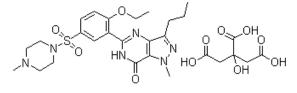


Certificate of Analysis Sildenafil Citrate USP

CAS # 171599-83-0 MF # C₂₈H₃₈N₆O₁₁S MW # 666.70 Batch # SP/07/19/147 Code # 1877



Mfg Date: 08/2019 Retest Date: 07/2024 Country of Origin: India

TEST

Appearance

Solubility

Identification by IR

SPECIFICATION

White or almost white slightly Hygroscopic crystalline powder Slightly soluble in water and in Methanol, practically insoluble in Hexane.

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 $Complies \leq 0.1\%$

RESULT

White slightly Hygroscopic crystalline powder

Complies

Not Detected

Not Detected

Not Detected

Not Detected

1.69%

0.03%

Complies

Complies

14ppm

Limit of Imidazole by TLC Related Substance by HPLC Impurity A $\leq 0.3\%$ Any Other Unspecified **Individual Impurity** $\leq 0.1\%$ Total Unspecified Impurities $\leq 0.3\%$ **Total Impurities** $\leq 0.5\%$ Water Content by KF < 2.5% **Residue on Ignition** $\leq 0.1\%$ Residual solvents by GC Methanol \leq 3000ppm Ethyl acetate \leq 5000ppm Acetone \leq 5000ppm



Methylenechloride Toluene Assay by HPLC (On Anhydrous and solvent free Basis) \leq 600ppm \leq 890ppm \geq 98.0% and \leq 102.0% Complies Complies 100.0%

This product complies with USP Specification

