

## HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

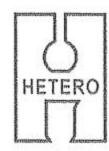
## CERTIFICATE OF ANALYSIS

<b>Product Name: SOF</b>	OVIR (Sofosbuvir Tablets 40	)0mg)	
Product Code	4011783	A.R. No.	H5FP18001053
Specification ID	FPS/B-3006320-1-02	Batch No.	31172037
Mfg. Date	11/2018	Batch Size	1.0 Lac.
Exp. Date	10/2020	Date Of Release	16/11/2018

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Orange, Oval, bevel	Orange, Oval, bevel
		biconvex, film coated tablets	biconvex, film coated tablets
		debbosed with 'H' on one	debbosed with 'H' on one
		side and 'S14' on other side.	side and 'S14' on other side.
2	Identification		
2.1	By HPLC	The retention time of the	The retention time of the
		major peak in the	major peak in the
		chromatogram of the sample	chromatogram of the sample
		solution corresponds to that	solution should corresponds
		in the chromatogram of the	to that in the chromatogram
		standard solution, as	of the standard solution, as
		obtained in the assay.	obtained in the assay.
2.2	By UV	The UV absorption spectrum	The UV absorption spectrum
		of sample preparation	of sample preparation
		exhibits maxima at the same	should exhibit maxima at the
		wavelength as that of	same wavelength as that of
		standard preparation.	standard preparation
3	Average Weight	1222.60 mg	1230.00 mg ± 3 % (1193.10
			mg - 1266.90 mg)
4	Uniformity of Weight		± 5.0% of Average Weight.
		Highest: 1.85 %	
		Lowest::-1.63 %	
5	Water Content (By KF)	1.75 % w/w	Not more than 6.0% w/w.
6	Dissolution (By UV)		Not less than 75% (D) of
		Tablet 1- : 99.2 %	labeled amount of
	- X	Tablet 2- : 95.1 %	Sofosbuvir should dissolve
		Tablet 3- : 98.3 %	in 15 minutes.
		Tablet 4- : 98.3 %	
		Tablet 5- : 95.1 %	
		Tablet 6- : 94.8 %	
		Average::96.8 %	
7	Related Substances (By		
	HPLC)		
7.1	Maximum Single Impurity	0.05 % w/w	Not more than 0.5% w/w

Remarks: APP	ROVED (Sample Conforms to	above Specification)	
Checked By	Nisha.Chandel	Approved By	D.S.N.Reddy
Date	16/11/2018	Date	16/11/2018
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Note: This d	ocument has been generat	ed electronically and is v	alid without signature.
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Office: 7-2-A/2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad-18, INDIA. Tel: 040-23704923/24/25, Fax: 040-23704926 Factory: Village: Kalyanpur, Chakkan Road, BADDI, Tehsil: Baddi, Distt. Solan, H.P. - 173 205 INDIA.



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Product Name: SOF	OVIR (Sofosbuvir Tablets 40	00mg)	
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7.2	Total Impurities	0.13 % w/w	Not more than 1.0% w/w
8	Assay (By HPLC) Each film coated tablet contains: Sofosbuvir (C22H29FN3O9P) (%) Labeled amount	99.6 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By Nisha.Chandel Approved By D.S.N.Reddy

Date 16/11/2018 Date 16/11/2018

Printed by: D.S.N.Reddy Printed on: 16/11/2018

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