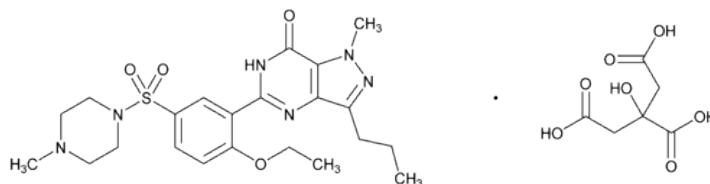


CERTIFICATE OF ANALYSIS

SILDENAFIL CITRATE USP



Molecular Formula: C₂₂H₃₀N₆O₄S·C₆H₈O₇
Molecular Weight: 666.70 g/mol

Lot No. 18011301181121
CAS # 171599-83-0
Storage Condition Room Temperature

Manufacture Date 12/2017
Expiration Date 11/2022
Country of Origin India

TEST	SPECIFICATION	RESULT
Description	White, slightly hygroscopic crystalline powder.	Complies
Solubility	Slightly soluble in Water and Methanol. Practically insoluble in Hexane.	Complies
Identification (IR)	Complies with USP specification	Complies
Identification (HPLC)	Complies with USP specification	Complies
Limit if Imidazole (TLC)	≤ 0.1%	< 0.1%
Related Compound A	≤ 0.3%	BDL
N-oxide Impurity	≤ 0.1%	BDL
Unspecified Individual Impurities	≤ 0.1%	BDL
Total Unspecified Impurities	≤ 0.3%	BDL
Total Impurities	≤ 0.5%	BDL
Water Content	≤ 2.0%	1.3%
Residue on Ignition	≤ 0.1%	0.04%
Heavy Metals	≤ 20 ppm	< 20 ppm
Assay (Anhydrous)	98.0% – 102.0%	100.3%
Methanol	≤ 1000 ppm	BDL
Methylene Chloride	≤ 100 ppm	BDL
Ethyl Acetate	≤ 200 ppm	BDL
Toluene	≤ 100 ppm	BDL
Citric Acid Content	28.0% – 30.0%	28.5%
Particle Size	90%, ≤ 50 μm	32.2%



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Quality Signature

A handwritten signature in black ink, appearing to read "J. V. 11/21/18", is positioned above a horizontal line.

Compendium

USP 39

Date

11/21/2018

Conclusion

APPROVED