



American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISHED PRODUCT ANALYSIS

Product Name:	Ondican 4- Injection (Ondansetron Hydrochloride Injection IP 2mg/ml)		
Batch No.	25AR065	A.R. No.	AFP250057
Batch Size	100500 Amps	Sample Quantity	60 Nos
Mfg. Date	11/2025	Date of Testing	16/11/2025
Exp. Date	10/2027	Date of Release	03/12/2025
Reference Batch No	25AR065	MFG. Lic. No.	HP-MB-LL-00235

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	3.70
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 Sterile	Sterile
9.	Assay:		



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Each ml contains:			
Ondansetron Hydrochloride IP	1.90 mg to 2.1 mg		2.02 mg
Eq. to Ondansetron 2 mg	(90.0 % to 110.0 %)		101.21 %

Remark: The sample is complies as per IP /BP/ USP/IH specification.

	Prepared By	Checked By	Approved By
Sign/Date	 03/12/2025	 03/12/2025	 03/12/2025
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

