



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: RESOF 400 (Sofosbuvir Tablets 400mg)			
Product Code	4011653	A.R. No.	H5FP18000787
Specification ID	FPS/B-3006320-1-02	Batch No.	RF80201
Mfg. Date	02/2018	Batch Size	1.0 Lac.
Exp. Date	01/2020	Date Of Release	21-02-2018

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		
2.1	By HPLC	The retention time of the major peak in the chromatogram of the sample solution 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 corresponds to that in the chromatogram of the standard solution, as obtained in the assay.
2.2	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 should exhibit maxima at the same wavelength as that of standard preparation
3	Average Weight	1228.24 mg	1230.00 mg \pm 3 % (1193.10 mg - 1266.90 mg)
4	Uniformity of Weight	Highest : 1.89 % Lowest:-1.93 %	\pm 5.0% of Average Weight.
5	Water Content (By KF)	1.96 % w/w	Not more than 6.0% w/w.
6	Dissolution (By UV)	Tablet 1- : 94.2 % Tablet 2- : 94.2 % Tablet 3- : 93.9 % Tablet 4- : 93.5 % Tablet 5- : 93.2 % Tablet 6- : 93.5 % Average::93.7 %	Not less than 75% (D) of labeled amount of Sofosbuvir should dissolve in 15 minutes.
7	Related Substances (By HPLC)		
7.1	Maximum Single Impurity	0.04 % w/w	Not more than 0.5% w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Rameshvar.Dhakedey	Approved By	D.S.N.Reddy
Date	21-02-2018 17:52	Date	21-02-2018 18:01
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7.2	Total Impurities	0.09 % w/w	Not more than 1.0% w/w
8	Assay (By HPLC) Each film coated tablet contains: Sofosbuvir (C₂₂H₂₉FN₃O₉P) (%) Labeled amount	98.0 %	Not less than 95.0% and Not more than 105.0%
9	Thickness	6.94 mm	6.9 mm ± 0.4mm (Between 6.5mm and 7.3mm)
10	Hardness	20.72 Kp	Between 12.00 Kp and 26.00 Kp

Remarks: APPROVED (Sample Conforms to above Specification)			
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