548-2



TEST STANDARD CERTIFICATE

QUALIFICATION OF TEST STANDARDONYROL LABOR

ITEM

DATE OF QUALIFICATION

DIRECTION FOR STORAGE

DIRECTION FOR USE VALIDITY OF USE TEST STANDARD No.

A.R.No. SOURCE B.NO.

: TS/C/S115/01

: KK1501648 : LDT150002

Evaluated With: TS/ADLS/S75/01: 17.04.2015

Store between 2° to 8°C in a well closed container & protect from light.

Use as such.

16.04.2017

. O. Box 297'Lo SOURCE A.R.NO .: KK1501285

Page 1 of 3

REFERENCE: Protocol No.: TP/TS/C/S115/01

Sr. No.	TESTS	STANDARDS	RESULTS	
1)	DESCRIPTION	A white to off-white coloured powder.	Complies	
2)	IDENTIFICATION By IR	The Infrared spectrum of sample is concordant with the Infrared spectrum of Sofosbuvir Standard obtained in the similar manner.	Complies	
	By HPLC	The retention time of the principal peak in the chromatogram of the sample solution corresponds with that of the principal peak in the chromatogram of the Standard solution, as obtained in the test of Assay.	Complies	
	POLYMORPH IDENTITY .By XRPD	The XRPD pattern of the sofosbuvir sample is concordant with that of Sofosbuvir standard obtained in similar manner.	Complies	
	By DSC	DSC thermogram of sample exihibit single endotherm with onset temperature at 120.0 ± 3.0° C	120.8 ° C	
3)	WATER CONTENT	Not more than 0.50 % w/w.	0.23 % w/w	
4)	CLARITY OF SOLUTION	Solution S is considered clear if its appearance is same as that of the solvent used for preparing the solution.		
5)	@RESIDUE ON IGNITION	For information only. 0.23 % w/w		
6)	HEAVY METALS	Not more than 10 ppm.		

REMARKS: Material qualifies the above tests and is certified to be used as Test standard. Note: # Third party may store as per specification, @ Test as per MOA,*Test as per QCP14.

HEAD QUALITY CONTROL

17.04.2017

DATE: 17.04.2015

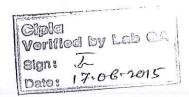
DATE:

DATE: 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

QCP14/F2/3









TEST STANDARD CERTIFICATE

QUALIFICATION OF TEST STANDARD ITEM : SOFOSBUVIR Evaluated With: TS/ADL3/S75/01 DATE OF QUALIFICATION : 17.04.2015 Batch No. : VRD-994-04-109 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 : 16.04.2017 TEST STANDARD No. : TS/C/S115/01 A.R.No. : KK1501648 SOURCE B.NO. : LDT150002 SOURCE A.R.NO.:KK1501285 Page 2 of 3 REFERENCE: Protocol No.: TP/TS/C/S115/01 Sr. **TESTS STANDARDS RESULTS** No. 7) RELATED SUBSTANCES BY HPLC SFB Uridine Not Detected Not more than 0.15 %. SFB Dimer Impurity Below LOQ (0.05 %) Not more than 0.15 %. SFB-C Not more than 0.15 %. Not Detected 2,3,4,5,6-Pentafluorophenol Not more than 0.15 %. Not Detected Unspecified impurity Not more than 0.10 %. Below LOQ (0.03 %) Total impurities Not more than 1.0 %. Below LOQ 8) **ASSAY BY HPLC** Not less than 98.0 % w/w and Not more than 100.1 % 102.0 % w/w (On Anhydrous basis) 9) RESIDUAL SOLVENTS BY GC (Method I) Methanol Not more than 3000 ppm. Not Detected Isopropyl alcohol Not more than 5000 ppm. Not Detected Not more than 5000 ppm. Ethyl acetate Not Detected n-Heptane Not more than 5000 ppm. Not Detected Not more than 5000 ppm. Methyl tertiary butyl ether Not Detected Not more than 290 ppm. n-Hexane Not Detected Chlorobenzene Not more than 360 ppm. **Not Detected** Not more than 720 ppm. Tetrahydrofuran **Not Detected** Not more than 600 ppm. Methylene dichloride 76 ppm Not more than 100 ppm. Diisopropyl ether Not Detected Not more than 5000 ppm. Isopropyl Acetate **Not Detected** Not more than 5000 ppm. Acetone **Not Detected** Acetonitrile Not more than 410 ppm. Not Detected Toluene Not more than 890 ppm. Not Detected RESIDUAL SOLVENTS BY GC (Method II) Triethylamine Not more than 320 ppm Not Detected REMARKS: Material qualifies the above tests and is certified to be used as Test standard. Note: # Third party may store as per specification, @ Test as per MOA,*Test as per QCP14. LAB QA HEAD -1811 17.04.2015 HEAD QUALITY CONTROL

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DIRE VALI TEST A.R.I	E OF QUALIFICATION ECTION FOR STORAGE ECTION FOR USE DITY OF USE I STANDARD No.	: SOFOSBUVIR : 17.04.2015 : # Store between 2° to 8°C in a well close : Use as such. : 16.04.2017 : TS/C/S115/01 : KK1501648 LDT150002 SOURCE	Evaluated With: TS/ADL3/S75/01 Batch No.: VRD-994-04-109 ed container & protect from light. A.R.NO.:KK1501285 Page 3 of 3
REF	ERENCE: Protocol No.: TP/TS/C	/S115/01	
Sr. No.	TESTS	STANDARDS	RESULTS
	RESIDUAL SOLVENTS BY GC (Method III) Acetic acid	Not more than 5000 ppm ,	Not Detected
10)	* PURITY (%) (Mass Balance Method)	Not applicable.	99.5 % (As such basis)
		* *	•
REM Note	IARKS: Material qualifies the about: # Third party may store as per	ove tests and is certified to be used as specification, @ Test as per MOA,*Tes	t as per QCP14.
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