



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

Address:No.8 Port Avenue ,Xi'an International Trade & Logistics Park ,Xi'an ,China

Tel:+86-29- 86712509

Email: james@xahnb.com

www.xahnb.com

http://xahnb.en.alibaba.com/

Certificate of Analysis

|  |                            |
|--|----------------------------|
| Product Name: Sildenafil Citrate                             | CAS No.: 171599-83-0       |
| Test sample: 30g   | Quantity: 800 KGS          |
| Manufacture Date: Nov 12, 2017                               | Anaysis Date: Nov 13, 2017 |
| Batch No.: HNB171112-1                                       | Expiry date: Nov 12, 2019  |
| 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                 | ≤0.1%  | <0.1%        |
| Heavy metals                              | ≤20ppm   | <20ppm       |
| Water determination                       | ≤2.50%w/w  | 0.83%w/w     |
| Residue on ignltion                       | NMT 0.10%w/w   | 0.08%w/w     |
| Assay by HPLC                             | 98% to 102% w/w  | 99.41%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%        |
| Any other Unspecified individual impurity | NMT0.1%  | 0.04%        |
| Total unspecified impurities              | NMT0.3%  | 0.07%        |
| Total impurities                          | NMT0.5%  | 0.09%        |
| <b>Conclusion</b>                         | COMPLIES WITH USP 36   |              |

QC MANAGER:

王要月

INSPECTOR:

杨思远



ANALYST:

杜静