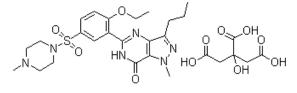


## Certificate of Analysis Sildenafil Citrate USP

CAS # 171599-83-0 MF # C<sub>28</sub>H<sub>38</sub>N<sub>6</sub>O<sub>11</sub>S 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

