



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 : K. Lalngilneia
Asst. Director (F&D)
CMO Office, Mamit District: Mamit
Pin - 796441
2. Serial No. and date of Inspector's memorandum : B.17011/12/09-CMO(M)/DRUGS/46 Date 9/1/2025
3. Number of Sample : MD08/46
4. Date of receipt :23-JAN-2025
5. Names of drugs purporting to be contained in the sample: Ondansetron Ora! Solution IP (2 mg/ 5 ml) (Onvin NF);30ml

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUWI/2024-25/1875	GUW/LS/2024-25/1893	SP236007	07/2023	06/2025	Sotac Pharmaceuticals Ltd. Plot No.PF/21& 22-A Nr. Acme Pharma, Opp. Teva Pharma, Sanand GIDC- II, Sanand, Ahmedabad,Gujarat (INDIA)

6. 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

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

Date of Testing : From 21-Feb-2025 To 13-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	Pink colour syrup in sealed amber colour plastic bottle along with volume measuring plastic cup.	NA
2	Identification	Gives positive test for Ondansetron.	NA
3	Weight per ml	1.0918g/ml.	NA
4	pH	Complies (Found: 3.8).	3.3 to 4.0.

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
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1	Ondansetron Hydrochloride Equivalent to Ondansetron	2.05 mg/5ml	2 mg/5ml	102.5	95 % to 105 %	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: 19-MAR-2025



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

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

