

## Regional Drugs Testing Laboratory

Directorate General of Health Services, Guwahati (India)- 781022 Fax: 0361-2338555/2330555 Phone No.0361 2338555 Email:rdtlguwahati@cdsco.nic.in

## **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

· Lalruatdika Varte,

**Drugs Inspector** 

Office of the Senior Chief Medical Officer

Kolasib, Mizoram-796082

2. Serial No. and date of Inspector's memorandum

: KLB/04/2024/DRUGS, Dated Kolasib, the 05-NOV-2024

Govt a Incia

Wahati

3. Number of Sample

Date of receipt

: 29-NOV-2024

5. Names of drugs purporting to be contained in the sample: Ondansetron Orally Disintegrating Tablets IP 4 mg

(EZIDAN MD)

Lab. Sample No.	Report No.	Batch No.	Date of Mfg.	Date of Exp.	Mfg. By
LSD/GUW/2024- 25/1568	GUW/LS/2024- 25/1589	TG23-2045G	Oct-2023	Sep-2025	Athens Life Sciences, Mauza Rampur Jattan, Nahan Road, Kala Amb, Distt. Sirmour, H.P. -173030

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-Jan-2025 To 22-Jan-2025

COMPOSITION

Each uncoated orally disintegrating tablet contains: Ondansetron HCI IP Eq. to Ondansetron 4 mg

Protocol Applied: I.P. 2023

सत्यमेव जयते

Test Name	Result	NA	
cription	Orange coloured, round, bi-convex, uncoated tablet in blister strip.		
Identification Gives the positive test.		NA	
rage weight	0.1102 g	NA	
solution	Complies.	NLT 80 %	
	cription  Itification  rage weight	Orange coloured, round, bi-convex, uncoated tablet in blister strip.  Gives the positive test.  rage weight  0.1102 g	

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Sr.No	Ingredient Name	Found	Claim	% of claim	Limits	Procedure / Method
-1	Ondansetron Hydrochloride eq. to Ondansetron	3.99 mg/Tablet	4 mg/Tablet	99.75	90 % to 110 %	I.P. 2022

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 conforms to I.P. with respect to the above tests only.

Date: 23-JAN-2025

Amar Jyofi Chamuah Government Analyst R.D.T.L., Guwahati-22

- END OF REPORT -