



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 : TIMOTHY THANCHUNGUNGA, Assistant Director (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
2. Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO (W)/DRUGS/43 , 21-JAN-2025
3. Number of Sample : SMP/MZ/TMT/2024-2025/038
4. Date of receipt : 03-FEB-2025
5. Names of drugs purporting to be contained in the sample : Ondansetron Oral Solution IP (2 mg/ 5 ml) (Onvin NF)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2024-25/1941	GUW/LS/2025-26/7	SP246003	Apr-2024 Mar-2026	NA	Sotac Pharmaceuticals Ltd. (A WHO:GMP Certified Company), Pf/21 & 21-A & 22-A, Nr. Acme Pharma, Opp. Teva Pharma, Sanand GIDC-II, Sanand, Ahmedabad, Gujarat (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 21-Feb-2025 To 24-Mar-2025

COMPOSITION : Each 5 ml contains:
Ondansetron Hydrochloride IP Equivalent to Ondansetron 2 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Orange colored syrup filled in amber color plastic bottles with screw cap, along with measuring cups.	NA
2	Identification	Gives positive test for Ondansetron.	NA
3	Weight per ml	1.0861 g/ml	NA
4	pH	3.65	3.3 to 4 .

Assay

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

1	Ondansetron Hydrochloride eq.to Ondansetron	2.02 mg/5ml	2 mg/5ml	101	95 % to 105 %	I.P. 2022
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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: 01-APR-2025

GOVERNMENT ANALYST

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

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

