

R14-4

WRS R14-4



MYLAN LABORATORIES LIMITED
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik - 422 113, Maharashtra, India.

**CERTIFICATE OF ANALYSIS
(WORKING STANDARD)**

Name: Ritonavir			
Source Batch No.	50063616	W.S. A.R. No.	MLNWS16000152
Date Of Standardization	Oct 14 2016 9:41AM	Standardized against	Ritonavir USPRS Lot No.: H0M427
Storage Condition	NMT 25°C	Validity	Oct 09, 2017
STP No.	RMPRIT003-13	Ref. Specification	RMSRIT003-16

S. No.	TEST	SPECIFICATION	RESULTS
1	Description	White or almost white powder.	White powder.
2	Identification (By IR)	The infrared absorption spectrum of the sample should exhibit maxima only at the same wavelengths as that of a similar preparation of USP Ritonavir reference standard / Ritonavir (Form II) working standard.	The infrared absorption spectrum of the sample exhibit maxima only at the same wavelengths as that of a similar preparation of Ritonavir USPRS Lot No: H0M427
3	Water determination (By KF)	Not more than 0.5% w/w	0.04 % w/w
4	Assay (By HPLC)	Not less than 97.0% w/w and not more than 102.0% w/w of $(C_{37}H_{48}N_{6/5}UB)O_5S_2$, calculated on anhydrous basis.	On 'anhydrous basis': 99.2 % w/w On 'as is basis': 99.2 % w/w



Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Bhushan.Amrutkar	Approved By	Gautam.Patil
Checked On	Oct 12 2016 5:14PM	Approved On	Oct 14 2016 9:41AM
Printed by: Gautam.Patil	Printed on: Oct 14 2016 9:59AM	Copy No.: 1	Page No.: 1 of 1
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