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CERTIFICATE OF ANALYSIS

| | J(X) - (-) | | | |
|--|--|---------------------------|--|--------------------------|
| Working standard | Nevirapine | Raw material source | | Shangai Desano Phar. Ltd |
| name | | | | |
| Working standard number | WRS NE15-102 | Raw material B/No | | DSH 027B-120 |
| Effective date | 07/2015 | Raw material Mfg date | | 01/2012 |
| Valid up to | 07/2016 | Raw material Exp date | | 01/2016 |
| Reference standard | | Reference standard source | | 1 |
| batch number | 1.0 | | | EDQM |
| Test(s) qualified for | Assay | Certificate No: | | WRS-0323 |
| Test protocol | INT, PH | | | |
| ITEMS | SPECIFICATIONS | | RESULTS | |
| Description | A white to almost white powder | | White powder. | |
| Description | | | | |
| Solubility | Practically insoluble in water, sparingly to slightly soluble in dichloromethane R, slightly soluble in methanol R | | Practically insoluble in water, slightly soluble in dichloromethane R, slightly soluble in methanol R | |
| Identification: A. IR absorption Spectrophotometry | A. The IR absorption spectrum of the substance is concordant with the reference spectrum of Nevirapine CRS | | A. The IR absorption spectrum of the substance is concordant with the reference spectrum of Nevirapine CRS | |
| Water Sulphated ash | NLT 31 mg/g and NMT 39 mg/g NMT 1.0 mg/g | | 34 mg/g 0.7 mg/g | |
| Assay (% w/w on as is | 98.0%-102.0% | | 99.15% | |
| basis) Storage | Kept in tightly closed container, protected from light and stored in a cool dry place [1] | | | |

The above referred material complies /dues not comply with the INT. PH specifications

Simon KAsim Name: Signature:

Date: _ **OUALITY CONTROL MANAGER** ANALYST

Signatur

HEAD QUALITY ASSURANCE

1.6 JUL 2015 STALL CONTERS



Date: