HETERO LABS LIMITED (UNIT-II)
(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: LEDIFOS (Ledipasvir 90mg and Sofosbuvir 400mg Tablets)			
Product Code	4013077	**A.R. No.**	H5FP16003099
Specification ID	FPS/B-3007107-1-02	**Batch No**	3117708
Mfg. Date	07/2017	**Batch Size**	1,5 Lac
Exp. Date	06/2019	**Date of Release**	04-07-2017

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	Brown coloured, capsule shaped, bevel biconvex film coated tablets debossed with "H" on one side and "L18" on other side	Brown coloured, capsule shaped, bevel biconvex film coated tablets debossed with "H" on one side and "L18" on other side
2	**Identification (By HPLC)**	The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution as obtained in the assay.	The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution as obtained in the assay.
3	**Average weight**	1030.55mg	1025.00mg ± 3.0% (994.25mg to 1055.75mg)
4	**Uniformity of weight**	Highest: 0.36% Lowest: -0.47%	±5% of Average weight
5	**Water content (by KF)**	3.26% w/w	Not more than 5% w/w
6	**Uniformity of content (By HPLC)** **Content of Ledipasvir**	Min: 102.1% Max: 106.5% Average: 104.0%	Not less than 85% and not more than 115% of average content
7	**Dissolution (By HPLC)**		
7.1	**Sofosbuvir**	Tablet 1 - 102.0% Tablet 2 - 102.9% Tablet 3 - 102.3% Tablet 4 - 102.1% Tablet 5 - 102.4% Tablet 6 - 102.7% Average - 102.4%	Not less than 75% (D) of labeled amount of Sofosbuvir should dissolve in 30 minutes
7.2	**Ledipasvir**	Tablet 1 - 101.6% Tablet 2 - 94.3% Tablet 3 - 99.5% Tablet 4 - 101.2% Tablet 5 - 100.8% Tablet 6 - 99.0% Average - 99.4%	Not less than 75% (D) of labeled amount of Ledipasvir should dissolve in 30 minutes

Remarks: APPROVED (Sample Conforms to above Specification)	
Checked By : Ramanuj Mishra	**Approved By** : Sudhakar Reddy.Jaggavarapu
Date: 04-07-2017 15:46	**Date:** 04-07-2017 15:47
Printed by: Sudhakar Reddy.Jaggavarapu	**Printed on:** : 04-07-2017 15:48
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C No: C7003303	

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Factory: Village: Kalyanpur, Chakkan Road BADDI, Tehsil, BADDI, Distt. Solan, H.P. - 173 205 INDIA

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8	**Related Substances (By HPLC)**		
8.1	**Sofosbuvir Related Compound -01**	0.01%	Not more than 0.50%
8.2	**Ledipasvir Related Compound -04**	0.13%	Not more than 1.0%
8.3	**Max. single Unknown Impurity**	0.08%	Not more than 0.50%
8.4	**Total Impurities**	0.43%	Not more than 2.0%
9	**Assay (By HPLC) Each film coated tablet contains**		
9.1	**Ledipasvir (C49H54F2N806), in mg**	92.02mg	Not less than 85.5mg and Not more than 94.5mg
9.2	**(%) Labeled amount**	102.2%	Not less than 95.0% and Not more than 105.0%
9.3	**Sofosbuvir (C22H29FN309P), in mg**	409.79mg	Not less than 380.0mg and Not more than 420.0mg
9.4	**(%) Labeled amount**	102.4%	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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