HETERO LABS LIMITED (UNIT-II)
(Formulations Division)

CERTIFICATEOFANALYSIS

Name of theProduct: Resof L (Ledipasvir and Sofosbuvir Tablets 90mg/400mg)			
BatchNo.	RSF80101	**A.R.No.**	H5FP15006569
Mfg.Date	Jan-2018	**Market**	INDIA
Exp.Date	Dec-2019	**BatchSize**	1,20,000Tablets
Ref.Spec. ID	FPS/B-3007107-1-01	**Date of Analysis**	Jan 24,2018

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 corresponds to that in the chromatogram of the standard solution as obtained in the assay.
3	**Average weight**	1032.53mg	1025.00mg ± 3% (994.25mg to 1055.75mg)
4	**Uniformity of weight**	Highest: 2.26% Lowest: -1.61%	±5% of Average weight
5	**Water content (by KF)**	3.10% w/w	Not more than 5% w/w
6	**Uniformity of content (By HPLC)**	Min: 98.2% Max: 100.6% Average: 99.1%	Not less than 85% and not more than 115% of average content
7	**Sofosbuvir**	Tablet 1 - 101.6% Tablet 2 - 100.8% Tablet 3 - 104.2% Tablet 4 - 101.5% Tablet 5 - 104.1% Tablet 6 - 101.5% Average - 102.3%	Not less than 75% (D) of labeled amount of Sofosbuvir should dissolve in 30 minutes
8	**Ledipasvir**	Tablet 1 - 92.5% Tablet 2 - 94.1% Tablet 3 - 96.5% Tablet 4 - 98.8% Tablet 5 - 99.2% Tablet 6 - 95.5% Average - 96.1%	Not less than 75% (D) of labeled amount of Ledipasvir should dissolve in 30 minutes

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By : Nisha Chandei	**Approved By** : D.S.N Reddy
Date: Jan,24 2018	**Approved On**: Jan,24 2018 15-30

Printed by: D.S.N Reddy	**Printed on:** : Jan,24 2018 15-33	**Copy No.: 1** **Page No.: 1 of 2**

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C No: C6007488

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

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S. No.	TEST	SPECIFICATION	RESULT
9	**Related Substances (By HPLC)**		
9.1	**Sofosbuvir Related Compound -01**	0.01%	Not more than 0.50%
9.2	**Ledipasvir Related Compound -04**	0.18%	Not more than 1.0%
9.3	**Max. single Unknown Impurity**	0.09%	Not more than 0.50%
9.4	**Total Impurities**	0.50%	Not more than 2.0%
10	**Assay (By HPLC) Each film coated tablet contains**		
10.1	**Ledipasvir (C49H54F2N806), in mg**	90.63mg	Not less than 85.5mg and Not more than 94.5mg
10.2	**(%) Labeled amount**	100.7%	Not less than 95.0mg and Not more than 105.0mg
10.3	**Sofosbuvir (C22H29FN309P), in mg**	402.74mg	Not less than 380.0mg and Not more than 420.0mg
10.4	**(%) Labeled amount**	100.7%	Not less than 95.0mg and Not more than 105.0mg

Remarks: APPROVED (Sample Conforms to above Specification)

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