Cipla
Verified by Lab QA
Sign. :
Date : 31.05.2016

A12-4

(1)

Cipla
Kurkumbh

WORKING STANDARD CERTIFICATE

QUALIFICATION OF WORKING STANDARD

ITEM : ABACAVIR SULFATE USP. EVALUATED WITH: USPRS/GN/A8/10
BATCH.NO. :F1L487

DATE OF QUALIFICATION : 31.05.2016
DIRECTION FOR STORAGE : # Store between 2° to 8°C in a well closed container & protect from light.
DIRECTION FOR USE : Use as such.
VALIDITY OF USE (PERIOD) : 30.05.2018
WORKING STANDARD No. : WS/C/A86/05
A.R.No. : KK1601474
SOURCE B.NO. : LDX160014 SOURCE A.R.NO.: 40000202661

REFERENCE: Protocol No. : WP/USP/WS/C/A86/01

Sr. No.	TESTS	STANDARDS	RESULTS
1)	DESCRIPTION	White to off-white powder.	Complies
2)	IDENTIFICATION Δ (A) BY IR	The infrared spectrum of the sample is concordant with the Spectrum obtained from the similar determination of USP Abacavir Sulfate RS.	Complies
	Δ (B) BY HPLC	The retention time of the major peak of the sample solution corresponds to that of the system suitability solution as directed in the test for Enanatiomeric purity.	Complies
	(C) TEST FOR SULFATE	It meets the requirements of the test for Sulfate.	Complies
	@(D) BY MASS SPECTROMETRY	The characterization of sample by Mass spectrum should obtain same molecular weight obtained by empirical formula.	Complies
	(E) POLYMORPHIC IDENTITY BY X-RAY POWDER DIFFRACTION	The XRPD pattern of sample is concordant with that of the Abacavir sulfate working standard obtained in the similar manner.	Complies
3)	ΔASSAY BY HPLC (on anhydrous and solvent free basis)	Not less than 97.0%w/w and Not more than 102.0 % w/w.	100.3 %w/w
4)	RESIDUE ON IGNITION	Not more than 0.20 % w/w	0.04 % w/w

Remarks: ΔTests qualified with USPRS.
All other tests comply as per USP and certified to use as Working standard.
Note : #Third party may store as per specification, @Test as per MOA, *Test as per 1035-L-0014.

HEAD QUALITY CONTROL Jadakh
DATE : 31-05-2016

LAB QA HEAD
DATE : 31.05.2016

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CIPLA LTD MUMBAI 400 013 INDIA PBP, LOWER PAREL

D.P

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REFERENCE: Protocol No. : WP/USP/WS/C/A86/01

Sr. No.	TESTS	STANDARDS	RESULTS
5)	**ΔORGANIC IMPURITIES** **PROCEDURE 1:RELATED COMPOUND By HPLC** Descyclopropyl abacavir Trance-Abacavir O-Pyrimidine derivative abacavir t-Butyl derivative abacavir Any unspecified impurity Total impurities	 Not more than 0.20% Not more than 0.20% Not more than 0.20 %. Not more than 0.20 %. Not more than 0.10 %. Not more than 0.80 %.	 **Below LOQ (0.05 %)** **Not Detected** **Below LOQ (0.05 %)** **Not Detected** **Below LOQ (0.05 %)** **Below LOQ**
6)	**ENATIOMERIC PURITY BY HPLC** Individual impurities	Not more than 0.30 % of Abacavir enantiomer.	**Not Detected**
7)	**WATER DETERMINATION**	Not more than 0.50 % w/w.	**0.15 % w/w**
8)	**SOLUBILITY**	Soluble in water.	**Complies**
9)	**CONTENT OF SULFATE (as H_2SO_4) BY POTENTIOMETRY**	Not less than 14.3 % and Not more than 14.9 % on anhydrous basis.	**14.6 % w/w**
10)	**RESIDUAL SOLVENT BY GC** Methanol Ethanol Acetone Dichloromethane Dimethylformamide Total residual solvents	 Not more than 3000 ppm Not more than 5000 ppm Not more than 5000 ppm Not more than 400 ppm Not more than 880 ppm Not more than 7000 ppm	 **Not Detected** **2578** **263** **Below LOQ (43)** **Not Detected** **2841**
11)	**SPECIFIC OPTICAL ROTATION** (On anhydrous basis)	Not less than -55.00° and Not more than -59.00° at 20 ° C	**-58.01 °**
12)	**HEAVY METALS**	Not more than 20 ppm	**Complies**
13)	*** PURITY (%)** **(By Mass Balance Method)**	Not applicable	**99.5 %** (On as such basis)

Remarks: ΔTests qualified with USPRS.
All other tests comply as per USP and certified to use as Working standard.
Note : #Third party may store as per specification, @Test as per MOA, *Test as per 1035-L-0014.

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