

WRS N₁-2

UNIVERSAL
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CERTIFICATE OF ANALYSIS

Working standard name	Nevirapine	Raw material source	Shangai Desano Phar. Ltd
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 batch number	1.0	Reference standard source	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.	
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 basis)	98.0%-102.0%	99.15%	
Storage	Kept in tightly closed container, protected from light and stored in a cool dry place		

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

Name: Simon Kasim

Signature: [Signature]

Date: 16/07/15

ANALYST

Name: DR. RADYAH J

Signature: [Signature]

Date: 16/07/15

QUALITY CONTROL MANAGER

Name: [Signature]

Signature: [Signature]

Date: 16/07/15

HEAD QUALITY ASSURANCE



UNIVERSAL
CORPORATION LIMITED



DIRECTORS: P.R Dhanani (British), R.R. Dhanani (Kenyan), P. Keskitalo (Finnish)
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