

CERTIFICATE OF FINISH PRODUCT ANALYSIS

Product Name:	ONDICAN 4 (Ondansetron Hydrochloride Injection IP 2mg/ml)		
Batch No.	24AJ074	A.R. No.	FP240090
Batch Size	100000 Ampoules	Sample Quantity	60 Nos
Mfg. Date	10/2024	Date of Testing	28/10/2024
Exp. Date	09/2026	Date of Release	12/11/2024
Reference Batch No	NA	MFG. Lic. No.	N-MB-2023/263

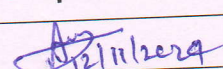
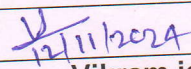
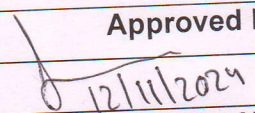
Sr. No.	Test	Specification	Observation
1.	Description	Clear and colorless liquid.	Clear and colorless liquid.
2.	Identification (By HPLC)	In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution	Complies
3.	pH	Between 3.3 to 4.0	3.62
4.	Related Substance Any other Impurity Total Impurity	NMT 0.2% NMT 1.5%	Complies Complies
5.	Extractable Volume	NLT 4.0 ml	4.0 ml
6.	Bacterial Endotoxins	NMT 9.9 Endotoxin unit per mg of Ondansetron	Less than 9.9 Endotoxin unit per mg of Ondansetron
7.	Particulate Matter	Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye.	Complies
8.	Sterility	Should be complies	Sterile
9.	Assay:		

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Each ml contains: Ondansetron Hydrochloride IP Eq. to Ondansetron 2 mg	1.90 mg to 2.1 mg (90.0 % to 110.0 %)	2.02 mg 100.88 %
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Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 12/11/2024	 12/11/2024	 12/11/2024
Name	Abhay Mishra	Vikram jeet	Bhupinder Navet
Designation	Sr. officer QC	Executive-QC	Head-QC