

CERTIFICATE OF ANALYSIS

Product	Silodosin JP		
Grade	JP	Batch No.	2604/ACCFP/001/LAB
Analysis Date	13-04-2026	Batch Qty.	5 Kg
MFG Date	APRIL-26	Retest Date	MARCH -31

Sr No	Tests	Specification	Result
1	Description	White to pale yellowish white powder	Pale yellowish white powder
2	Solubility	Freely soluble in ethanol & methanol (99.5 %) and in dichloromethane.	Complies
3	Identification		
	A) By IR Spectrophotometry	The absorption spectrum of sample preparation and standard preparation should exhibit similar intensities at the same wave number.	Complies
	B) Test of Fluorides	Should respond to test for fluorides.	Complies
	C) By UV	The absorption spectrum of sample preparation and standard preparation should exhibit similar intensities at same wavelengths.	Complies
4	Optical rotation (on the anhydrous basis)	(-13°) to (-17°)	(-15.0°)
5	Melting Point	105° C-109°C	107°C
6	Residue on ignition	NMT 0.1% W/W	0.05 %
7	Water Content	NMT 0.1% W/W	0.04 %
8	Appearance of solution	Solution A is clear and colorless.	Complies
9	Assay	Between 98.0% to 102.0 % W/W	99.97
10	Heavy Metal	NMT 10 ppm	Complies
11	Enantiomeric Purity	NMT 0.15%	0.05%
12	Related Substance by HPLC		
	1.3 RRT Impurity	NMT 0.15 %	0.09%
	1.6 RRT Impurity	NMT 0.06%	ND
	2.0 RRT Impurity	NMT 0.06%	0.05%
	Highest unknown Impurity	NMT 0.10%	0.00%
	Total Impurity	NMT 0.35%	0.26%

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13	Residual Solvents (by GCHS)		
	Dichloromethane	NMT 600 ppm	71 ppm
	Acetonitrile	NMT 410 ppm	70 ppm
	Isopropanol	NMT 5000 ppm	77 ppm
	Acetone	NMT 3000 ppm	409 ppm
	Toluene	NMT 890 ppm	10 ppm
	Cyclohexane	NMT 3880 ppm	84 ppm
	Ethyl acetate	NMT 5000 ppm	2454 ppm
	Dimethyl Sulfoxide	NMT 5000 ppm	1166 ppm
Storage condition: Store in airtight container below 15°C - 30° C and protect from light.			
Remarks: All above test parameters complies as per JP specifications / monograph.			

Signature			
	Analysed by (Q.C. Designee) 13/04/2026	Checked by (Q.C. In-charge) 13/04/2026	Approved by (Q.A In charge) 13/04/2026

End of the Test Report

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