

**CERTIFICATE OF ANALYSIS**

Product Name	ONDICAN 2		
Generic Name	Ondansetron Injection IP 2mg/ml, 2ml	Product Code	OD
Batch No	ODA24004	Batch size	250 Liters
Mfg. Date	APR.2024	Exp. Date	MAR.2026
Date of sampling	04/04/2024	Completed Date	19/04/2024
A.R. No	RLS/FP/240087	Specification No.	FPS045

Sr. No.	Tests	Method	Specification	Result	
1	Description	IH	A clear, colourless solution filled in USP type I glass container.	A clear colourless solution filled in USP type-I, 2 ml clear ampoule with blue dot.	
2	Identification	IP	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 (a).	Complies	
3	pH	IP	NLT 3.3 to NMT 4.0	3.80	
4	Density	IH	For information	1.003 g/ml	
5	Extractable volume	IP	NLT nominal volume	2.0 ml	
6	Particulate Matter :		IP	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
	A	Visual inspection			
	B	Particle size $\geq 10\mu\text{m}$	IH	NMT 6000 per container.	156.80 particles per container
Particle size $\geq 25\mu\text{m}$		NMT 600 per container.		3.33 particles per container	
7	Related substances by HPLC	IP	Any secondary peak - NMT 0.2%	0.009%	
			Sum of all secondary peaks- NMT 1.5%	0.146%	
8	Assay (Each 1 ml of solution contains 2 mg Ondansetron)	IP	NLT 95.0% and NMT 105.0% of the labeled amount of Ondansetron ( $\text{C}_{18}\text{H}_{19}\text{N}_3\text{O}$ )	99.4 % ( 1.987 mg/ml)	

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9	BET	IP	NMT 9.9 EU per mg of Ondansetron	Less than 4.8 EU/mg
10	Sterility	IH	Should be sterile	Sterile
Additional tests				
11	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	99.9 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	100.2 %

Remarks: The Sample complies as per IP and In-house specification.

	Analysed by	Checked by	Approved by
Signature	<i>PSH</i>	<i>CF</i>	<i>Yd famat</i>
Date	19/04/2024	19/04/2024	19/04/2024