



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: SOFOVIR (Sofosbuvir Tablets 400mg)			
Product Code	4011783	A.R. No.	H5FP19003994
Specification ID	FPS/B-3006320-1-02	Batch No.	31172822
Mfg. Date	09/2019	Batch Size	1.25 Lac.
Exp. Date	08/2021	Date Of Release	30-09-2019

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	1238.42 mg	1230.00 mg \pm 3 % (1193.10 mg - 1266.90 mg)
4	Uniformity of Weight	Highest : 1.88 % Lowest:-1.48 %	\pm 5.0% of Average Weight.
5	Water Content (By KF)	2.42 % w/w	Not more than 6.0% w/w.
6	Dissolution (By UV)	Tablet 1- : 98.5 % Tablet 2- : 99.2 % Tablet 3- : 96.3 % Tablet 4- : 97.5 % Tablet 5- : 98.7 % Tablet 6- : 97.3 % Average::97.9 %	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	0.02 % w/w	Not more than 0.5% w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Ramanuj.Mishra	Approved By	D.S.N.Reddy
Date	30-09-2019 15:51	Date	30-09-2019 15:52
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7.2	Total Impurities	0.03 % w/w	Not more than 1.0% w/w
8	Assay (By HPLC) Each film coated tablet contains: Sofosbuvir (C₂₂H₂₉FN₃O₉P) (%) Labeled amount	100.1 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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