METAPHARMACEUTICAL

N DE LOTE: 0060824

26/08/2024

SMS Lifesciences India Limited
Unit - I, Sy No. 180/2, Kazipally Village, Jinnaram Mandal,
Sangareddy , Telangana - 502 319, INDIA(IND).
Tel : +91-8458-277067 / 277068 / +91-8374455598
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CERTIFICATE OF ANALYSIS

Product	: SILDENAFIL CITRATE Ph.Eur.		
Batch No.	: SLC0400724	Mfg. Date	: April 2024
Quantity	: 40 Kg	Retest Date	: March 2029
Date of analysis	: 27/04/24	Source Batch No.	: SLC/24/010
		A.R.No.	: FP/0411/24

Storage	:	Store in air tight container at controlled room temperature (20-25°C) with excursions permitted between 15-30°C.

S.NO.	TEST PARAMETER	SPECIFICATION	RESULT
1.	Characters		
	a) Appearance	White or almost white, slightly hygroscopic, crystalline powder.	White slightly hygroscopic, crystalline powder.
	b) Solubility	Slightly soluble in water and in methanol. Practically insoluble in hexane.	Complies
2.	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
3.	~~Impurity E by TLC (%)~~	~~Not more than 0.1~~	~~Less than 0.1~~
4.	Related substances by HPLC (%,w/w)		
	Impurity A	Not more than 0.15	*BDL
	Impurity D	Not more than 0.15	**BDL
	Any Unspecified impurity	Not more than 0.10	0.03
	Total impurities	Not more than 0.5	0.06
5.	Water content by KF (%, w/w)	Not more than 2.5	1.60
6.	Sulphated ash (%, w/w)	Not more than 0.1	0.03

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S.NO.	TEST PARAMETER	SPECIFICATION	RESULT
7.	Assay by HPLC (Anhydrous basis) (%, w/w)	Not less than 98.0 and not more than 102.0	100.7
8.	Citric acid content by HPLC (%, w/w)	Not less than 28.0 and not more than 30.0	29.1
9.	*# Residual solvents (ppm)*		
	Methanol	Not more than 1000	BDL
	Dichloromethane	Not more than 100	BDL
	Ethyl acetate	Not more than 200	BDL
	Toluene	Not more than 100	BDL

Conclusion: The material conforms to Ph.Eur. and additional specifications.
**BDL: Below Detection Limit. (LOD: 0.003 %, & LOQ: 0.01%)*
***BDL: Below Detection Limit. (LOD: 0.001 %, & LOQ: 0.004%)*
Note: BDL: Below Detection limit.
Methanol: (LOD:29.1 ppm & LOQ: 88.2 ppm) Dichloromethane: (LOD: 8.3 ppm & LOQ: 25.3 ppm) Ethyl acetate: (LOD: 11.1 ppm & LOQ: 33.9 ppm) Toluene: (LOD: 6.1 ppm & LOQ: 18.5 ppm)

#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/SLC3/04-01].*

Prepared by:	Checked by:	Approved by:
Date: 11/07/24	Date: 11/07/24	Date: 11/07/24
V. Venkatesh	K. Pradeep	Ch. Ram Prasad
Executive - QA	Dy. Manager - QC	Sr. Manager - QC