



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 : Mrs. C. Ramdinmawii
Assistant Director (Food & Drugs)
C.M.O. Office, Champhai-796321
Mizoram.
2. Serial No. and date of Inspector's memorandum : 044/IPA-CPI/24 Date: 17/01/2025
3. Number of Sample : Nil
4. Date of receipt : 03-FEB-2025
5. Names of drugs purporting to be contained in the sample: Ondansetron Injection I.P. (Ontasyn); 2ml.

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-26/0193	GUW/LS/2025-26/201	LI40747	09/2024 08/2026	NA	Captab Biotech Unit-II Plot No.125, E.P.I.P.Road, Mauja, Jharmajri, Baddi, Distt. Solan (H.P.) - 173 205

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 18-Feb-2025 To 09-May-2025

COMPOSITION : Each ml contains:
Ondansetron Hydrochloride I.P.
(As Dihydrate) Eq. to Ondansetron 2 mg

Protocol Applied: I.P.2022

Sr No.	Test Name	Result	Limits
1	Description	Colorless solution in sealed transparent glass ampoule with a yellow ring on the neck in blister pack.	NA
2	Identification	Gives positive test for Ondansetron.	NA
3	Sterility	Complies.	NA
4	Bacterial endotoxins	Complies.	NA
5	Particulate Matter	Complies.	NA
6	Extractable Volume	Complies.	NA
7	pH	Complies (Found: 3.84).	3.3 to 4.0

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure/ Method
1	Ondansetron Hydrochloride Eq.to Ondansetron	1.99 mg/ml	2 mg/ml	99.5	95 % to 105 %	I.P.2022

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: 13-MAY-2025


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

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

