Natco Pharma Limited

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

CERTIFICATE OF ANALYSIS

Product Name:Hepcinat LP Generic Name : Ledipasvir and Sofosbuvir Tablets, 90mg/400mg		B. No.: 1900389
Batch size: 7283 Tablets	Sampling Date : 10/09/2016	Mfg. Date: 07/2016
Qty. Sampled: 1x28 Tablets	Analysis Date : 10/09/2016	Exp. Date: 06/2018
Sampled by: Debasish	Reporting Date: 11/09/2016	A.R. No.: FP/AR/435/16

S.No	TEST	SPECIFICATION	RESULT
1.	Description	Green colored, oval shaped, film-coated tablets debossed with 'SL' on one side and plain on other side.	Green colored, oval shaped, film-coated tablets debossed with 'SL' on one side and plain on 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.	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. The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelengths.
3.	Uniformity of dosage units (By content uniformity)	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)	4.9 (Sofosbuvir) 4.2 (Ledipasvir)
4.	Average weight per tablet	1030.0 mg ± 5.0 %	1032.62 mg
5.	Water content (by KF)	Not more than 5.0% w/w	1.5 %w/w

WORKS : PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
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6.	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	Minimum = 96 % Maximum = 98 % Average = 96 %
	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Ledipasvir is dissolved in 45 minutes.	Minimum = 99 % Maximum = 101 % Average = 100 %
7.	Assay (By HPLC) Each film coated tablet contains Ledipasvir 90 mg	Not less than 95.0% and not more than 105.0% of the labeled amount of Ledipasvir.	100.0 %
	Sofosbuvir 400 mg	Not less than 95.0% and not more than 105.0% of the labeled amount of Sofosbuvir.	100.1%
8.	Related impurities (By HPLC)		
	a) Sofosbuvir		
	Any individual impurity	Not more than 0.30 %	0.04 %
	Total impurities	Not more than 1.0 %	0.10 %
	b) Ledipasvir		
	Keto impurity	Not more than 0.8%	0.13 %
	Any individual unspecified impurity	Not more than 0.20 %	0.01 %
	Total impurities	Not more than 1.2 %	0.17 %

Remarks: The product complies as per Specification No. : FP/SPC/008-00

11/09/2016
PREPARED BY

13/09/2016
CHECKED BY

13/09/2016
APPROVED BY

WORKS : PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
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