HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: SOFOVIR (Sofosbuvir Tablets 400mg)			
Product Code	4011783	A.R. No.	H5FP19000880
Specification ID	FPS/B-3006320-1-02	Batch No.	31172275
Mfg. Date	02/2019	Batch Size	1.0 Lac.
Exp. Date	01/2021	Date Of Release	25-02-2019

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Orange, Oval, bevel biconvex, film coated tablets debbosed with 'H' on one side and 'S14' on other side.	Orange, Oval, bevel biconvex, film coated tablets debbosed 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	1229.39 mg	1230.00 mg ± 3 % (1193.10 mg - 1266.90 mg)
4	Uniformity of Weight	Highest : 1.54 % Lowest::-1.40 %	± 5.0% of Average Weight.
5	Water Content (By KF)	2.36 % w/w	Not more than 6.0% w/w.
6	Dissolution (By UV)	Tablet 1- : 92.7 % Tablet 2- : 92.9 % Tablet 3- : 92.4 % Tablet 4- : 93.7 % Tablet 5- : 93.4 % Tablet 6- : 92.4 % Average::92.9 %	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	0.03 % 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	25-02-2019 17:37	Date	25-02-2019 17:38
Printed by: D.S.N.Reddy		Printed on: 25-02-2019 17:39	
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CNo: C100000875

HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: SOFOVIR (Sofosbuvir Tablets 400mg)			
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7.2	Total Impurities	0.15 % w/w	Not more than 1.0% w/w
8	Assay (By HPLC) Each film coated tablet contains: Sofosbuvir ($C_{22}H_{29}FN_3O_9P$) (%) Labeled amount	98.6 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Rameshvar.Dhakedey	Approved By	D.S.N.Reddy
Date	25-02-2019 17:37	Date	25-02-2019 17:38
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CNo: C100000875

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