

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

Email: rdtlguwahati@cdsco.nic.in



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

: MR. R. VANLALRUATA

ASSISTANT DIRECTOR (F & D) OFFICE OF CHIEF MEDICAL OFFICER.

AIZAWL, MIZORAM, PIN:-796017

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

:MZ/24/A 'E'/12

Date 1/11/2024

3. Number of Sample

:Nil

4. Date of receipt

:14-NOV-2024

5. Names of drugs purporting to be contained in the sample: COMPOUND SODIUM LACTATE INJECTION I.P. (RL)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1475	GUW/LS/2024- 25/1499	4D340253	MAY-2024	APR-2027	IHL LIFESCIENCES PVT. LTD. 8th Floor, Office No.836-C, Jhabua
		5		(G	Tower, RNT Marg, Indore-452001 At Village Panwa, Tehsil: Kasrawad,
14 4 4 4 4	Call gillia				Dist: Khargone 451228 (M.P.) 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

From 26-Nov-2024 To 06-Jan-2025

COMPOSITION

Each 100 ml contains:

Lactic Acid I.P.

0.240 ml

(equivalent to Sodium Lactate 0.32g)

Sodium Chloride I.P.

0.600 g

Potassium Chloride L.P.

0.040 g

Calcium Chloride I.P.

0.027 q

Protocol Applied: I.P. 2022

Test Name	Result	Limits NA NA
Description	Clear, colourless liquid in sealed translucent plastic container.	
Identification	Gives positive for the test.	
pH	Complies (Found: 6.48).	5.0 to 7.0.
Sterility	Complies.	NA
-		
Bacterial endotoxins	Complies.	NA
Particulate Contamination	Complies.	NA
	Description Identification pH Sterility Bacterial endotoxins	Description Clear, colourless liquid in sealed translucent plastic container. Identification Gives positive for the test. pH Complies (Found: 6.48). Sterility Complies. Bacterial endotoxins Complies.

Assay

Sr.No	Ingredient Name	Found	Limits	Procedure / Method
1	Sodium	0.277 % w/v	0.27 % to 0.32 % w/v	
2	Potassium	0.02188 % w/v	0.019 to 0.022 % w/v	
3	Total Chloride	0.38 % w/v	0.37 % to 0.42 % w/v	I.P. 2022
4	Calcium Chloride (CaCl ₂ ,2H ₂ O)	0.0288 % w/v	0.025 to 0.029 % w/v	old hilling.
5	Lactate (calculated as C ₃ H ₆ O ₃)	0.265 % w/v	0.23 % to 0.28% w/v	les sedunds d

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: 06-JAN-2025

GOVERNMENT ANALYST

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

- END OF REPORT -

सत्यमेव जयत