



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.	H5FP18002346
Specification ID	FPS/B-3007107-1-02	Batch No.	31171613
Mfg. Date	05/2018	Batch Size	1.5 Lac.
Exp. Date	04/2020	Date Of Release	22-05-2018

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	1029.56 mg	1025.00mg \pm 3.0% (994.25mg to 1055.75mg)
4	Uniformity of weight	Highest : 1.73 % Lowest:-1.28 %	\pm 5% of Average weight
5	Water content (By KF)	2.38 %w/w	Not more than 5.0%w/w
6	Uniformity of Content (By HPLC) Content of Ledipasvir	Min. : 97.4 % Max. : 101.3 % Average::99.1 %	Not less than 85.0% and Not more than 115.0% of average content.
7	Dissolution (By HPLC)		
7.1	Ledipasvir	Tablet 1- : 95.9 % Tablet 2- : 96.3 % Tablet 3- : 92.6 % Tablet 4- : 93.3 % Tablet 5- : 96.1 % Tablet 6- : 95.3 % Average::94.9 %	Not less than 75 % (D) of labeled amount of Ledipasvir should dissolve in 30 minutes.
7.2	Sofosbuvir	Tablet 1- : 101.2 % Tablet 2- : 104.2 %	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	22-05-2018 17:17	Date	22-05-2018 17:18
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		Tablet 3- : 101.9 % Tablet 4- : 102.2 % Tablet 5- : 101.8 % Tablet 6- : 102.1 % Average::102.2 %	in 30 minutes.
8	Related Substances (By HPLC)		
8.1	Sofosbuvir Related compound -01	0.01 %	Not more than 0.50%
8.2	Ledipasvir Related compound -04	0.05 %	Not more than 1.0%
8.3	Max. single Unknown Impurity	0.16 %	Not more than 0.50%
8.4	Total Impurities	0.44 %	Not more than 2.0%
9	Assay (By HPLC) Each film coated tablet contains		
9.1	Ledipasvir (C49H54F2N8O6), in mg	91.74 mg	Not less than 85.5mg and Not more than 94.5mg
9.2	(%) Labeled amount	101.9 %	Not less than 95.0 and Not more than 105.0
9.3	Sofosbuvir (C22H29 FN3O9P) in mg	404.18 mg	Not less than 380.0mg and Not more than 420.0mg
9.4	(%) Labeled amount	101.0 %	Not less than 95.0 and Not more than 105.0

Remarks: APPROVED (Sample Conforms to above Specification)

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