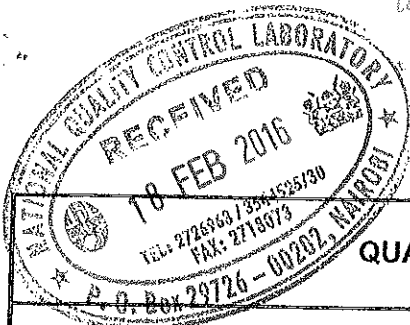


WRS  
R14-2



To bring sample COA for CBS

**Cipla**  
God

# WORKING STANDARD CERTIFICATE

## QUALIFICATION OF WORKING STANDARD

ITEM : Ritonavir (Form I) USP  
EVALUATED WITH: USPRS/MD/R14/03  
BATCH No. : HOM427

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

PAGE 3 of 4

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

*[Signature]*

LAB QA HEAD

*[Signature]*

DATE :

02-01-2016

DATE :

02-01-2016

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1035-L-0014/F15

*[Signature]*  
02-01-2016

**WORKING STANDARD CERTIFICATE**
**QUALIFICATION OF WORKING STANDARD**

ITEM : Ritonavir (Form I) USP  
 EVALUATED WITH: USPRS/MD/R 14/03  
 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

PAGE 4 of 4

 REFERENCE: Specification No.: ACR0079/01,  
 ACR0079A/01

Protocol No. : WP/USP/WS/C/R55

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.

NOTE: # Third party may store as per specification.

HEAD QUALITY CONTROL



LAB QA HEAD



DATE :

02-01-2016

DATE :

02-01-2016

 Refd  
 02-01-2016