

CERTIFICATE OF ANALYSIS

Product Name	ONDICAN 2		
Generic Name	Ondansetron Injection IP 2mg/ml, 2ml	Product Code	OD
Batch No.	ODA25005	Batch Size	250 Liters
Mfg. Date	MAR.2025	Exp. Date	FEB.2028
Date of Sampling	21/03/2025	Completed Date	NA
A. R. No.	RLS/FP/250051	Specification No.	FPS045

Sr. No.	Tests	Method	Specification	Results	
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	3.78	
4	Density	IH	For information	1.004 g/ml	
5	Extractable volume	IP	NLT nominal volume	2.0 ml	
Particulate matter					
6	A Visual inspection	IP	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies	
	B	IH	Particle size $\geq 10\mu\text{m}$	NMT 6000 per container	413.20
			Particle size $\geq 25\mu\text{m}$	NMT 600 per container	18.13
7	Related substances by HPLC	IP	Any secondary peak - NMT 0.2%	0.014%	
			Sum of all secondary peaks - NMT 1.5%	0.107%	
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 ($\text{C}_{18}\text{H}_{19}\text{N}_3\text{O}$)	100.3% (2.005 mg/ml)	
9	BET	IP	NMT 9.9 EU per mg of Ondansetron	Less than 4.8 EU per mg	
10	Sterility	IH	Should be sterile	Sterility under observation	



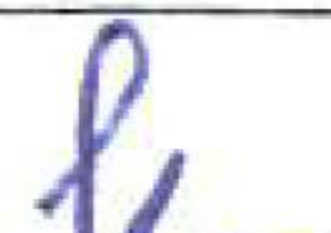
 Corporate Office: No.07, KHB, Industrial Estate, Yelahanka New Town, Bengaluru-560064, India
 CIN : U24111KA19991PT012343

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Sr. No.	Tests	Method	Specification	Results
Additional tests				
11	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	98.1%
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	98.4%

Remarks: The product complies as per IP and In-house specification. Sterility under observation.

	Analysed by	Checked by	Approved by
Signature			
Date	02/04/2025	02/04/2025	02/04/2025

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