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: Ledikast		B.No. : 1901059
Generic Name : Ledipasvir and Sofosbuvir Tablets		Product Code : GSL42AZ
Batch size: 108318 Tablets	Sampling Date: 04/12/2018	Mfg. Date: 11/2018
Qty. Sampled: 01 Container	Analysis Date: 04/12/2018	Exp. Date: 10/2020
Sampled by: Bikumani	Reporting Date: 06/12/2018	A.R. No.: FP/AR/374/18

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	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 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 solution and standard solution shall exhibit maxima at the same wavelengths.	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)	4.57 (Sofosbuvir) 5.31 (Ledipasvir)

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	06/12/2018	06/12/2018	06/12/2018
Name	Jayanta Sarma	Bijaukam Hazarika	Sanjay S. Chavhan
Designation	Asst. Officer	Executive	Sr. Manager QA

WORKS : PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
Guwahati, Assam, 781125, Office : + 91-362-3230 470, 471, 472, 473

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S.No	TEST	SPECIFICATION	RESULT
4.	Average weight per tablet	1030.0 mg ± 5.0 %	1032.64 mg
5.	Water content (by KF)	Not more than 5.0% w/w	2.74 %w/w
6.	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	Minimum : 96.5 % Maximum :102.3 % Average : 98.3 %
	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Ledipasvir is dissolved in 45 minutes.	Minimum : 95.2 % Maximum : 99.5 % Average : 96.8 %
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.	100.4 %
	Sofosbuvir 400 mg	Not less than 95.0% and not more than 105.0% of the labeled amount of Sofosbuvir.	99.2 %

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	06/12/2018	06/12/2018	06/12/2018
Name	Jayanta Sarma	Dipankar Hazarika	Sanjay S. Chandhok
Designation	Asst. Officer	Executive	Sr Manager-QC

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S.No	TEST	SPECIFICATION	RESULT
8.	Related impurities (% w/w, By HPLC)		
	a) Sofosbuvir		
	Any individual impurity	Not more than 0.30 %	0.08 %
	Total impurities	Not more than 1.0 %	0.12 %
	b) Ledipasvir		
	Keto impurity	Not more than 0.8%	Below LOQ* (0.048)
	Any individual unspecified impurity	Not more than 0.20 %	0.05 %
	Total impurities	Not more than 1.2 %	0.06 %

*LOQ = Limit of Quantification

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

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	06/12/2018	06/12/2018	06/12/2018
Name	Jayanta Sarma	Dipankar Hazarika	Sanjay S. Chaudhari
Designation	Asst. officer	Executive	Sr manager-QC

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