



ISO 9001 : 2008 Certified

# NATCO PHARMA LIMITED

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CIN : L24230TG1981PLC003201, www.natcopharma.co.in



## Million Health Pharmaceuticals CERTIFICATE OF ANALYSIS

Product Name: <b>MYHEP TABLETS (SOFOSBUVIR TABLETS, 400 mg)</b>	B. No.: MYSF 15010	
Batch size: 90,000 Tablets	Sampling Date: 20/10/2015	Mfg. Date: Sep.2015
Qty. Sampled: 45 Tablets	Analysis Date: 20/10/2015	Exp. Date: Aug.2017
Sampled by: A.Anvesh Kumar	Reporting Date: 24/10/2015	A.R.No. :U4/FP/832/15

S.No.	TEST	RESULT	SPECIFICATION
1.	Description	Brick red coloured, capsule shaped, film-coated tablets debossed with '400' on one side and plain on other side.	Brick red coloured, capsule shaped, film-coated tablets debossed with '400' on one side and plain on other side.
2.	Identification		
	a) By HPLC	The sample retention time corresponds with the standard retention time as obtained in the assay.	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.
	b) By UV	The UV absorption spectrum of the sample and standard solutions exhibits maxima at the same wavelengths.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.
3.	Uniformity of dosage units (By weight variation)	2.2	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)
4.	Average weight per tablet	37.3 mg	37.3 mg ± 3.0%
5.	Water content (by KF)	1.64% w/w	Not more than 4.0% w/w
6.	Dissolution (%w/w,By UV)	101.3% 101.3% 98.5%	102.6% 99.6% 101.7%
			Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.
7.	Assay (By HPLC): Each film coated tablet contains 400 mg of Sofosbuvir	102.3%	Not less than 90.0% and not more than 110.0% of the labeled amount of Sofosbuvir.
8.	Related impurities (By HPLC)		
	a) Individual unknown impurity	Less than 0.05%	Not more than 0.5%
	b) Total impurities	Less than 0.05%	Not more than 2.0%

Remarks: The product **Conforms / Does not conform**s to Specification No.: K/ FPS/394-01

Prepared by:

Date:

*[Signature]*  
20/10/2015

Checked by:

Date:

*[Signature]*  
24/10/2015

Approved:

Date:

*[Signature]*  
24/10/2015

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