



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 : B.LALZAMLIANA,
Drugs Inspector (F & D),
CMO West Office,
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/63
Dated Aizawl, the 26th March, 2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/061
4. Date of receipt : 02-APR-2025
5. Names of drugs purporting to be contained in the sample: Ondansetron Orally Disintegrating Tablets IP 4 mg
(Ondancure Tablets)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0289	GUW/LS/2025-26/298	T-2409070B	09/2024 08/2026	NA	White Eagle Laboratories, Plot No. D-280, Focal Point, Patiala- 147 001, Punjab, India

6. Condition of seals on : Seals were intact & identical to the
[the packet or on portion of sample or container] 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 23-May-2025 To 26-May-2025

COMPOSITION : Each uncoated orally disintegrating tablet contains:
Ondansetron Hydrochloride I.P.
Eq. to Ondansetron 4 mg

Protocol Applied: I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Pink colour, round, bi-convex, scored on one side, uncoated orally disintegrating tablet in alu-alu blister pack.	NA
2	Identification	Gives positive test for Ondansetron.	NA
3	Average weight	0.1401 gm.	NA
4	Dissolution	Complies (Drug release of all 6 units are found more than 80+5%).	NLT 80 % of claim
5	Disintegration	Complies (Time taken for Disintegration: 10 seconds).	NMT 30 seconds

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method

1	Ondansetron Hydrochloride Eq. to Ondansetron	4.27 mg/Tablet	4 mg/Tablet	106.75	90 % to 110 %	I.P. 2022
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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: 28-MAY-2025

GOVERNMENT ANALYST

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

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

