



# ALVENTA PHARMA LIMITED

VILL. KISHANPURA, TEHSIL BADDI- NALAGARH ROAD, DISTT.- SOLAN (H.P) 174101

Quality Control Department

## CERTIFICATE OF ANALYSIS (FINISHED PRODUCT)

Product Name	Ondican Injection	A.R. No.	FG/G/25A1633
Generic Name	Ondansetron Injection IP	Sample Quantity	65 Ampoules
Batch No.:	AA50903	Sample Received on	27/09/2025
Batch Size:	102000 Amps	Analysis Date	27/09/2025
Mfg. Date.	09/2025	Release Date	11/10/2025
Exp. Date	08/2027	Page No.:	Page 1 of 1

Sr. No.	Test Parameter	Acceptance Criteria	Result		
1.	Description	A clear colourless liquid filled in 2 ml clear glass ampoule.	A clear colourless liquid filled in 2 ml clear glass ampoule.		
2.	Identification	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution (a).	Complies		
3.	pH	Between 3.3 to 4.0	3.6		
4.	Extractable volume	Not less than 2.0 ml and not more than 2.30 ml	2.01 ml		
5.	Particulate Matter	The Solution should be clear, colourless and free from any visible particle.	The Solution is clear, colourless and free from any visible particle.		
6.	Bacterial Endotoxins Tests	NMT 9.9 EU/mg of Ondansetron	Less than 9.9 EU/mg		
7.	Sterility	Should be sterile	Sterile		
8.	Related Substances:				
	Any secondary impurity	Not more than 0.2%	Not Detected		
	Total impurities	Not more than 1.5%	Not Detected		
9.	Assay:				
	Each ml contains:	Claim	Limit	mg	%
	Ondansetron Hydrochloride IP eq. to Ondansetron	2 mg	Between 95.00 % to 105.00 % of stated amount of Ondansetron. (Between 1.90 mg to 2.10 mg)	2.0112 mg	100.56%

Remarks: The above test parameters are complies/ not complies as per IP/BP/USP & In-House Specification.

Particulars	Prepared By	Checked By	Approved By
Name	Praveen Kumar	Kamal Kant	Fuljeet Kaur
Designation	Executive	Executive	Head QC.
Signature			
Date	11/10/2025	11/10/2025	11/10/2025