L42-1 (2)

L42-1

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Verified by Lab QA
Sign:
Date: 25.04.2015

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WORKING STANDARD CERTIFICATE

QUALIFICATION OF WORKING STANDARD

ITEM	:	Lamivudine USP.	EVALUATED WITH: USPRS/KK/L1/06
DATE OF QUALIFICATION	:	25.04.2015	BATCH NO: I0M388
DIRECTION FOR STORAGE	:	# Store between 2 to 8°C in well-closed container. Protect from light.	
DIRECTION FOR USE	:	Use as such.	
VALIDITY OF USE	:	24.04.2017	
WORKING STANDARD No.	:	WS/C/L82/03	
A.R.No.	:	KK1501878	
SOURCE B. NO.	:	LDC150076	SOURCE A.R.No. KK1501610 PAGE 1 OF 3

REFERENCE : Protocol No. : WP/USP/WS/C/L82/01.

Sr. No.	TESTS	STANDARDS	RESULTS
1.	DESCRIPTION	White to off white solid.	Complies
2.	MELTING POINT	It melts at about 176.0°C	176.8°C
3.	IDENTIFICATION Δ (A) By IR Spectrophotometry	The Infrared spectrum of the sample is concordant with the spectrum obtained from the similar determination of USP Lamivudine RS.	Complies
	(B) By HPLC	The retention time of the major peak obtained in the chromatogram of the sample solution corresponds to that in the chromatogram of the system suitability solution, as obtained in the test for Limit of Lamivudine enantiomer.	Complies
	*(C) By Polymorphic Identity	The XRPD pattern of the sample conforms to that of Lamivudine (Form II) standard similarly determined.	Complies
	@(D) By Mass Spectrometry	The characterization of sample by Mass spectrum should obtain same molecular weight obtained by empirical formula.	Complies
4.	Δ ASSAY BY HPLC (On anhydrous and solvent free basis)	Not less than 98.0 % w/w & Not more than 102.0 % w/w	100.7 % w/w
5.	LIMIT OF LAMIVUDINE ENANTIOMER BY HPLC	Not more than 0.30 %	Not Detected

REMARKS: Δ Test/s qualified as per USPRS. All other tests complies as per USP and certified to be used as Working standard.

Note : #Third party may store as per specification ,* Inhouse test , @Test as per MOA ,**Test as per QCP14 , Value of residual solvents test to be reported as per A.R No. KK1501610.

HEAD QUALITY CONTROL Padalkar DATE : 25-04-2015

LAB QA HEAD DATE : 25.04.2015

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NATIONAL QUALITY CONTROL LABORATORY P.O. CIPLA LTD. MUMBAI 400 013 INDIA AUG 2016

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SOURCE B. NO.	:	LDC150076	SOURCE A.R.No. KK1501610 PAGE 2 OF 3

REFERENCE : Protocol No. : WP/USP/WS/C/L82/01.

Sr. No.	TESTS	STANDARDS	RESULTS
6.	ΔOTHER RELATED COMPOUND BY HPLC		
	Lamivudine- Carboxylic acid	Not more than 0.30 %	0.06 %
	Lamivudine–trans(Lamivudine Diastereomer)	Not more than 0.20 %	0.02 %
	Salicylic acid	Not more than 0.10 %	Not Detected
	Any other Individual Impurity	Not more than 0.10 %	0.01 %
	Total Impurities	Not more than 0.60 %	0.09 %
7.	WATER DETERMINATION	Not more than 0.20 % w/w	0.08 % w/w
8.	LIGHT ABSORPTION	The absorptivity of the sample solution at 440 nm, determined in 4 cm cells is not more than 0.0015.	0.0003
9.	*RESIDUE ON IGNITION	Not more than 0.10 % w/w	0.04 % w/w
10.	*HEAVY METALS	Not more than 0.002 %	Complies
11.	*SPECIFIC OPTICAL ROTATION (Calculated on anhydrous and solvent-free basis)	Not less than -135.00 ° and Not more than -145.00 °	-137.86 °

REMARKS: ΔTest/s qualified as per USPRS. All other tests complies as per USP and certified to be used as Working standard.

Note : #Third party may store as per specification ,* Inhouse test , @Test as per MOA ,**Test as per QCP14 , Value of residual solvents test to be reported as per A.R No. KK1501610.

HEAD QUALITY CONTROL Fadatf

DATE : 25.04.2015

LAB QA HEAD

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SOURCE B. NO.	:	LDC150076	SOURCE A.R.No. KK1501610 PAGE 3 OF 3

REFERENCE : Protocol No. : WP/USP/WS/C/L82/01.

Sr. No.	TESTS	STANDARDS	RESULTS
12.	*LIMIT OF RESIDUAL SOLVENTS BY GC		
	Ethanol	Not more than 2000 ppm	292
	Methylene Dichloride	Not more than 600 ppm	Not Detected
	Ethyl Acetate	Not more than 2000 ppm	Below LOQ (65 ppm)
	Triethylamine	Not more than 320 ppm	Not Detected
	Toluene	Not more than 890 ppm	Not Detected
	Total residual solvents	Not more than 3000 ppm	292
13.	** PURITY (Mass Balance Method)	Not applicable	99.8 % (On as such basis)

REMARKS: ΔTest/s qualified as per USPRS. All other tests complies as per USP and certified to be used as Working standard.

Note : #Third party may store as per specification ,* Inhouse test , @Test as per MOA ,**Test as per QCP14 , Value of residual solvents test to be reported as per A.R No. KK1501610.

HEAD QUALITY CONTROL : Gadakh
DATE : 25.04.2015

LAB QA HEAD : DP
DATE : 25.04.2015

QUALITY CONTROL LABORATORY 11 AUG 2016 CIPLA LTD. MUMBAI 400 013 INDIA PBR, LOWER PAREL

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