SMS Lifesciences India Limited
Unit - I, Sy No. 180/2, Kazipally Village, Jinnaram Mandal,
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Tel : +91-8458-277067 / 277068 / +91-8374455598
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CERTIFICATE OF ANALYSIS

Product	: SILDENAFIL CITRATE USP		
Batch No.	: SLC 114 10 20	Mfg. Date	: September 2020
Quantity	: 150 Kg	Retest Date	: August 2025
Date of analysis	: 28/09/20	Source Batch No. A.R.No.	: SLC/20/050 : FP/1268/20

Storage	: Preserve in air tight containers. Do not store above 25°C.

S.NO.	TEST PARAMETER	SPECIFICATION	RESULT
1.	Description	White or almost white 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 infrared absorption spectrum of the potassium bromide dispersion of the sample preparation should be exhibit maxima only at the same wave numbers as that of a similar preparation of Sildenafil citrate working standard/Reference standard.	Complies.
4.	Assay by HPLC (%,w/w) (Anhydrous and solvent-free basis)	Not less than 98.0 and not more than 102.0	101.0
5.	Residue on ignition (%, w/w)	Not more than 0.1	0.03
6.	Limit of imidazole by TLC (%,w/w)	Any spot corresponding to imidazole in the sample solution is not more intense than the principal spot from standard solution-2 (0.1%)	Less than 0.1
7.	Water by KF(%,w/w)	Not more than 2.5	1.4

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S.NO.	TEST PARAMETER	SPECIFICATION	RESULT
8.	*Organic impurities by HPLC (%,w/w)*		
	Sildenafil related compound-A	Not more than 0.3	0.01
	Any other unspecified individual impurity	Not more than 0.10	0.02
	Total unspecified impurities	Not more than 0.3	0.06
	Total impurities	Not more than 0.5	0.06
9.	# Residual solvents (ppm)		
	a) Methanol	Not more than 1000	45
	b) Methylene chloride	Not more than 100	Not detected
	c) Ethyl acetate	Not more than 200	Not detected
	d) Toluene	Not more than 100	*BQL

Conclusion: The Material conforms to USP specifications.
**LOQ: Limit of quantification (LOQ: 17.0 µg/g and LOD: 5.1 µg/g)*
#Periodical testing (Skip test): *Frequency – This test is performed for the first batch produced in a year and there after 1/20 ± 01 batch. This test is performed according to the defined frequency and also as per requirement by following the validated procedure which is incorporated in the Sildenafil Citrate Standard test method provided below*

Reference Specification and Test Method (STM) No. & Revision No.: *[STM/FP/SLC3/03-03].*

Prepared by:	Checked by:	Approved by:
Date: 26/10/20	Date: 26/10/20	Date: 26/10/20
I.V.V. Subrahmanyam	K. Pradeep	Ch. Ram Prasad
Sr. Officer - QA	Asst. Manager - QC	Sr. Manager - QC