



XI'AN HARMONIOUS NATURAL BIO-TECH CO.,LTD

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Certificate of Analysis

Product Name: Sildenafil Citrate	CAS No.: 171599-83-0
Test sample: 30g	Quantity: 800 KGS
Manufacture Date: Dec 12, 2018	Analysis Date: Dec 13, 2018
Batch No.: HNB1212-1	Expiry date: Dec 12, 2020
Storage: Store in cool&dry place, in well-closed containers.	
Shelf life: 24 Months when properly stored.	
Standard: USP 36	

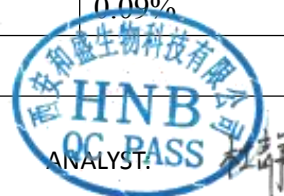
ITEMS	SPECIFICATIONS	RESULT
Appearance	White or almost white powder	Complies
Solubility	Slightly soluble in water and in methanol.	Complies
Identification by IR	The absorption maxima in the spectrum obtained with sample corresponds in position and relative.	Complies
Limit of Imidazole by TLC	NMT 0.1%	<0.1%
Heavy metals	NMT 20ppm	<20ppm
Water determination	NMT 2.50%	0.83%
Residue on ignltion	NMT 0.10%	0.08%
Assay by HPLC	98% to 102%	99.41%
Methanol	NMT 3000ppm	56ppm
Methylenechloride	NMT 600ppm	Not detected
Ethyl acetate	NMT 5000ppm	Not detected
Toluene	NMT 890ppm	Not detected
Acetone	NMT 5000ppm	Not detected
Related substances by HPLC		
Related compound-A	NMT 0.3%	0.02%
Any other Unspecified individual impurity	NMT0.1%	0.04%
Total unspecified impurities	NMT0.3%	0.07%
Total impurities	NMT0.5%	0.09%
Conclusion	COMPLIES WITH USP 36	

QC MANAGER:

王要月

INSPECTOR:

杨思远



ANALYST:

杜静