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

Million Health Pharmaceuticals

CERTIFICATE OF ANALYSIS

Product Name: **MyHep LVIR™ (Ledipasvir & Sofosbuvir Tablets)**		B. No.: MYSL15003
Batch size: 1,00,000 Tablets	Sampling Date: 25/12/2015	Mfg. Date: Dec.2015
Qty. Sampled: 20 Tablets	Analysis Date: 25/12/2015	Exp. Date: Nov.2017
Sampled by: K.Tharun Kumar	Reporting Date: 02/01/2016	A.R.No.: U4/FP/1007/15

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 wavelengths.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelength.
3.	Uniformity of dosage units (By content uniformity)	Ledipasvir = 2.2 Sofosbuvir = 2.7	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	1028.8 mg	1030.0mg ±5.0%
5.	Water content	1.80 % w/w	Not more than 5.0% w/w
6.	Dissolution (By HPLC)		
	Ledipasvir	98.4% / 98.4% 97.9% / 99.3% 97.3% / 98.0%	Not less than 80% (Q) of the labeled amount of Ledipsavir and Sofosbuvir are dissolved in 45 minutes
	Sofosbuvir	101.7% / 100.9% 100.2% / 101.1% 99.4% / 100.3%	

Prepared by: Date: 02/01/2016

Reviewed by: Date: 02/01/2016

Approved: T. Malliwar Date: 02/01/2016

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

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S.No.	TEST	RESULT	SPECIFICATION
7.	Assay: (By HPLC): Each film coated tablet contains.		
	Ledipasvir 90mg	99.7%	Not less than 95.0% and Not more than 105.0% of the labeled amount of Ledipasvir.
	Sofosbuvir 400mg	103.6%	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 unspecified impurity	Less than 0.05%	Not more than 0.20%
	Total impurities	Less than 0.05%	Not more than 1.2%
9.	Microbial Enumeration tests and Test for specified microorganisms		
	Total aerobic microbial count	30 cfu/g	Not more than 1000 cfu/g
	Total combined molds and yeasts	Less than 10 cfu/g	Not more than 100 cfu/g
	Escherichia coli	Absent	Should be absent /g
	Salmonella species	Absent	Should be absent /g
	Pseudomonas aeruginosa	Absent	Should be absent /g
	Staphylococcus aureus	Absent	Should be absent /g

Remarks: The product **Conforms** / ~~**Does not conforms**~~ to Specification No.: K/FPS/436-01

Prepared by: Date: 02/01/2016

Reviewed by: Date: 02/01/2016

Approved: T. Mallikarjuna Date: 02/01/2016

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