

HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

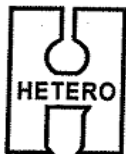
CERTIFICATE OF ANALYSIS

Product Name: RESOF 400 (Sofosbuvir Tablets 400mg)			
Product Code	4011653	A.R.No.	H5FP16003243
Specification ID	FPS/B-3006318-1-02	Batch No.	RF80201
Mfg. Date	02/2018	Batch Size	1.0 Lac
Exp. Date	01/2020	Date Of Release	06-02-2018

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Orange, Oval, bevel biconvex, film coated tablets debossed with 'H' on one side and 'S14' on other side.	Orange, Oval, bevel biconvex, film coated tablets debossed with 'H' on one side and 'S14' on other side.
2	Identification		
	a) By HPLC	The retention time of the major peak in the chromatogram of the sample preparation 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 preparation corresponds to that in the chromatogram of the standard solution, as obtained in the Assay.
	b) By UV	The UV absorption spectrum of sample preparation exhibits maxima at the same wavelength as that of standard preparation.	The UV absorption spectrum of sample preparation exhibits maxima at the same wavelength as that of standard preparation.
3	Uniformity of Weight	Highest: 1.41% Lowest: -1.09%	±5.0% of Average Weight
4	Average weight	1232.47 mg	1230.0mg±3.0% (1193.10 - 1266.9mg)
5	Water content (by KF)	2.35 % w/w	Not more than 6.0% w/w
6	Dissolution (%w/w, By UV)	Tablet 1 - 99.6% Tablet 2 - 98.7% Tablet 3 - 101.0% Tablet 4 - 102.4% Tablet 5 - 99.9% Tablet 6 - 100.4% Average - 100.3%	Not less than 75% (D) of the labeled amount of Sofosbuvir are dissolved in 15 minutes.

Remarks: APPROVED (Sample Conforms to above Specifications)

Checked By	Ramanuj.Mishra	Approved By	D.S.N. Reddy
Date	06-02-2018 17:35	Date	06-02-2018 17:37
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7	Related Substances (By HPLC)		
7.1	Maximum Single Impurity	0.04% w/w	Not more than 0.5% w/w
7.2	Total Impurities	0.07% w/w	Not more than 1% w/w
8	Assay (By HPLC) Each film coated tablet contains: Sofosbuvir (C ₂₂ H ₂₉ FN ₃ O ₉ P) (%) Labeled amount	99.4%	Not less than 95% and Not more than 105.0%
9	Thickness	7.15mm	6.9mm ± 0.4mm (Between 6.5mm and 7.3mm)
10	Hardness	14.09Kp	Between 12.00Kp and 26.00Kp
11	Microbial Limits		
11.1	Total viable aerobic count		
11.1.1	Total aerobic microbial count	Less than 10cfu/g.	Not more than 1000 cfu per g.
11.1.2	Total molds and yeast count	Less than 10cfu/g.	Not more than 100 cfu per g.
11.2	Test for specified micro organisms		
11.2.1	Bile-Tolerant Gram Negative bacteria	Absent in 1 g.	Absent in 1 g.
11.2.2	Escherichia coli	Absent in 1 g.	Absent in 1 g.
11.2.3	Salmonella species	Absent in 10 g.	Absent in 10 g.
11.2.4	Pseudomonas aeruginosa	Absent in 1 g.	Absent in 1 g.
11.2.5	Staphylococcus aureus	Absent in 1 g.	Absent in 1 g.

Remarks: APPROVED (Sample Conforms to above Specifications)			
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