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Mylan

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CERTIFICATE OF ANALYSIS

WORKING STANDARD

Name	:	Nevirapine USP (Anhydrous)	A.R. No.	:	MLAWSD15000141
Source Batch No.	:	C5028-15-195M	Batch No	:	50049126
Date of Standardization	:	25/12/2015	Retest Date	:	11/06/2016
Ref.Specification	:	RMSNVP503-02	Validity	:	11/12/2016
Storage Condition	:	Store in well closed container below 30°C.	Standardized against:		Nevirapine Anhydrous USPRS Lot No.G0M270

S.No.	Test	Specification	Results
1)	Description	White to off-White, odorless to nearly odorless, crystalline powder.	Off white, odorless, crystalline powder.
2)	Identification By Infrared absorption	The infrared absorption spectrum of the sample in potassium bromide dispersion should exhibit maxima only at the same wavelengths as that of a similar preparation of Nevirapine anhydrous RS/WS.	The infrared absorption spectrum of the sample in potassium bromide dispersion exhibits maxima only at the same wavelengths as that of a similar preparation of Nevirapine anhydrous USPRS Lot.No.:G0M270
3)	Water determination (By KF)	Not more than 0.2% w/w	0.04 % w/w
4)	Assay (By HPLC)	Not less than 98.0 % w/w and not more than 102.0% w/w of $C_{15}H_{14}N_4O$, calculated on the anhydrous basis.	98.9% w/w
		Also report on 'as-is' basis.	98.8% w/w

Remarks: This working standard complies/does ~~not comply~~ with above reference specification.

	Prepared By	Checked By	Approved By
Name	Mohsin Mokashi	Gopinath M. P.	S. Gokulakrishnan
Sign			
Date	25/12/15	25/12/15	28 JUN 2016 25/12/15

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