



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 : B.LALZAMLIANA, Drugs Inspector (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/16 , 12-DEC-2024
- Number of Sample : SMP/MZ/TMT/2024-25/021
- Date of receipt : 06-JAN-2025
- Names of drugs purporting to be contained in the sample : Ondansetron Injection IP 4 mg (Emigo Injection 4 mg)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0051	GUW/LS/2025-26/56	ZLT4AA4001	Mar-2024 Aug-2026	NA	Zuventus Healthcare Limited, Block No. 33/1, C-403/404, Third Floor, Kanchan Pharma House, N.H. No. 08, Aslali, Taluka Daskroi, District Ahmedabad- 382 427

- 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

- Result of test or analysis with protocols or test or analysis applied : Please see below
Date of Testing : From 28-Jan-2025 To 04-Apr-2025

COMPOSITION : Each ml contains:
Ondansetron Hydrochloride IP equivalent to Ondansetron 2 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Clear and colorless liquid filled in colorless sealed glass ampoules, having yellow colored ring on the neck of the ampoules.	NA
2	Identification	Gives positive test for Ondansetron Hydrochloride.	NA
3	Sterility	Passes the test.	NA
4	Bacterial Endotoxins	Complies.	NA
5	pH	3.85 .	3.3 to 4 .

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ondansetron Hydrochloride equivalent to Ondansetron	1.942 mg/ml	2 mg/ml	97.1	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: 08-APR-2025

Rinku Kalita
GOVERNMENT ANALYST

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

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