

CERTIFICATE OF ANALYSIS

Product Name	ONDICAN 2		
Generic Name	Ondansetron Injection IP 2mg/ml, 2ml	Product Code	OD
Batch No.	ODA24014	Batch size	400 Liters
Mfg. Date	OCT.2024	Exp. Date	SEP.2027
Date of sampling	08/10/2024	Completed Date	22/10/2024
A.R. No.	RLS/FP/240241	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	3.77
4	Density	IH	For information	1.0038 g/ml
5	Extractable volume	IP	NLT nominal volume	2.0 ml
6	Particulate Matter :		Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
	A	Visual inspection		
	B	Particle size $\geq 10\mu\text{m}$ Particle size $\geq 25\mu\text{m}$	IH	NMT 6000 per container. NMT 600 per container.
7	Related substances by HPLC		Any secondary peak - NMT 0.2%	0.012%
			Sum of all secondary peaks- NMT 1.5%	0.092%
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 ($\text{C}_{18}\text{H}_{19}\text{N}_3\text{O}$)	103.5 % (2.070 mg/ml)

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9	BET	IP	NMT 9.9 EU per mg of Ondansetron	Less than 4.8 EU/mg of Ondansetron
10	Sterility	IH	Should be sterile	Sterile
Additional tests				
11	Methyl paraben content	IH	NLT 90.0% and NMT 110.0%	101.3 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	98.0%

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

	Analysed by	Checked by	Approved by
Signature	<u>PSH</u>	<u>PA</u>	<u>PK</u>
Date	11/11/2024	11/11/2024	11/11/2024