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.**	H5FP19001874
Specification ID	FPS/B-3007107-1-02	**Batch No.**	31172398
Mfg. Date	04/2019	**Batch Size**	0.97 Lac.
Exp. Date	03/2021	**Date Of Release**	11-05-2019

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 should correspond to that in the chromatogram of the standard solution, as obtained in the assay.
3	**Average weight**	1031.15 mg	1025.00mg ± 3.0% (994.25mg to 1055.75mg)
4	**Uniformity of weight**	Highest : 0.81 % Lowest::-1.07 %	± 5% of Average weight
5	**Water content (By KF)**	3.00 %w/w	Not more than 5.0%w/w
6	**Uniformity of Content (By HPLC) Content of Ledipasvir**	Min. : 98.1 % Max. : 100.9 % Average::99.3 %	Not less than 85.0% and Not more than 115.0% of average content.
7	**Dissolution (By HPLC)**		
7.1	**Ledipasvir**	Tablet 1- : 92.8 % Tablet 2- : 87.1 % Tablet 3- : 99.5 % Tablet 4- : 99.5 % Tablet 5- : 100.4 % Tablet 6- : 95.0 % Average::95.7 %	Not less than 75 % (D) of labeled amount of Ledipasvir should dissolve in 30 minutes.
7.2	**Sofosbuvir**	Tablet 1- : 95.3 % Tablet 2- : 94.1 %	Not less than 75 % (D) of labeled amount of Sofosbuvir should dissolve

Remarks: APPROVED (Sample Conforms to above Specification)			
Checked By	Anand.Singh	Approved By	D.S.N.Reddy
Date	11-05-2019 16:18	Date	11-05-2019 16:19
Printed by: D.S.N.Reddy		**Printed on: 11-05-2019 16:19**	
Copy No.: 1		**Page No.: 1 of 2**	
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CNo: C100001920			

HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

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		Tablet 3- : 98.2 % Tablet 4- : 98.3 % Tablet 5- : 98.4 % Tablet 6- : 95.5 % Average::96.6 %	in 30 minutes.
8	**Related Substances (By HPLC)**		
8.1	**Sofosbuvir Related compound -01**	0.00 %	Not more than 0.50%
8.2	**Ledipasvir Related compound -04**	0.08 %	Not more than 1.0%
8.3	**Max. single Unknown Impurity**	0.04 %	Not more than 0.50%
8.4	**Total Impurities**	0.26 %	Not more than 2.0%
9	**Assay (By HPLC) Each film coated tablet contains**		
9.1	**Ledipasvir (C49H54F2N8O6), in mg**	90.79 mg	Not less than 85.5mg and Not more than 94.5mg
9.2	**(%) Labeled amount**	100.9 %	Not less than 95.0 and Not more than 105.0
9.3	**Sofosbuvir (C22H29 FN3O9P) in mg**	401.94 mg	Not less than 380.0mg and Not more than 420.0mg
9.4	**(%) Labeled amount**	100.5 %	Not less than 95.0 and Not more than 105.0

Remarks: APPROVED (Sample Conforms to above Specification)

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