Natco Pharma Limited

Regd. Office : 'NATCO HOUSE', Road, No.2, Banjara Hills, Hyderabad, Telangana - 500 034 INDIA.
Tel.:+91-40-23547532, Fax :+91-40-23548243

CERTIFICATE OF ANALYSIS
(FINISHED PRODUCT)

Product Name: **HEPCINAT**		B. No.: **602035**
Generic Name: **Sofosbuvir Tablets, 400 mg**		
Batch size: 150000 Tablets	Sampling Date: 17/06/2016	Mfg. Date: 06/2016
Qty. Sampled: 56 Tablets	Analysis Date: 17/06/2016	Exp. Date: 05/2018
Sampled by: Chandrakant	Reporting Date: 18/06/2016	A.R.No.: NAFD/0262/16

S. No.	TEST	SPECIFICATION	RESULTS		
1.	Description	Brick red coloured, capsule shaped, film-coated tablets debossed with '400' on one side and plain on the other side.	Brick red coloured, capsule shaped, film-coated tablets debossed with '400' on one side and plain on the other side.		
2.	Identification a) By HPLC b) By UV	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the Assay. The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.	Complies Complies		
3.	Uniformity of dosage units (By weight variation)	The acceptance value of the first 10 dosage units is less than or equal to L1 (L1 is 15.0 and L2 is 25.0)	1.19		
4.	Average weight per tablet	1236.0 mg ± 3.0 %	1239.41		
5.	Water content (By KF)	Not more than 4.0%	1.71 %		
6.	Dissolution (By UV)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.	101.02 %	107.13 %	103.34 %
			100.60%	104.39 %	101.87 %

Prepared By	Checked By		Approved By
18/06/2016	18/06/2016	18/06/2016	18/06/2016
Sign & Date	Sign & Date		Sign & Date

Pharma Division Works: Pharmacity, Plot No. 19, Selaqui, Dehradun- 248197 (Uttarakhand)
Ph. No. : 0135-2699093/94, Fax No. : 0135-2698979, Email: hr-uk@natcopharma.co.in

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S. No.	TEST	SPECIFICATION	RESULTS
7.	Assay(By HPLC) Each film coated tablet contains 400 mg of Sofosbuvir.	Not less than 90.0% and not more than 110.0 % of the labeled amount of Sofosbuvir.	98.54 %
8.	Related Impurities (By HPLC) a) Individual Unknown impurity b) Total Impurities	 Not more than 0.50% Not more than 2.0%	 0.07% 0.15%
Additional Test			
9.	Disintegration Time	Not more than 30 minutes	8 - 9 Minutes

Remarks: The product **CONFIRMS** to **NAT/D/S/SPC/FP/084-00**

Prepared By	Checked By		Approved By
18/06/2016	18/06/2016	18/06/2016	18/06/2016
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