



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.	H5FP19000151
Specification ID	FPS/B-3008267-1-02	Batch No.	31172197
Mfg. Date	01/2019	Batch Size	1.0 Lac.
Exp. Date	12/2020	Date Of Release	15-01-2019

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	1033.55 mg	1030.00mg \pm 3% (999.10mg to 1060.90mg)
4	Uniformity of weight	Highest : 1.99 % Lowest:-2.33 %	\pm 5% of Average weight
5	Water content (By KF)	3.17 %w/w	Not more than 6.0% w/w
6	Uniformity of Content (By HPLC)		
6.1	Velpatasvir	Min. : 98.8 % Max. : 102.5 % Average::100.4 %	Not less than 85.0% and Not more than 115.0% of average content.
7	Dissolution (By HPLC)		
7.1	Sofosbuvir	Tablet 1- : 96.0 % Tablet 2- : 96.6 % Tablet 3- : 96.4 % Tablet 4- : 96.6 % Tablet 5- : 96.8 % Tablet 6- : 97.0 % Average::96.6 %	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	Rameshvar.Dhakedey	Approved By	D.S.N.Reddy
Date	15-01-2019 18:36	Date	15-01-2019 18:38
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		Tablet 1- : 98.7 % Tablet 2- : 99.1 % Tablet 3- : 98.4 % Tablet 4- : 99.4 % Tablet 5- : 99.4 % Tablet 6- : 98.9 % Average::99.0 %	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	0.29 % 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	0.04 % w/w	Not more than 0.5% w/w
8.5	Maximum single unknown impurity	0.06 % w/w	Not more than 0.5% w/w
8.6	Total impurities	0.79 % w/w	Not more than 2.0% w/w
9	Assay (By HPLC) Each film coated tablet contains		
9.1	Sofosbuvir 400mg (C22H29FN3O9P) (%) Labeled amount	98.1 %	Not less than 95.0% and Not more than 105.0%
9.2	Velpatasvir 100mg (C49H54N8O8) (%) Labeled amount	102.1 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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