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 8mg/4ml)**		
Batch No.	26AR113	**A.R. No.**	AFP260127
Batch Size	10100 Ampoules	**Sample Quantity**	60 Amps.
Mfg. Date	10/2026	**Date of Testing**	15/10/2026
Exp. Date	09/2028	**Date of Release**	30/10/2026
Reference Batch No	26AR113	**MFG. Lic. No.**	HP-MB-LL-00235

Sr. No.	Test	Specification	Observation
1.	**Description**	Clear and colorless solution filled in clear colourless ampoule.	Clear and colorless solution filled in clear colourless ampoule.
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	3.73
4.	**Related Substance** **Any other Impurity** **Total Impurity**	 NMT 0.2% NMT 1.5%	 Not Detected Not Detected
5.	**Extractable Volume**	NLT 4.0 ml	4.0 ml
6.	**Bacterial Endotoxins**	NMT 9.9 EU/mg	Less than 9.9 EU/mg
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

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9.	**Assay:** **Each ml contains:** **Ondansetron Hydrochloride IP** **Eq. to Ondansetron 2 mg**	1.90 mg to 2.10 mg (95.0 % to 105.0 %)	2.04 mg 102.12 %

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

	Prepared By	Checked By	Approved By
Sign/Date	30/10/2026	30/10/2026	30/10/2026
Name	**Diksha Saini**	**Vinay Kumar**	**Bhupinder Navet**
Designation	**Officer QC**	**Sr.Executive-QC**	**Head-QC**

AMERICAN REMEDIES HEALTHCARE PVT. LTD. QUALITY CONTROL MANAGER

Name: Bhupinder Navet
Designation: Head QC
Qualification: M. Pharma
Registration No: 12-DVI-103
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