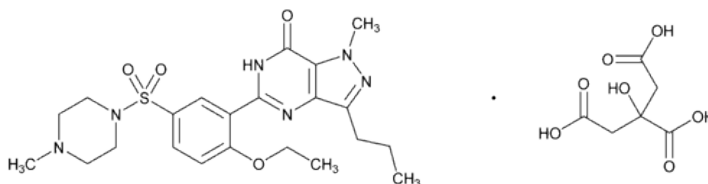


CERTIFICATE OF ANALYSIS

SILDENAFIL CITRATE USP



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

Lot No. 17033001171023
CAS # 171599-83-0
Storage Condition Room Temperature

Manufacture Date 06/2016
Expiration Date 05/2021
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%



115 W. 3rd Street, Suite 720 Tulsa, OK 74103 | (P): 539.777.0720 | (F): 539.777.2487 | www.triovarx.com

Quality Signature
Compendium
Date
Conclusion

A handwritten signature in black ink, appearing to be "A. L.", is written above a horizontal line.

USP 39
10/23/2017
APPROVED