Natco Pharma Limited

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

Email: info@natcopharma.co.in

CERTIFICATE OF ANALYSIS

Product Name: Ledihep		B.No. : 1900659
Generic Name : Ledipasvir and Sofosbuvir Tablets		Product Code : GSL42ZY
Batch size: 107781 Tablet	Sampling Date: 27/07/2017	Mfg. Date: 05/2017
Qty. Sampled: 28 Tablets	Analysis Date: 27/07/2017	Exp. Date: 04/2019
Sampled by: Maheswar Behera	Reporting Date: 28/07/2017	A.R. No.: FP/AR/295/17

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)	6.30 (Sofosbuvir) 7.28 (Ledipasvir)

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	28/07/2017	RAcam 28/07/2017	28/07/2017
Name	B N Pattnaik	Purotam Acam	Sanjay S. Chandhoke
Designation	Officer-Q.C.	officer Q.C.	Sr manager-QC

WORKS : PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
Guwahati, Assam, 781125, Office : + 91-362-3230471, 472, 473

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S.No	TEST	SPECIFICATION	RESULT
4.	Average weight per tablet	1030.0 mg ± 5.0 %	1040.86 mg
5.	Water content (by KF)	Not more than 5.0% w/w	2.87 %w/w
6.	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	Minimum = 94.1 % Maximum = 100.2 % Average = 97.8 %
	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Ledipasvir is dissolved in 45 minutes.	Minimum = 96.3 % Maximum =102.1 % Average = 99.5 %
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.	99.2 %
	Sofosbuvir 400 mg	Not less than 95.0% and not more than 105.0% of the labeled amount of Sofosbuvir.	99.3 %

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	28/07/2017	28/07/2017	28/07/2017
Name	B N Patwari	Rustam Alam	Sanjay S. Chandhoke
Designation	Officer - Q.C.	Officer Q.C.	Sr. Manager

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S.No	TEST	SPECIFICATION	RESULT
8.	Related impurities (By HPLC)		
	a) Sofosbuvir		
	Any individual impurity	Not more than 0.30 %	0.03 %
	Total impurities	Not more than 1.0 %	0.06 %
	b) Ledipasvir		
	Keto impurity	Not more than 0.8%	Below LOQ* (Limit 0.048 %)
	Any individual unspecified impurity	Not more than 0.20 %	0.02 %
	Total impurities	Not more than 1.2 %	0.04 %

*LOQ-Limit of quantification

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

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	28/07/2017	28/07/2017	28/07/2017
Name	B N Pathani	Ratan Alam	Sanjay S. Chavan
Designation	Officer-Q.C.	Officer Q.C.	Sr Manager-QC

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