HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: VIRPAS (Ledipasvir 90mg and Sofosbuvir 400mg Tablets)			
Product Code	4014882	A.R. No.	H5FP17001337
Specification ID	FPS/B-3007107-1-02	Batch No.	BM17005
Mfg. Date	03/2017	Batch Size	0.28 Lac.
Exp. Date	02/2019	Date Of Release	09-03-2017

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 should correspond to that in the chromatogram of the standard solution, as obtained in the assay.
3	Average weight	1026.72 mg	1025.00mg ± 3.0% (994.25mg to 1055.75mg)
4	Uniformity of weight	Highest : 1.58 % Lowest::-1.33 %	± 5% of Average weight
5	Water content (By KF)	3.42 %w/w	Not more than 5.0%w/w
6	Uniformity of Content (By HPLC) Content of Ledipasvir	Min. : 102.4 % Max. : 104.0 % Average::103.2 %	Not less than 85.0% and Not more than 115.0% of average content.
7	Dissolution (By HPLC)		
7.1	Ledipasvir	Tablet 1- : 97.2 % Tablet 2- : 97.7 % Tablet 3- : 96.0 % Tablet 4- : 95.7 % Tablet 5- : 96.5 % Tablet 6- : 98.2 % Average::96.9 %	Not less than 75 % (D) of labeled amount of Ledipasvir should dissolve in 30 minutes.
7.2	Sofosbuvir	Tablet 1- : 95.9 % Tablet 2- : 97.2 %	Not less than 75 % (D) of labeled amount of Sofosbuvir should dissolve in 30

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Nisha.Chandel	Approved By	D.S.N.Reddy
Date	09-03-2017 17:52	Date	09-03-2017 17:53
Printed by: D.S.N.Reddy		**Printed on: 09-03-2017 17:56**	
Copy No.: 1		**Page No.: 1 of 2**	

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CNo: C8001403

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

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		Tablet 3- : 94.9 % Tablet 4- : 95.6 % Tablet 5- : 94.9 % Tablet 6- : 96.0 % Average::95.8 %	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**	0.18 %	Not more than 1.0%
8.3	**Max. single Unknown Impurity**	0.05 %	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**	91.58 mg	Not less than 85.5mg and Not more than 94.5mg
9.2	**(%) Labeled amount**	101.8 %	Not less than 95.0 and Not more than 105.0
9.3	**Sofosbuvir (C22H29 FN3O9P) in mg**	406.91 mg	Not less than 380.0mg and Not more than 420.0mg
9.4	**(%) Labeled amount**	101.7 %	Not less than 95.0 and Not more than 105.0

Remarks: APPROVED (Sample Conforms to above Specification)

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