CERTIFICATE OF ANALYSIS

Product Name	ONDICAN 2		
Generic Name	Ondansetron Injection IP 4 mg/2ml	Product Code	OD
Batch No.	ODA24013	Batch size	250 Liters
Mfg. Date	OCT.2024	Exp. Date	SEP.2027
Date of sampling	04/10/2024	Completed Date	19/10/2024
A.R. No.	RLS/FP/240239	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	3.96
4	Density	IH	For information	1.0047 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 ≥ 10µm	IH	NMT 6000 per container.	248.67 per container
	B Particle size ≥ 25µm		NMT 600 per container.	7.33 per container
7	Related substances by HPLC	IP	Any secondary peak - NMT 0.2%	0.012%
			Sum of all secondary peaks- NMT 1.5%	0.095%
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 ($C_{18}H_{19}N_3O$)	97.9 % (1.959 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%	100.7 %
	Propyl paraben content	IH	NLT 90.0% and NMT 110.0%	97.3%

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

	Analysed by	Checked by	Approved by
Signature	PSH		
Date	19/10/2024	19/10/2024	19/10/2024