



# HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

## CERTIFICATE OF ANALYSIS

Product Name: LEDIHEP (Ledipasvir 90mg and Sofosbuvir 400mg Tablets)			
Product Code	4019806	A.R. No.	H5FP18000148
Specification ID	FPS/B-3007107-1-02	Batch No.	PHL80101
Mfg. Date	01/2018	Batch Size	1.5 Lac.
Exp. Date	12/2019	Date Of Release	16-01-2018

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	1031.06 mg	1025.00mg $\pm$ 3.0% (994.25mg to 1055.75mg)
4	Uniformity of weight	Highest : 1.62 % Lowest:-0.67 %	$\pm$ 5% of Average weight
5	Water content (By KF)	2.84 %w/w	Not more than 5.0%w/w
6	Uniformity of Content (By HPLC) Content of Ledipasvir	Min. : 101.3 % Max. : 104.4 % Average::103.0 %	Not less than 85.0% and Not more than 115.0% of average content.
7	Dissolution (By HPLC)		
7.1	Ledipasvir	Tablet 1- : 95.6 % Tablet 2- : 92.8 % Tablet 3- : 94.3 % Tablet 4- : 92.1 % Tablet 5- : 93.0 % Tablet 6- : 91.8 % Average::93.3 %	Not less than 75 % (D) of labeled amount of Ledipasvir should dissolve in 30 minutes.
7.2	Sofosbuvir	Tablet 1- : 98.2 % Tablet 2- : 97.2 %	Not less than 75 % (D) of labeled amount of Sofosbuvir should dissolve

Remarks: APPROVED (Sample Conforms to above Specification)			
Checked By	Ramanuj.Mishra	Approved By	Sudhakar Reddy.Jaggavarapu
Date	16-01-2018 18:06	Date	16-01-2018 18:07
Printed by:	Sudhakar Reddy.Jaggavarapu	Printed on:	16-01-2018 18:08
Copy No.:	1	Page No.:	1 of 2
Note : This document has been generated electronically and is valid without signature.			
CNo: C9000208			