



ISO 9001:2008 Certified

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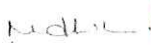

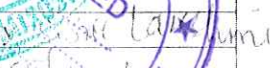
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**CERTIFICATE OF ANALYSIS – WORKING STANDARD**

Material Name: SOFOSBUVIR IH	
A. R. No. : U4/NAR/010/16	Working standard B. No: U4/WS/002/16
Mfd. by : Laurus Labs Private Limited	Ref. Std. B. No.: U4/WS/019/15
Date of Reporting: 08/02/2016	Use before Date: 31/10/2016
Specification No.: K/RMS/623-00	Storage : Store at 2-8°C

S. No.	TEST	RESULT	SPECIFICATIONS
1.	Description	White solid	White to off white solid
2.	IR absorption Spectrum	Complies	The sample IR spectrum should be concordant with that of working /reference standard IR spectrum.
3.	Water Content (By KF) (Method - I)	0.134 %	Not more than 2.0 % w/w
4.	Assay (By HPLC)	100.3 %	Not less than 98.0% w/w and not more than 102.0% w/w on anhydrous basis
5.	Assay (as is basis)	100.2 %	N/A
6.	Related Substance (by HPLC)		
	Isomer-1(Impurity at RRT 0.84)	0.009%	Not less than 0.15%
	Isomer-2(Impurity at RRT 0.87)	Not detected	Not less than 0.15%
	Isomer-3(Impurity at RRT 0.91)	0.006%	Not less than 0.15%
	3' analogue	0.006%	Not less than 0.15%
	Dicoupled	0.002%	Not less than 0.15%
	Any major unknown impurity	0.02%	Not less than 0.1%
	Total impurities	0.045%	Not less than 1.0%

Remarks: The sample conforms the above specifications

	
Prepared by N. Srikanth	Checked by 
Date 09/05/2016	Date 09/05/2016
	
Approved by 	
Date 09/05/2016	
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GQC/025/F04-00