

Regional Drugs Testing Laboratory Directorate General of Health Services, Guwahati (India)-781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555

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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

: MR. R. VANLALRUATA

ASSISTANT DIRECTOR (F&D)

OFFICE OF CHIEF MEDICAL OFFICER,

AIZAWL, MIZORAM, PIN: - 796017

Serial No. and date of Inspector's memorandum

: MZ/2025/CMO 'E'/IPA/8

Date 20/1/25

3. Number of Sample

:Nil

Date of receipt

:29-JAN-2025

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.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1876	GUW/LS/2024- 25/1894	SP236007	Jul-2023	Jun-2025	Sotac Pharmaceuticals Pvt. 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

Protocol Applied: I.P. 2022

Sr No. Test Name 1 Description		Result Pink colour syrup in sealed amber colour plastic bottle along with volume measuring plastic cup.		
3	Weight per ml			
4	рН	Complies (Found: 3.84).	3.3 to 4.0	

Assay

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

1	Ondansetron Hydrochloride Equivalent to Ondansetron	2.07 mg/5ml	2 mg/5ml	103.5	95 % to 105 %	I.P. 2022
	26 A-					

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: 20-MAR-2025

GOVERNMENT ANALYST

Dilip Kr. Sarkar

Government Analyst

R.D.T.L., Guwahati-22

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

