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

CERTIFICATE OF ANALYSIS

Product Name: VELASOF (Sofosbuvir 400mg and Velpatasvir 100mg Tablets)			
Product Code	4018042	**A.R. No.**	H5FP17002309
Specification ID	FPS/B-3008269-1-01	**Batch No**	31171732
Mfg. Date	JUN.2018	**Batch Size**	0,5 Lac
Exp. Date	MAY.2020	**Date of Release**	05-06-2018

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	Blue coloured, oval shaped, biconvex, film coated tablets debossed with "S21" on one side and "H" on other side	Blue coloured, oval shaped, biconvex, film coated tablets debossed with "S21" on one side and "H" 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**	1034.36mg	1030.00mg ± 3.0% (999.10mg to 1060.90mg)
4	**Uniformity of weight**	Highest: 0.53% Lowest: -0.75%	±5% of Average weight
5	**Water content (by KF)**	2.97% w/w	Not more than 6.0% w/w
6	**Uniformity of content (By HPLC)** **Content of Velpatasvir**	Min: 100.8% Max: 103.5% Average: 102.4%	Not less than 85.0% and not more than 115.0% of average content
7	**Dissolution (By HPLC)**		
7.1	**Sofosbuvir**	Tablet 1 - 101.1% Tablet 2 - 99.1% Tablet 3 - 100.3% Tablet 4 - 99.2% Tablet 5 - 103.6% Tablet 6 - 99.5% Average - 100.5%	Not less than 75% (D) in 30 minutes
7.2	**Velpatasvir**	Tablet 1 - 98.7% Tablet 2 - 100.2% Tablet 3 - 100.7% Tablet 4 - 100.6% Tablet 5 - 100.6% Tablet 6 - 101.5% Average - 100.4%	Not less than 75% (D) in 30 minutes

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By : Nisha.Chandel	**Approved By** : D.S.N.Reddy
Date: 05-06-2018 16:17	**Date:** 05-06-2018 16:18
Printed by: D.S.N.Reddy	**Printed on:** : 05-06-2018 16:18
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C No: C8002524

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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
8	**Related Substances (By HPLC)**		
8.1	**H-SFBRC01**	0.01% w/w	Not more than 0.50% w/w
8.2	**Hydroxy Impurity**	0.14% w/w	Not more than 1.0% w/w
8.3	**S-Phenyl diastereomer**	0.01% w/w	Not more than 0.50% w/w
8.4	**Lactone Impurity**	0.01% w/w	Not more than 0.50% w/w
8.5	**Maximum Single Unknown Impurity**	0.05% w/w	Not more than 0.50% w/w
8.6	**Total Impurities**	0.46% w/w	Not more than 2.0% w/w
9	**Assay (By HPLC) Each film coated tablet contains**		
9.1	**Velpatasvir 100mg (C49H54F2N8O8) (%) Labeled amount**	100.8%	Not less than 95.0% and Not more than 105.0%
9.2	**Sofosbuvir 400mg (C22H29FN3O9P) (%) Labeled amount**	100.5%	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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