



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

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Certificate of Analysis

Product Name: **Sildenafil**

Batch Number: HNB211128

Batch Quantity: 300kg

Manufacture Date: Nov.28,2021 Analysis Date: Nov.29,2021

Storage: Store in cool & dry place. Store in well-closed containers.

Shelf life: 24 Months when properly stored.

ITEMS OF ANALYSIS	SPECIFICATIONS	RESULT
Appearance	White powder	Complies
Assay by HPLC	98% to 102% w/w	99.41%w/w
Solubility	Slightly soluble in water and in methanol.	Complies
Identification by IR	The absorption max. in the spectrum obtained with sample corresponds in position and relative intensity to those in the spectrum obtained with Sildenafil citrate CRS	Complies
Limit of Imidazole by TLC	≤0.1%	<0.1%
Heavy metals	≤20ppm	<20ppm
Water determination	≤2.50%w/w	0.83%w/w
Residue on ignition	NMT 0.10%w/w	0.08%w/w
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%
Impurities	Any other Unspecified individual impurity: NMT0.1%	0.04%
	Total unspecified impurities: NMT0.3%	0.07%
	Total impurities: 0.5%	0.09%

Conclusion

Complied with the standard

QC MANAGER:

王翠月

INSPECTOR:

杨思远

