



## American Remedies Healthcare Pvt. Ltd.

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

### CERTIFICATE OF FINISHED PRODUCT ANALYSIS

<b>Product Name:</b>	<b>Ondican-4 Injection (Ondansetron Hydrochloride Injection IP 2mg/ml)</b>		
<b>Batch No.</b>	26AR004	<b>A.R. No.</b>	AFP260011
<b>Batch Size</b>	100800 AMPS	<b>Sample Quantity</b>	60 Nos
<b>Mfg. Date</b>	01/2026	<b>Date of Testing</b>	21/01/2026
<b>Exp. Date</b>	12/2027	<b>Date of Release</b>	06/02/2026
<b>Reference Batch No</b>	26AR004	<b>MFG. Lic. No.</b>	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	<b>Description</b>	Clear and colorless liquid.	Clear and colorless liquid.
2.	<b>Identification (By HPLC)</b>	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.	<b>pH</b>	Between 3.3 to 4.0	3.66
4.	<b>Related Substance</b> <b>Any other Impurity</b> <b>Total Impurity</b>	NMT 0.2% NMT 1.5%	Complies Complies
5.	<b>Extractable Volume</b>	NLT 4.0 ml	4.0 ml
6.	<b>Bacterial Endotoxins</b>	NMT 9.9 Endotoxin unit per mg of Ondansetron	Less than 9.9 Endotoxin unit per mg of Ondansetron
7.	<b>Particulate Matter</b>	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.	<b>Sterility</b>	Should be Sterile	Sterile
9.	<b>Assay:</b>		



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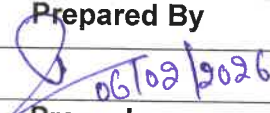
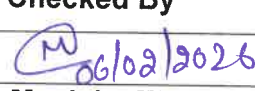

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Each ml contains:			
Ondansetron Hydrochloride IP			
Eq. to Ondansetron 2 mg	1.90 mg to 2.1 mg (90.0 % to 110.0 %)	2.03 mg	101.40 %

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

	Prepared By	Checked By	Approved By
Sign/Date	 06/02/2026	 06/02/2026	 06/02/2026
Name	Prayash	Manisha Thakur	Bhupinder Navet
Designation	Officer QC	Executive-QC	Head-QC

Name: Bhupinder Navet  
Designation: Head QC  
Qualification: M. Pharma  
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Pt BD Sharma University of  
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