

S48-2

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Cipla
Kurkumbh**TEST STANDARD CERTIFICATE****QUALIFICATION OF TEST STANDARD**

ITEM : SOFOSBUVIR
 DATE OF QUALIFICATION : 17.04.2015
 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

Evaluated With : TS/ADL/S75/01
 Batch No. : VRD-994-04-109



SOURCE A.R.NO.: KK1501285

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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 exhibit 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.	Complies
5)	@RESIDUE ON IGNITION	For information only.	0.23 % w/w
6)	HEAVY METALS	Not more than 10 ppm.	Complies

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

LAB QA HEAD

DATE :

17.04.2015

DATE:

17.04.2015

Cipla Ltd., Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013, India
 Phone: (91 22) 25756210.

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QCP14/F2/3

VERIFIED BY
 "QC"
 Sign:
 Date: 17.06.2015

Cipla
 Verified by Lab QA
 Sign:
 Date: 17.06.2015

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. No.	TESTS	STANDARDS	RESULTS
7)	RELATED SUBSTANCES BY HPLC SFB Uridine SFB Dimer Impurity SFB-C 2,3,4,5,6-Pentafluorophenol Unspecified impurity Total impurities	Not more than 0.15 %. Not more than 0.15 %. Not more than 0.15 %. Not more than 0.15 %. Not more than 0.10 %. Not more than 1.0 %.	Not Detected Below LOQ (0.05 %) Not Detected Not Detected Below LOQ (0.03 %) Below LOQ
8)	ASSAY BY HPLC (On Anhydrous basis)	Not less than 98.0 % w/w and Not more than 102.0 % w/w	100.1 %
9)	RESIDUAL SOLVENTS BY GC (Method I) Methanol Isopropyl alcohol Ethyl acetate n-Heptane Methyl tertiary butyl ether n-Hexane Chlorobenzene Tetrahydrofuran Methylene dichloride Diisopropyl ether Isopropyl Acetate Acetone Acetonitrile Toluene	Not more than 3000 ppm. Not more than 5000 ppm. Not more than 5000 ppm. Not more than 5000 ppm. Not more than 5000 ppm. Not more than 290 ppm. Not more than 360 ppm. Not more than 720 ppm. Not more than 600 ppm. Not more than 100 ppm. Not more than 5000 ppm. Not more than 5000 ppm. Not more than 410 ppm. Not more than 890 ppm.	Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected Not Detected 76 ppm Not Detected Not Detected Not Detected Not Detected
	RESIDUAL SOLVENTS BY GC (Method II) Triethylamine	Not more than 320 ppm	Not Detected

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TEST STANDARD CERTIFICATE

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
ITEM	: SOFOSBUVIR	Evaluated With : TS/ADL3/S75/01
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TEST STANDARD No.	: TS/C/S115/01	
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SOURCE B.NO.	: LDT150002	SOURCE A.R.NO.:KK1501285 Page 3 of 3

REFERENCE: 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)

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