ISO 9001 : 2008 Certified

NATCO PHARMA LIMITED
Regd. Off. : 'NATCO HOUSE', Road No. 2,
Banjara Hills, Hyderabad - 500 034. Telangana, INDIA.
Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

CERTIFICATE OF ANALYSIS

Product name: Hepcinat Plus (DACLATASVIR 60mg & SOFOSBUVIR TABLETS 400mg)		Batch No.: 1901052
Batch size: 90,000 Tablets	Sampling Date: 24/11/2018	Mfg. Date: 11/2018
Qty. Sampled: 45 Tablets	Analysis Date: 24/11/2018	Exp. Date: 10/2020
Sampled by: M.V.Sireesha	Reporting Date: 28/11/2018	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 standardsolutions exhibits maxima at the same wavelenghts.		The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelenght.
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%	101.0%	Not less than 80% (Q) of the labeled amount of Ledipasvir and Sofosbuvir are dissolved in 30 minutes.
		96.8%	99.4%	
		100.5%	97.8%	
	Daclatasvir & Sofosbuvir	102.3%	100.8%	
		100.0%	99.0%	
		100.3%	102.2%	

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

Prepared by: Date: 28/11/2018

Reviewed by: Date: 28/11/2018

Approved: Date: 28/11/2018

Pharma Division : KOTHUR-509 228, Mahaboob Nagar Dt. Telangana. 08548 - 257289, Fax : 08548 - 257290 • e_mail: kothur@natcopharma.co.in