



# HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

## CERTIFICATE OF ANALYSIS

<b>Product Name: VELASOF (Sofosbuvir 400mg and Velpatasvir 100mg Tablets)</b>			
<b>Product Code</b>	4018042	<b>A.R. No.</b>	H5FP18000164
<b>Specification ID</b>	FPS/B-3008267-1-01	<b>Batch No.</b>	31171350
<b>Mfg. Date</b>	01/2018	<b>Batch Size</b>	0.58 Lac.
<b>Exp. Date</b>	12/2019	<b>Date Of Release</b>	20-01-2018

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	1025.62 mg	1030.00mg $\pm$ 3% (999.10mg to 1060.90mg)
4	Uniformity of weight	Highest : 1.83 % Lowest:-1.83 %	$\pm$ 5% of Average weight
5	Water content (By KF)	2.91 %w/w	Not more than 6.0% w/w
6	Uniformity of Content (By HPLC)		
6.1	Velpatasvir	Min. : 99.7 % Max. : 103.0 % Average::101.0 %	Not less than 85.0% and Not more than 115.0% of average content.
7	Dissolution (By HPLC)		
7.1	Sofosbuvir	Tablet 1- : 97.5 % Tablet 2- : 100.3 % Tablet 3- : 99.3 % Tablet 4- : 97.3 % Tablet 5- : 100.2 % Tablet 6- : 99.2 % Average::99.0 %	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	Nisha.Chandel	Approved By	D.S.N.Reddy
Date	20-01-2018 12:42	Date	20-01-2018 12:43
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		Tablet 1- : 97.7 % Tablet 2- : 100.5 % Tablet 3- : 99.6 % Tablet 4- : 97.5 % Tablet 5- : 100.5 % Tablet 6- : 99.4 % Average: 99.2 %	minutes.
8	<b>Related Substances (By HPLC)</b>		
8.1	<b>H-SFBRC01</b>	0.01 %w/w	Not more than 0.5% w/w
8.2	<b>Hydroxy impurity</b>	0.17 % w/w	Not more than 1.0 % w/w
8.3	<b>S-Phenyl diastereomer</b>	0.05 % w/w	Not more than 0.5% w/w
8.4	<b>Lactone impurity</b>	0.01 % w/w	Not more than 0.5% w/w
8.5	<b>Maximum single unknown impurity</b>	0.07 % w/w	Not more than 0.5% w/w
8.6	<b>Total impurities</b>	0.47 % w/w	Not more than 2.0% w/w
9	<b>Assay (By HPLC) Each film coated tablet contains</b>		
9.1	<b>Sofosbuvir 400mg (C<sub>22</sub>H<sub>29</sub>FN<sub>3</sub>O<sub>9</sub>P) (%) Labeled amount</b>	100.5 %	Not less than 95.0% and Not more than 105.0%
9.2	<b>Velpatasvir 100mg (C<sub>49</sub>H<sub>54</sub>N<sub>8</sub>O<sub>8</sub>) (%) Labeled amount</b>	99.6 %	Not less than 95.0% and Not more than 105.0%

<b>Remarks: APPROVED (Sample Conforms to above Specification)</b>			
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