



# HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

## CERTIFICATE OF ANALYSIS

<b>Product Name: LEDIFOS (Ledipasvir 90mg and Sofosbuvir 400mg Tablets)</b>			
<b>Product Code</b>	4013077	<b>A.R. No.</b>	H5FP18001692
<b>Specification ID</b>	FPS/B-3007107-1-02	<b>Batch No.</b>	31171544
<b>Mfg. Date</b>	04/2018	<b>Batch Size</b>	1.5 Lac.
<b>Exp. Date</b>	03/2020	<b>Date Of Release</b>	16-04-2018

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	1026.66 mg	1025.00mg $\pm$ 3.0% (994.25mg to 1055.75mg)
4	Uniformity of weight	Highest : 1.39 % Lowest:-1.33 %	$\pm$ 5% of Average weight
5	Water content (By KF)	2.79 %w/w	Not more than 5.0%w/w
6	Uniformity of Content (By HPLC) Content of Ledipasvir	Min. : 98.4 % Max. : 101.6 % Average::99.9 %	Not less than 85.0% and Not more than 115.0% of average content.
7	Dissolution (By HPLC)		
7.1	Ledipasvir	Tablet 1- : 94.7 % Tablet 2- : 88.7 % Tablet 3- : 95.2 % Tablet 4- : 85.2 % Tablet 5- : 86.7 % Tablet 6- : 90.6 % Average::90.2 %	Not less than 75 % (D) of labeled amount of Ledipasvir should dissolve in 30 minutes.
7.2	Sofosbuvir	Tablet 1- : 100.6 % Tablet 2- : 99.4 %	Not less than 75 % (D) of labeled amount of Sofosbuvir should dissolve

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Rameshvar.Dhakedey	Approved By	D.S.N.Reddy
Date	16-04-2018 18:23	Date	16-04-2018 18:24
Printed by: D.S.N.Reddy	Printed on: 16-04-2018 18:24		
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		Tablet 3- : 97.0 % Tablet 4- : 95.3 % Tablet 5- : 97.4 % Tablet 6- : 99.4 % Average::98.2 %	in 30 minutes.
8	<b>Related Substances (By HPLC)</b>		
8.1	<b>Sofosbuvir Related compound -01</b>	0.01 %	Not more than 0.50%
8.2	<b>Ledipasvir Related compound -04</b>	0.09 %	Not more than 1.0%
8.3	<b>Max. single Unknown Impurity</b>	0.05 %	Not more than 0.50%
8.4	<b>Total Impurities</b>	0.28 %	Not more than 2.0%
9	<b>Assay (By HPLC) Each film coated tablet contains</b>		
9.1	<b>Ledipasvir (C<sub>49</sub>H<sub>54</sub>F<sub>2</sub>N<sub>8</sub>O<sub>6</sub>), in mg</b>	88.06 mg	Not less than 85.5mg and Not more than 94.5mg
9.2	<b>(%) Labeled amount</b>	97.8 %	Not less than 95.0 and Not more than 105.0
9.3	<b>Sofosbuvir (C<sub>22</sub>H<sub>29</sub>FN<sub>3</sub>O<sub>9</sub>P) in mg</b>	398.84 mg	Not less than 380.0mg and Not more than 420.0mg
9.4	<b>(%) Labeled amount</b>	99.7 %	Not less than 95.0 and Not more than 105.0

**Remarks: APPROVED (Sample Conforms to above Specification)**

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