



ISO 9001 : 2008 Certified

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**CERTIFICATE OF ANALYSIS - WORKING STANDARD**

Material Name: SOFOSBUVIR	
A. R. No. : U4/NAR/266/15	Working standard B. No: U4/WS/019/15
Mfd. by : Laurus Labs Private Limited	Ref. Std. B. No.: U4/WS/005/15
Date of Reporting: 30/05/2015	Use before Date: 30/05/2016
Specification No.: K/RMS/597-01	Storage : Store at 2-8°C

S. No.	TEST	RESULT	SPECIFICATIONS
1.	Description	White solid	White to off white solid
2.	Identification (By IR)	Complies	The sample IR spectrum should be concordant with that of working / reference standard IR spectrum.
3.	Water Content (By KF)	0.17 %	Not more than 2.0%w/w
4.	Assay (by HPLC)	100.5 %	Between 98.0%w/w to 102.0%w/w on anhydrous basis
5.	Assay (as is basis)	100.3 %	N/A
6.	Related Substance (by HPLC)		
	a. Isomer-1	0.03 %	Not more than 0.15%
	b. Isomer-2	Not detected.	Not more than 0.15%
	c. Isomer-3	0.03 %	Not more than 0.15%
	d. 3' analogue	0.01 %	Not more than 0.15%
	e. Dicoupled	Not detected.	Not more than 0.15%
	f. Any major unknown impurity	0.08 %	Not more than 0.1%
	g. Total impurities	0.19 %	Not more than 1.0%

Remarks: The sample conforms to the above specifications

Prepared by <u>U. S. Jadhav</u>	Checked by <u>H. Ravi Kumar</u>	Approved by <u>T. Malwa</u>
Date <u>30/05/2015</u>	Date <u>30/05/2015</u>	Date <u>30/05/2015</u>

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GQC/025/F04-00



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FOR INFORMATION ONLY



4th February 2016

The Director
National Quality Control Laboratory
P.o. Box 29726 – 00202,
Nairobi, Kenya.

Dear Sir,

**RE : SUBMISSION FOR ANALYSIS OF 1 PRODUCT FROM NATCO PHARMA LTD
– INDIA.**

Please receive the following product(s) for analysis :-

1. **HEPCINAT 400 TABS 10's**
2. **Sofosbuvir working std 1 vial + COA**
3. **FP Specs and MOA for both products**

NB. We hereby undertake to replace the short expiry Sofosbuvir working std with a longer expiry one, failure to which NQCL will not be held responsible for lack of analysis of said product.

Please issue COA at the earliest.

Kindly sign copy of this letter to acknowledge receipt of all items.

Yours faithfully,

for
Dr. Vandna Bhudhia
Company Pharmacist



PHARMA SPECIALITIES LIMITED

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