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 2 Injection (Ondansetron Hydrochloride Injection IP 4mg/2ml)**		
Batch No.	26AR114	**A.R. No.**	AFP260124
Batch Size	151000 Ampoules	**Sample Quantity**	60 Amps.
Mfg. Date	10/2026	**Date of Testing**	09/10/2026
Exp. Date	09/2028	**Date of Release**	24/10/2026
Reference Batch No	26AR114	**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	3.64
4.	**Related Substance** **Any other Impurity** **Total Impurity**	 NMT 0.2% NMT 1.5%	 Not Detected Not Detected
5.	**Extractable Volume**	NLT 2.0 ml	2.0 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

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8.	**Sterility**	Should be Sterile	Sterile
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 %)	2.01 mg 100.34 %

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

	Prepared By	Checked By	Approved By
Sign/Date	24/10/2026	24/10/2026	24/10/2026
Name	**Diksha Saini**	**Vinay Kumar**	**Bhupinder Navet**
Designation	**Officer QC**	**Sr.Executive-QC**	**Head-QC**

Name: Bhupinder Navet
Designation: Head QC
Qualification: M. Pharma
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