



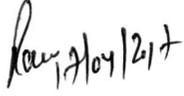
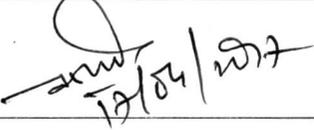
Natco Pharma limited

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.: 602271
Generic Name: Sofosbuvir Tablets, 400 mg		
Batch size: 150000 Tablets	Sampling Date: 11/04/2017	Mfg. Date: 04/2017
Qty. Sampled: 56 Tablets	Analysis Date: 11/04/2017	Exp. Date: 03/2019
Sampled by: Manoj Rawat	Reporting Date: 17/04/2017	A.R.No.: NAFD/0087/17

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	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.	Complies
	a) By HPLC b) By UV	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.	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)	2.07
4.	Average weight per tablet	1236.0 mg \pm 3.0 %	1226.21
5.	Water content (By KF)	Not more than 4.0%	1.48%
6.	Dissolution (By UV)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.	100.37% 101.20% 99.75%
			102.45% 101.83% 103.08%

Prepared By	Checked By	Approved By
 17/04/2017	 17/04/2017	 17/04/2017
Sign & Date	Sign & Date	Sign & Date

Format No.: QCC/013/F-005,Rev.:04

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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

FOR INFORMATION ONLY



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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.	99.76%
8.	Related Impurities (By HPLC) a) Individual Unknown impurity b) Total Impurities	Not more than 0.50% Not more than 2.0%	0.05% 0.20%
9.	Microbial Limit Tests i) Total Aerobic Microbial count ii) Total combined molds and Yeasts a) Escherichia coli b) Salmonella species c) Pseudomonas aeruginosa d) Staphylococcus aureus	Not more than 1000 cfu/g Not more than 100 cfu/g Should be absent/g Should be absent/10 g Should be absent/g Should be absent/g	20 cfu/g Less than 10 cfu/g Absent/g Absent/10g Absent/g Absent/g
Additional Test			
10.	Disintegration Time	Not more than 30 minutes	5 - 6 Minutes

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

Prepared By	Checked By		Approved By
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