

WRS N1-6

UNIVgRSAL

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CORPORATION LIMITED

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Email: info@ucl.co.ke

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

MATERIAL : NEVIRAPINE
MANUFACTURER : SHANGHAI DESANO CHEM PHARMA CO. LTD
SUPPLIER : STRIDES SHASUN
BATCH No . DBH027-C16A-160912
QUANTITY . 175KGS
MFG DATE • 09/16 EXP DATE
• 09/20
C REF CR17/01/0031

TEST PROTOCOL : USP

TEST	SPECIFICATIONS	RESULTS
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co.ke

Reviewed
03/08/2017
JH



Description	White to off white crystalline powder.	White crystalline powder
Identification	IR spectrum of sample is concordant to that of CRS/WRS.	IR spectrum of sample was concordant to that of CRS/WRS.
*B. HPLC	The retention time of the major peak in the chromatogram of the Assay preparation should correspond to that of standard preparation, as obtained in the Assay.	Complies
Solubility	Practically insoluble in water, slightly soluble in alcohol and methanol	Practically insoluble in water, slightly soluble in alcohol and methanol
*Polymorphisim	The XRPD pattern of sample should be concordant with the reference XRPD pattern.	Complies
Water	NMT 0.2%	0.08%
ROI	NMT 0.1%	0.06%
*Heavy metals	NMT 0.001%	
Foreign matter	The sample should be free from foreign matter visual inspection	Sample is free from foreign matter
*Melting range	240 °c to 250°C	246.7° C to 248.9° C
*Bulk density IH	For information only	0.26g/ml
*Tapped density IH	For information only	0.48g/ml
*Residual solvents	Diglyme: ~ 0.005% Ethanol: 0.3%	Not detected Not detected
*Particle size	NMT 1 Ogm by Malvern master	8gm

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DIRECTORS: Perviz Dhanani (British), Pentti Keskitalo (Finnish), Rupen Haria (Kenyan), Umesh Pralhadrao (Indian), Sinhue Noronha (Indian), Ravi Shankar (Indian),

*Specified and unspecified impurities by HPLC		BQL
i. Nevirapine related compound A	NMT 0.2%	
ii. Nevirapine related compound B	NMT 0.2%	0.02%
iii. Nevirapine Impurity C	NMT 0.2%	BQL
iv. Butenyl analogue of Nevirapine IH	NMT 0.	BQL
V. Any other individual unspecified impurity	NMT 0.	0.02%
vi. Total impurities	NMT 0.6%	0.04%
*Assay (On dried basis)	98.0% to 102.0%	99.8%
*Assay (On as is basis)	For information only	99.7%

* As per the Manufacturer's COA.

The above -referred material **complies / does not comply** with the tests done as per USP specifications.

Name: Francis
Signature: [Signature]
Date: 16/02/17

ANALYST

Name: DR. RADINAH J
Signature: [Signature]
Date: 16/02/17

QUALITY CONTROL MANAGER

Name: Dr. G. M. K. K. K.
Signature: [Signature]
Date: 17/02/17

HEAD QUALITY ASSURANCE



UNIVERSAL CORPORATION LIMITED

Name:

Signature:

Date:

Akhilesh Kumar (Indian), Coutts Otolu (Kenyan)

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