

**Regional Drugs Testing Laboratory** 

Directorate General of Health Services, Guwahati (India) - 781022 ting

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 THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER THE STATE OF TEST OR ANALYSIS BY GOVERNMENT ANAL 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

: MZ/24/A E/11, 01-NOV-2024

**Number of Sample** 

: NIL

Date of receipt

: 14-NOV-2024

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. | · ·   |
|--------------------------|-------------------------|-----------|--------------|--------------|---|
| LSD/GUW/2024-<br>25/1600 | GUW/LS/2024-<br>25/1630 | 3D340088  | Dec-2023     | Nov-2026     | IHL LIFESCIENCES PVT LTD,<br>8th Floor, Office No. 836-C,<br>Jhabua Tower, RNT Marg,    |
|                          | Ś                       |           |              |              | Indore-452001, At- Village<br>Panwa, Tehsil: Kasrawad,<br>Dist: Khargone 451228 (M.P.), |
|                          |                         |           |              |              | India   |

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 26-Nov-2024 To 20-Jan-2025

COMPOSITION

Each 100 ml contains: Lactic Acid I.P. 0.240 ml (equivalent to Sodium Lactate

0.32 g, Sodium Chloride I.P. .0.600 g, Potassium Chloride I.P. 0.040 g,

Calcium Chloride I.P. 0.027 g

## 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 compound Sodium Lactate.                                   | NA           |
| 3      | pH                         | 6.5  | 5.0 to 7.0 . |
| 4      | Sterility Passes the test. |  | NA .         |
| 5      | BET                        | Complies.  | NA           |
|        | A                          | 5 W  |              |

Assay

| Sr.No | Ingredient Name           | Found        | Limits                  | Procedure / Method |
|-------|---------------------------|--------------|-------------------------|--------------------|
| 1     | Lactate<br>As Lactic Acid | 0.26 % w/v   | 0.23 %w/v to 0.28%w/v   | I.P. 2022          |
| 2     | Sodium                    | 0.29 % w/v   | 0.27 % w/v to 0.32%w/v  | I.P. 2022          |
| 3     | Potassium                 | 0.022 % w/v  | 0.019%w/v to 0.022%w/v  | I.P. 2022          |
| 4     | Calcium Chloride          | 0.0274 % w/v | 0.025%w/v to 0.029 %w/v | I.P. 2022          |
| 5     | Total Chloride            | 0.39 % w/v   | 0.37 %w/v to 0.42%w/v   | 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: | 29-JAN-2025  |
|-------|--------------|
| Date. | 23-3/11-2023 |

**GOVERNMENT ANALYST** 

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

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