



## RAKSHIT PHARMACEUTICALS LIMITED Plot No 68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District, Andhra Pradesh, India-531021

## **CERTIFICATE OF ANALYSIS**

<b>Product Name</b>	SILDENAFIL CITRATE Ph.Eur.		
Batch Number	200190010323	A.R Number	FP/23/03/052
Mfg. Date	MAR-2023	Retest / Expiry Date	FEB-2028
Dispatch Qty	20.00 Kg	Ref STP No.	STP/FP/SC/005/03
Customer Name	M/S.F&A PHARMA – HANDELS GMBH.		
CEP Number	R1-CEP 2014-361 - Rev 01		./

S. No.	Test	Specification	Result
1.	Appearance	A White or almost White powder, slightly hygroscopic crystalline powder.	White, Slightly hygroscopic crystalline powder
2.	Solubility	Slightly soluble in water and in methanol, Practically insoluble in hexane.	Complies
3.	Identification by IR	The IR absorption spectrum of sample should match to the spectrum of Sildenafil citrate working standard.	Complies
4.	Water content by KF(%w/w)	Not more than 2.5	1.26
5.	Sulphated ash(%w/w)	Not more than 0.1	0.04
6.	Impurity E (By Thin Layer Chromatography, %)	Not more than 0.1	Less than 0.1
	Related Substances by HPLC (%)		
	Impurity-A	Not more than 0.15	Not detected
7.	Impurity-D	Not more than 0.15	Not detected
	Unspecified Impurity	Not more than 0.10	Not detected
	Total impurities	Not more than 0.5	Not detected
<b>8</b> .	Assay by HPLC (on anhydrous basis, %w/w)	Not less than 98.0 and Not more than 102.0	99.9

	Prepared By	Reviewed By	Approved By
Department	Quality Assurance	Quality Assurance	Quality Assurance
Sign & Date	OGlioho23	139 No 110 20 23	001012013

Format No.: QAD/028-F13-02

Page 1 of 2





## RAKSHIT PHARMACEUTICALS LIMITED Plot No 68/A, Jawaharlal Nehru Pharma City, Parawada Mandal, Anakapalli District, Andhra Pradesh, India-531021

## CERTIFICATE OF ANALYSIS

<b>Product Name</b>	SILDENAFIL CITRATE PI	n.Eur.	
Batch Number	200190010323	A.R Number	FP/23/03/052
Mfg. Date	MAR-2023	Retest / Expiry Date	FEB-2028
Dispatch Qty	20.00 Kg	Ref STP No.	STP/FP/SC/005/03
Customer Name	M/S.F&A PHARMA – HANDELS GMBH.		
CEP Number	R1-CEP 2014-361 - Rev 01		. /

S. No.	Test	Specification	Result	
	Residual solvents by HSGC (ppm)			
	Dimethyl Formamide	Not more than 500	Not detected	
	Methanol	Not more than 1500	10	
9.	Ethyl acetate	Not more than 3000	7	
	Toluene	Not more than 500	Not detected	
	Acetone	Not more than 3000	11	
	Methylenechloride	Not more than 400	Not detected	

REMARKS: The product conforms as per above specifications.

Storage condition: In air-tight containers.

Prepared By Reviewed By Approved By Department Quality Assurance Quality Assurance Quality Assurance obluboas Toblisho23 Sign & Date

Format No.: QAD/028-F13-02