

HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

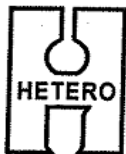
CERTIFICATE OF ANALYSIS

Product Name: SOFOVIR (Sofosbuvir Tablets 400mg)			
Product Code	4011783	A.R.No.	H5FP16003077
Specification ID	FPS/B-3006320-1-04	Batch No.	31171527
Mfg. Date	04/2018	Batch Size	1.0 Lac
Exp. Date	03/2020	Date Of Release	06-04-2018

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Orange, Oval, bevel biconvex, film coated tablets debossed with '400' on one side and 'S14' on other side.	Orange, Oval, bevel biconvex, film coated tablets debossed with '400' 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 preparation, 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 preparation, as obtained in the Assay.
	b) By UV	The UV absorption spectrum of the sample and standard solutions exhibits maxima at the same wavelengths.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelength.
3	Uniformity of Weight	Highest: 0.43% Lowest: -0.61%	±5.0% of Average Weight
4	Average weight	1229.42 mg	1230.0mg±3.0% (1193.10 - 1266.9mg)
5	Water content (by KF)	2.65 % w/w	Not more than 6.0% w/w
6	Dissolution (%w/w, By UV)	Tablet 1 - 100.8% Tablet 2 - 101.4% Tablet 3 - 101.2% Tablet 4 - 100.7% Tablet 5 - 101.1% Tablet 6 - 102.7% Average - 101.3%	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	Naveen Kumar. Pundir	Approved By	Sudhakar Reddy. Jaggavarapu
Date	06-04-2018 17:35	Date	06-04-2018 17:37
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7	Related Substances (By HPLC)		
7.1	Maximum Single Impurity	0.03% w/w	Not more than 0.5% w/w
7.2	Total Impurities	0.09% 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	101.1%	Not less than 95% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specifications)			
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