

**CERTIFICATE OF ANALYSIS**

Product Name	Ondican 2		
Generic Name	Ondansetron Injection IP 4mg/2ml, 2ml	Product Code	OD
Batch No.	ODA24002	Batch size	400 Liters
Mfg. Date	JAN.2024	Exp. Date	DEC.2026
Date of sampling	31/01/2024	Completed Date	14/02/2024
A.R. No.	RLS/FP/240018	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	3.73
4	Density	IH	For information	1.004 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	IH	NMT 6000 per container.	20.53 particles per container
	Particle size $\geq 25\mu\text{m}$		NMT 600 per container.	0.13 particles per container
7	Related substances by HPLC	IP	Any secondary peak - NMT 0.2%	0.0031%
			Sum of all secondary peaks- NMT 1.5%	0.0434%
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 ( $\text{C}_{18}\text{H}_{19}\text{N}_3\text{O}$ )	100.8 % ( 2.016 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%	100.1 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	99.9 %

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

	Analysed by	Checked by	Approved by
Signature			
Date	22/06/2024	22/06/2024	22/06/2024