



CHIMAK HEALTHCARE

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QUALITY CONTROL DEPARTMENT
THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER

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CERTIFICATE OF ANALYSIS

Product Name : SILDALIST	
Generic Name : Sildenafil citrate and Tadalafil Tablets (HS)	
Batch No. : LRMD23006	A.R. No. : FGLT05232601
Batch Size : 2,00,000.000 TAB	Qty. of Sample : 60.000 TAB
Mfg. Dt. : MAY-2023	Exp. Dt. : APR-2026
Parent Product Code : SMD000475	Received Dt. : 31/05/2023
Parent Batch No. : LHAD23006	Release Dt. : 31/05/2023
Parent Batch Size : 2,00,000.000 TAB	Specification No. : CHC/QC/FGPS/973
Storage Condition : Store at a temperature not exceeding 25°C in a dry place, protect from light	

Sr.	Test	Result	Specification
1	Description	Brown coloured, rectangular shaped, flat one side breakline and other side two line film coated tablet, contains in Blister pack, imprinted with SILDALIST.	Brown coloured, rectangular shaped, flat one side breakline and other side two line film coated tablet, contains in Blister pack, imprinted with SILDALIST.
2	Identification test	Complies	Should be positive for Sildenafil citrate & Tadalafil,
3	Average weight	585.50 mg	582.0 mg \pm 5.0%
4	Uniformity of weight	-1.34%, +1.21%	\pm 5.0 % of average weight
5	Length in mm	16.85 mm	16.80 mm \pm 0.2 mm
6	Width in mm	6.58 mm	6.50 mm \pm 0.2 mm
7	Thickness	4.06 mm	4.00 mm \pm 0.5 mm
8	Hardness in Kg/cm ²	26.6 kg/cm ²	NLT 5 kg/cm ²
9	Dissolution for Sildenafil citrate U.S.P. eq. to Sildenafil 100 mg	Min 99.55% & Max 104.36%	NLT 70.0%
10	Dissolution for Tadalafil USP 20 mg	Min 88.30% & Max 92.01%	NLT 60.0%
11	Assay for Sildenafil Citrate USP eq. to Sildenafil 100 mg	99.522 mg (99.52%)	NLT 90.0% & NMT 110.0% of the label claim
12	Assay for Tadalafil USP 20 mg	19.644 mg (98.22%)	NLT 90.0% & NMT 110.0% of the label claim

In the opinion of undersigned the sample referred to above is standard quality / not of standard quality, as per IHS specification.

Analysed By

Prash
31/05/2023

Reviewed By

31/05/2023

QA Department

31/05/2023

Approved By

31/05/2023