To bring complete COA for CRS

WRS
R14-2

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WORKING STANDARD CERTIFICATE

QUALIFICATION OF WORKING STANDARD

ITEM : Ritonavir (Form I) USP **EVALUATED WITH:** USPRS/MD/R14/03
BATCH No. : H0M427

DATE OF QUALIFICATION : 02.01.2016
DIRECTION FOR STORAGE : Store between 2°C to 8°C in tightly closed container. Protect from light#.
DIRECTION FOR USE : Use as such.
VALIDITY OF USE (PERIOD) : 30.09.2017
WORKING STANDARD No. : WS/C/R55/02
A.R. No. : MD1508668
SOURCE B. No. : RI0041013 **SOURCE A.R. No.:** MD1309079

REFERENCE: Specification No.: ACR0079/01; ACR0079A/01 **Protocol No.** : WP/USP/WS/C/R55

SR. No.	TESTS	STANDARDS	RESULTS
6)	SPECIFIC TESTS: WATER DETERMINATION	Not more than 0.50 % w/w.	0.08 % w/w.
7)	SPECIFIC TESTS: X-RAY DIFFRACTION	The X-ray diffraction pattern of the Sample conforms to that of USP Ritonavir RS (Form I).	Meets the requirement
8)	SPECIFIC ROTATION (On anhydrous substances)	Not less than +7.0° and not more than +10.5°, calculated with reference to the anhydrous substance.	+8.4°
9)	RESIDUAL SOLVENTS <By Gas Chromatography>	Ethanol : Not more than 2000 ppm. Dichloromethane : Not more than 300 ppm. Ethyl acetate : Not more than 3000 ppm. n-Heptane : Not more than 3000 ppm. Other class 1, 2, 3 residual solvents and other organic solvents : Meets the requirements of other class 1, 2 and 3 residual solvents as per USP chapter < 467 > and no other organic solvents are present.	Not detected Not detected Not detected 161

REMARKS: * **Test/s qualified with USPRS. All other tests comply with USP 38 and certified to be used as working standard.**
NOTE: # Third party may store as per specification.

HEAD QUALITY CONTROL **LAB QA HEAD**

DATE : 02.01.2016 **DATE :** 02-01-2016

Cipla Ltd. Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013, India
Phone: (91 22) 25756210
e-mail: savio@cipla.com WebSite:www.cipla.com

02-01-2016

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SR. No.	TESTS	STANDARDS	RESULTS
10)	PURITY (In % on as such basis) (By Mass Balance Method)	Not applicable.	99.4 %

REMARKS: * **Test/s qualified with USPRS. All other tests comply with USP 38 and certified to be used as working standard.**
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HEAD QUALITY CONTROL **LAB QA HEAD**

DATE : 02-01-2016 **DATE :** 02-01-2016

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