ISO 9001 : 2008 Certified

NATCO PHARMA LIMITED
Regd. Off. : 'NATCO HOUSE', Road No. 2,
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Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

CERTIFICATE OF ANALYSIS

Product name: Ledikast (Ledipasvir & Sofosbuvir Tablets 90mg/400mg)		Batch No.: 1900993
Batch size: 100,000 Tablets	Sampling Date: 09/08/2018	Mfg. Date: 08/2018
Qty. Sampled: 20 Tablets	Analysis Date: 09/08/2018	Exp. Date: 07/2020
Sampled by: A.Anvesh Kumar	Reporting Date: 14/08/2018	A.R.No.: U4/FP/1016/24

S. No.	TEST	RESULT		SPECIFICATION
1	Description	Green coloured, oval shaped, film-coated tablets debossed with 'SL' on one side and plain on other side.		Green coloured, oval shaped, film-coated tablets debossed with 'SL' 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 peak maxima of the standard and sample spectra exhibit at 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 content uniformity)	Ledipasvir = 1.3 Sofosbuvir = 1.4		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	1026.8 mg		1030.0mg±5.0%
5	Water content	1.75 % w/w		Not more than 5.0% w/w
6	Dissolution (By HPLC)			
	Ledipasvir	102.2%	100.9%	Not less than 80% (Q) of the labeled amount of Ledipasvir and Sofosbuvir are dissolved in 45 minutes.
		99.7%	101.2%	
		98.4%	99.8%	
	Sofosbuvir	101.2%	102.4%	
		102.1%	99.2%	
		100.8%	102.4%	

Prepared by: Date: 14/08/2018

Reviewed by: Date: 14/08/2018

Approved: Date: 14/08/2018

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S. No.	TEST	RESULT	SPECIFICATION
7	Assay (By HPLC): Each film coated tablet contains.		
	Ledipasvir: 90mg	100.3%	Not less than 95.0% and Not more than 105.0% of the labeled amount of Ledipasvir.
	Sofosbuvir: 400 mg	101.3%	Not less than 95.0% and Not more than 105.0% of the labeled amount of Sofosbuvir.
8	Related impurities (%w/w, By HPLC)		
	a) Sofosbuvir		
	Any individual impurity	Less than 0.05%	Not more than 0.30%
	Total impurities	Less than 0.05%	Not more than 1.0%
	b) Ledipasvir		
	Keto impurity	Less than LOQ (0.048%)	Not more than 0.8%
	Any Individual unspecifield impurity	Less than 0.05%	Not more than 0.20%
	Total impurities	Less than 0.05%	Not more than 1.20%
9	Microbial Enumeration tests and Test for specified microorganisms		
	Total aerobic microbial count	Less than 10 gfu/g	Not more than 1000 cfu/g
	Total combined molds and yeasts	Less than 10 gfu/g	Not more than 100 cfu/g
	Escherichia coli	Adsent	Should be absent/g
	Salmonella species	Adsent	Should be absent/10g
	Pseudomonas aeruginosa	Adsent	Should be absent/g
	Staphylococcus aureus	Adsent	Should be absent/g

Remarks: The product **Conforms / ~~Does not conforms~~** to Specification No.: K/FPS/445

Prepared by: Date: 14/08/2018

Reviewed by: Date: 14/08/2018

Approved: Date: 14/08/2018