sms Pharmaceuticals Limited

Registered & Corporate Office :
Plot No. 72, H. No. 8-2-334/3 & 4, Road No. 5,
Opp. SBI Executive Enclave, Banjara Hills,
Hyderabad - 500 034, Telangana, INDIA.
Tel : +91-40-2525 9999, Fax : +91-40-2525 9889
CIN : L24239TG1987PLC008066
www.smspharma.com

CERTIFICATE OF ANALYSIS

Name of the Product	: **Sildenafil Citrate Ph. Eur.**		
Batch No.	: SLC/0719018	A.R. No.	: FP/19/0292
Quantity	: 3.00 kg	Date of Analysis	: 29.07.2019
Mfg. Date	: July – 2019	Expiry date	: June – 2024

S. No.	Test parameter	Result	Specifications (Ref. No.CS-FP-5042-02,Rev.05)
1.	Characters		
	a) Appearance	White, slightly hygroscopic crystalline powder.	White or almost white, slightly hygroscopic, crystalline powder.
	b) Solubility	Slightly soluble in water and in methanol, Practically insoluble in hexane.	Slightly soluble in water and in methanol, Practically insoluble in hexane.
2.	Identification by IR	The infrared absorption spectrum of the potassium bromide dispersion of the sample preparation is exhibit maxima only at the same wave numbers as that of a similar preparation of Sildenafil citrate Working standard.	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.
3.	Impurity-E by TLC (%)	Less than 0.1	Not more than 0.1
4.	Related substances by HPLC (%,w/w)		
	Sildenafil Impurity – A	BRT (0.05)	Not more than 0.15
	Sildenafil Impurity – D	BRT (0.05)	Not more than 0.15
	Unspecified Impurity	BRT (0.05)	Not more than 0.10
	Total impurities	BRT (0.05)	Not more than 0.5

	Prepared by	Reviewed by	Approved by
Sign & Date	24/10/19	24/10/19	24/10/19
Name	P. Sriram	J. Naresh Babu	M. Yedukondalu
Designation	Officer – QA	Dy. Manager – QC	Asst. Manager – QA

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5.	Water content by KF (%, w/w)	1.1	Not more than 2.0
6.	Sulphated ash (%, w/w)	0.03	Not more than 0.1
7.	Assay by HPLC (anhydrous substance) (%, w/w)	99.6	Not less than 98.0 and Not more than 102.0
8.	Residual solvents by GC (ppm)		
	Methanol	Below LOQ (29)	Not more than 1000
	Methylene chloride	Below LOD (17)	Not more than 100
	Ethyl acetate	Below LOD (8)	Not more than 200
	Toluene	Below LOD (5)	Not more than 100
9.	Identification of polymorph		
	XRD	XRD difractogram exhibits specific 2θ value at 8.0, 10.2, 14.4, 16.1, 19.8, 22.6 and 28.8	XRD difractogram should exhibit specific 2θ value at $\pm 0.2^0$ of 8.1, 10.3, 14.4, 16.2, 19.9, 22.7 and 28.9
	DSC	The DSC thermogram exhibits a single peak at 201.9^0 as an indication of melting.	The DSC thermo gram should exhibit a single peak at about 201^0 as an indication of melting.

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S. No.	Test parameter	Result	Specifications (Ref. No.CS-FP-5042-02,Rev.05)
Skip tests:			
#10.	Determination of 'SLC-II' Content by HPLC (ppm)	Not required	Not more than 15
#11.	Determination of 'SLC-III' Content by HPLC (ppm)	Not required	Not more than 15
#12.	Determination of 'Sildenafil Methyl sulfonate' Content by HPLC (ppm)	Not required	Not more than 15

Conclusion: - The product conforms to the **Sildenafil Citrate** Ph. Eur. (9.4) specifications.
LOD: - Limit of Detection, LOQ: - Limit of Quantitation & BRT: - Below Reporting Threshold.

SLC-II: 1-Methyl-3-propyl-4-nitropyrazolo-5-carboxylic acid.
SLC-III: 1-Methyl-3-propyl-4-nitropyrazolo-5-carboxamide.

 # Skip tests: Frequency - First batch produced and there after 1/10 batches produced in a year. The specified tests were performed according to the defined frequency, following the validated procedures which were incorporated in the Sildenafil Citrate standard test procedure [TP-FP-5042-02].

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