



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 : TIMOTHY THANCHUNGNUNGA, Assistant Director (F and D)
State FDA
KULIKAWN, AIZAWL-796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/77 , 25-JUN-2025
- Number of Sample : 021/IPA-AZL W/II-25
- Date of receipt : 09-JUL-2025
- Names of drugs purporting to be contained in the sample : Sodium Chloride (0.9%w/v) and Dextrose (5%w/v)
Injection IP (DNS)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0655	GUW/LS/2025-26/659	5B340104	Mar-2025 Feb-2028	NA	IHL LIFESCIENCES PVT LTD, 8th Floor, Office No. 836-C, Jhabua Tower, RNT Marg, Indore-452001, At- Village Panwa, Tehsil: Kasrawad, Dist: Khargone 451228 (M.P.), India

6. Condition of seals on : Seals were intact & identical to the specimen impression of the seal received from Drugs Inspector
[the packet or on portion of sample or container]

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

Date of Testing : From 11-Aug-2025 To 26-Aug-2025

COMPOSITION : Each 100 ml Contains:
Dextrose Anhydrous IP 5.0 gm
Sodium Chloride IP 0.9 gm
Water For Injections IP q.s.

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 Sodium Chloride and Dextrose.	NA
3	Sterility	Passes the test.	NA
4	Bacterial endotoxins	Complies.	NA
5	pH	4.28 .	3.5 to 6.5 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Sodium chloride	0.92 gm/100ml	0.9 gm/100ml	102.222	95 % to 105 %	I.P. 2022
2	Dextrose Anhydrous	5.102 gm/100ml	5 gm/100ml	102.04	95 % to 105 %	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: 04-SEP-2025

GOVERNMENT ANALYST

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

END OF REPORT

