

CERTIFICATE OF ANALYSIS

Generic Name	Zuclopenthixol Decanoate Injection BP 200 mg/ml, 1ml		
Brand Name	ZUXOL DEPOT 200	Product Code	ZD
Batch No.	ZDA25002A	Batch Size	10 Liters
Mfg. Date	JUN.2025	Exp. Date	MAY 2028
Date of Sampling	12/01/2026	Completed Date	13/01/2026
A. R. No.	RLS/FP/260016	Specification No.	FPS076-00

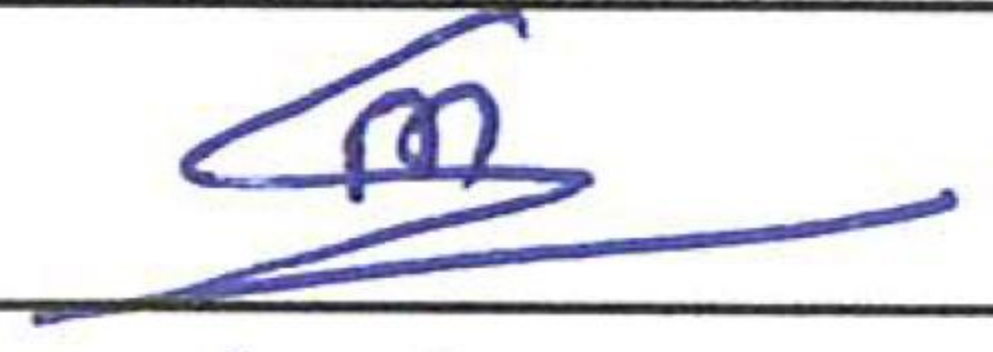
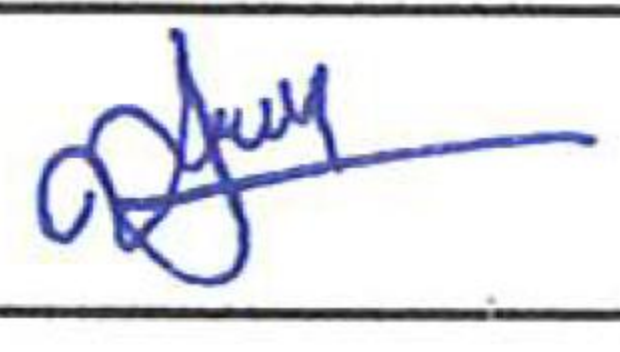
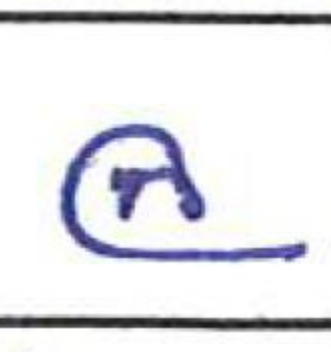
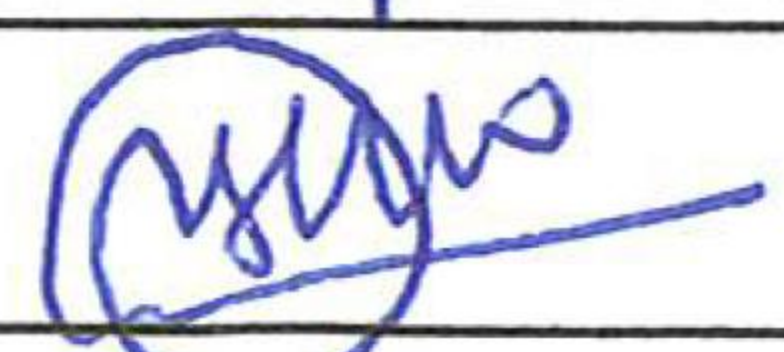
Sr. No.	Tests	Method	Specification	Results
1	Description	IH	Clear colourless or pale yellow solution practically free from particles.	Pale yellow solution practically free from particles filled in USP type I, 1ml clear ampoule with yellow ring.
2	Identification A by TLC	BP	The principal spot in the chromatogram obtained with Solution (1) corresponds to that in the chromatogram obtained with Solution (2).	Complies
	Identification B by HPLC		The chromatogram obtained with Solution (1) shows the peak with the same retention time as the peak due to Zuclopenthixol deconoate in the chromatogram obtained with Solution (2).	Complies
3	Extractable volume	BP	NLT nominal volume	1.0 ml
4	Particulate Matter by visual inspection	IH	Clear and practically free from particles when observed by visual inspection by the unaided eyes.	Complies
5	Related substances (By HPLC)	BP	The area of any peak corresponding to Zuclopenthixol is not greater than the area of the principal peak in the chromatogram obtained with Solution (2) (3%)	0.0545%
			The area of any peak corresponding to 2-chlorothioxanthone is not greater than the area of the principal peak in the chromatogram obtained with Solution (3) (0.5%)	0.0186%
			The area of any peak corresponding to trans-clopenthixol decanoate is not greater than the area of the principal peak in the chromatogram obtained	0.0572%

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Sr. No.	Tests	Method	Specification	Results
			with Solution (4) (1%)	
6	Assay (By HPLC) Content of Zuclopenthixol decanoate, C ₃₂ H ₄₃ CIN ₂ O ₂ S	BP	NLT 95.0 % and NMT 105.0%	100.4 % (200.744 mg/ml)
7	BET	IH	NMT 0.58 EU/mg units per mg of Zuclopenthixol	Less than 0.28 EU per mg
8	Sterility	IH	Should be sterile.	Sterile

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

	Prepared by	Reviewed by	Approved by	Authorized by
Department	Quality Control	Quality Control	Quality Control	Quality Assurance
Name	Manoj Jadhav	Sumit Kumar	Manjunath	Dattajirao S. Desai
Designation	Trainee chemist	Executive	Team Leader	Manager QA
Signature				
Date	13/01/2026	13/01/2026	13/01/2026	13/01/2026.