



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.	H5FP22001708
Specification ID	FPS/B-3008267-1-02	Batch No.	HH2204159
Mfg. Date	04/2022	Batch Size	3500 Tablets
Exp. Date	03/2024	Date Of Release	30-04-2022

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	1038.92 mg	1030.00mg $\pm$ 3% (999.10mg to 1060.90mg)
4	Uniformity of weight	Highest : 0.82 % Lowest:-1.47 %	$\pm$ 5% of Average weight
5	Water content (By KF)	2.88 %w/w	Not more than 6.0% w/w
6	Uniformity of Content (By HPLC)		
6.1	Velpatasvir	Min. : 101.5 % Max. : 102.6 % Average::102.0 %	Not less than 85.0% and Not more than 115.0% of average content.
7	Dissolution (By HPLC)		
7.1	Sofosbuvir	Tablet 1- : 97.9 % Tablet 2- : 97.9 % Tablet 3- : 97.9 % Tablet 4- : 97.7 % Tablet 5- : 98.6 % Tablet 6- : 98.7 % Average::98.1 %	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	ARIMARDAN.SINGH	Approved By	Naveen Kumar.Pundir
Date	30-04-2022 17:05	Date	30-04-2022 17:07
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		Tablet 1- : 97.1 % Tablet 2- : 96.9 % Tablet 3- : 97.7 % Tablet 4- : 98.1 % Tablet 5- : 99.7 % Tablet 6- : 100.5 % Average::98.3 %	minutes.
8	Related Substances (By HPLC)		
8.1	H-SFBRC01	Not Detected	Not more than 0.5% w/w
8.2	Hydroxy impurity	0.17 % 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	0.03 % w/w	Not more than 0.5% w/w
8.5	Maximum single unknown impurity	0.09 % w/w	Not more than 0.5% w/w
8.6	Total impurities	0.57 % 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	100.1 %	Not less than 95.0% and Not more than 105.0%
9.2	Velpatasvir 100mg (C49H54N8O8) (%) Labeled amount	102.6 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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