



ISO 9001 : 2008 Certified

**NATCO PHARMA LIMITED**

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**CERTIFICATE OF ANALYSIS**

<b>Product name: Hepcinat (SOFOSBUVIR TABLETS 400mg)</b>		Batch No.: 602362
Batch size: 90,000 Tablets	Sampling Date: 12/06/2017	Mfg. Date: 06/2017
Qty. Sampled: 45 Tablets	Analysis Date: 12/06/2017	Exp. Date: 05/2019
Sampled by: M.V.Sireesha	Reporting Date: 16/06/2017	A.R.No.: U4/FP/450/18

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 corresponds 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 wavelength.
3	Uniformity of dosage units (By weight variation)	3.9	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	1251.0 mg	1236.0mg±3.0%
5	Water content	1.58 % w/w	Not more than 4.0% w/w
	Dissolution (% w/w, By UV)	98.9% 96.8% 100.5%	Not less than 80% (Q) of the labeled amount of Ledipasvir and Sofosbuvir are dissolved in 30 minutes.
		101.0% 99.4% 97.8%	
	Sofosbuvir	102.3% 100.0% 100.3%	
		100.8% 99.0% 102.2%	

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

Prepared by:

Date: 16/06/2017

Reviewed by:

Date: 16/06/2017

Approved:

Date: 16/06/2017