 ml contains: Dextrose Anhydrous I.P. 5 gm

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits	
1	Description	Clear and colorless liquid filled in colorless translucent sealed plastic bottles.	NA	
2	Identification	Gives positive test for Dextrose.	NA	
3	Sterility	Passes the test.	NA	
4	BET	Complies.	NA	
5	5-Hdroxymethylfurfural and related substances	Complies.	NA	
6	рН	Found 4.3	3.5 to 6.5 .	

<u>Assay</u>

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
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1	Dextrose Anhydrous	4.94 g/100 ml	5 g/100 ml	98.8	95 % to 105 %	I.P. 2022
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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: 13-FEB-2025

GOVERNMENT ANALYST

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

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