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.**	H5FP19002120
Specification ID	FPS/B-3008267-1-02	**Batch No.**	31172442
Mfg. Date	05/2019	**Batch Size**	0.4 Lac.
Exp. Date	04/2021	**Date Of Release**	28-05-2019

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	Blue coloured, oval shaped, biconvex, film coated tablets debossed with 'S21' on the one side and 'H' on the other side.	Blue coloured, oval shaped, biconvex, film coated tablets debossed with 'S21' on the one side and 'H' on the other side.
2	**Identification (By HPLC)**	The retention time of the major peak in the chromatogram of the sample solution is 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**	1044.82 mg	1030.00mg ± 3% (999.10mg to 1060.90mg)
4	**Uniformity of weight**	Highest : 1.43 % Lowest::-1.75 %	± 5% of Average weight
5	**Water content (By KF)**	3.31 %w/w	Not more than 6.0% w/w
6	**Uniformity of Content (By HPLC)**		
6.1	**Velpatasvir**	Min. : 96.2 % Max. : 99.3 % Average::97.6 %	Not less than 85.0% and Not more than 115.0% of average content.
7	**Dissolution (By HPLC)**		
7.1	**Sofosbuvir**	Tablet 1- : 98.1 % Tablet 2- : 99.7 % Tablet 3- : 98.4 % Tablet 4- : 99.2 % Tablet 5- : 99.4 % Tablet 6- : 98.1 % Average::98.8 %	Not less than 75% (D) in 30 minutes.
7.2	**Velpatasvir**		Not less than 75% (D) in 30

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Naveen Kumar.Pundir	Approved By	D.S.N.Reddy
Date	28-05-2019 18:46	Date	28-05-2019 18:56
Printed by: D.S.N.Reddy		**Printed on: 28-05-2019 19:00**	
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HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: VELASOF (Sofosbuvir 400mg and Velpatasvir 100mg Tablets)			
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		Tablet 1- : 92.7 % Tablet 2- : 93.8 % Tablet 3- : 92.7 % Tablet 4- : 93.1 % Tablet 5- : 91.6 % Tablet 6- : 88.9 % Average::92.2 %	minutes.
8	**Related Substances (By HPLC)**		
8.1	**H-SFBRC01**	0.01 %w/w	Not more than 0.5% w/w
8.2	**Hydroxy impurity**	0.42 % w/w	Not more than 1.0 % w/w
8.3	**S-Phenyl diastereomer**	0.03 % w/w	Not more than 0.5% w/w
8.4	**Lactone impurity**	0.09 % w/w	Not more than 0.5% w/w
8.5	**Maximum single unknown impurity**	0.14 % w/w	Not more than 0.5% w/w
8.6	**Total impurities**	1.15 % w/w	Not more than 2.0% w/w
9	**Assay (By HPLC) Each film coated tablet contains**		
9.1	**Sofosbuvir 400mg ($C_{22}H_{29}FN_3O_9P$) (%) Labeled amount**	100.5 %	Not less than 95.0% and Not more than 105.0%
9.2	**Velpatasvir 100mg ($C_{49}H_{54}N_8O_8$) (%) Labeled amount**	97.5 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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