WRS-T1-3

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SUN PHARMA

CERTIFICATE OF ANALYSIS
WORKING REFERENCE STANDARD

PRODUCT NAME : **Tadalafil USP**

EFFECTIVE DATE : **23.10.13**

EVALUATED WITH : **USP RS LOT F0L003**

VALIDITY OF USE : **22.10.15**

STORAGE CONDITION : **Preserve in tight, light resistant container at 20°C to 25°C, Excursions permitted between 15°C and 30°C**

WORKING STANDARD NO. : **TDL/WRS/1856**

SOURCE : **BATCH NO. : AHMTDLFL004**

Sr. No.	Test	Result	Specifications
1	Description	White crystalline powder.	White or almost white crystalline powder.
2	Identification		
2.1	By IR	The Infrared Spectrum of the sample in potassium bromide dispersion is concordant with similarly recorded spectrum of Tadalfil USP RS LOT F0L003	The Infrared spectrum of the sample in potassium bromide dispersion should be concordant with similarly recorded Infrared spectrum of Tadalafil USP RS
2.2	By HPLC	The retention time of the major peak of the sample solution is correspond to that of the identification solution as obtained in the enantiomeric and diastereomeric purity test	The retention time of the major peak of the sample solution should correspond to that of the identification solution as obtained in the enantiomeric and diastereomeric purity test
2.3	X-ray Diffraction	Complies	The characteristics 2-theta peaks 7.3°, 10.6°, 12.6°, 14.6°, 18.5°, 21.8° and 24.3° of sample corresponds to Form I should be within ±0.2°
3	Assay by HPLC		
3.1	Assay by HPLC	99.7 % (On dried basis) 99.5 % (On as is basis)	Between 97.5% and 102.5% w/w (On dried basis)
4	Related Substances (By HPLC)		
	Known Impurities		
	Impurity A	Not Detected	Not more than 0.1%
	Impurity B	BDL	Not more than 0.1%
	Impurity C	BDL	Not more than 0.1%
	Impurity D	BDL	Not more than 0.1%
	Impurity I	BDL	Not more than 0.1%