



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: SOFOVIR (Sofosbuvir Tablets 400mg)			
Product Code	4011783	A.R. No.	H5FP15003512
Specification ID	FPS/B-3006320-1-00	Batch No.	3115475
Mfg. Date	07/2015	Batch Size	0.82 Lac.
Exp. Date	06/2017	Date Of Release	10-07-2015

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	1237.83 mg	1230.00 mg \pm 3 % (1193.10 mg - 1266.90 mg)
4	Uniformity of Weight	Highest : 0.77 % Lowest:-0.96 %	\pm 5.0% of Average Weight.
5	Water Content (By KF)	2.12 % w/w	Not more than 6.0% w/w.
6	Dissolution (By UV)	Tablet 1- : 97.4 % Tablet 2- : 99.6 % Tablet 3- : 100.8 % Tablet 4- : 99.1 % Tablet 5- : 97.7 % Tablet 6- : 100.5 % Average::99.2 %	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	0.10 % w/w	Not more than 0.5% w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Nisha.Chandel	Approved By	D.S.N.Reddy
Date	10-07-2015 15:01	Date	10-07-2015 15:06
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7.2	Total Impurities	0.17 % w/w	Not more than 1.0% w/w
8	Assay (By HPLC) Each film coated tablet contains: Sofosbuvir (C22H29FN3O9P) (%) Labeled amount	100.9 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

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