



FORM 13
(See rule 46)

CERTIFICATE OF TEST OR ANALYSIS BY GOVERNMENT ANALYST UNDER
SECTION 25(1) OF THE DRUGS AND COSMETICS ACT, 1940

- Name of Inspector from whom received : TIMOTHY THANCHUNG NUNGA Assistant Director (F and D)
CMO West Office
Kulikawn, Aizawl- 796005
- Serial No. and date of Inspector's memorandum : B.11012/5/2024-CMO(W)/DRUGS/110 , 11-NOV-2025
- Number of Sample : 058/IPA-AZL W/III-25
- Date of receipt : 17-NOV-2025
- Names of drugs purporting to be contained in the sample : Ondansetron Injection IP (Honda-8)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg. & Exp	Marketed By	Mfg. By
LSD/GUW/2025-GUW/LS/2025-26/1130	26/1105	LA24174B	Feb-2025 Jan-2027	NA	M/s Symbiosis Pharmaceuticals Pvt. Ltd. Suketi Road, Kala Amb Distt. Sirmour, Himachal Pradesh - 173030

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 03-Dec-2025 To 09-Jan-2026

COMPOSITION : Each ml contains:
Ondansetron Hydrochloride IP eq. to Ondansetron 2 mg

Protocol Applied : I.P. 2022

Sr No.	Test Name	Result	Limits
1	Description	Clear and colorless liquid filled in colorless, transparent sealed glass ampoules, in blister packaging, supplied in paper carton.	
2	Identification	Gives positive test for Ondansetron Hydrochloride.	
3	pH	3.86	3.3 to 4.0
4	Sterility	Does not pass the test.	
5	Bacterial Endotoxins Test(BET)	Does not comply.	

Assay

Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
1	Ondansetron Hydrochloride equivalent to Ondansetron	2.07 mg/ml	2 mg/ml	103.5	95 % to 105 %	I.P. 2022

In the opinion of the undersigned the sample referred to above **is not of standard quality** as defined in the Drugs and Cosmetics Act, 1940, and Rules there under for the reasons given below:-

The sample does not comply as per I.P. 2022 with respect to the test for "Sterility and BET(Bacterial Endotoxins Test)."

Date: 13-JAN-2026

GOVERNMENT ANALYST

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

Report in the red colored paper indicates the sample is not of standard quality.

END OF REPORT

