

HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: SOF	OVIR (Sofosbuvir Tablets 40	0mg)	
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	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		ŕ
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 should
		exhibits maxima at the same	exhibit maxima at the same
		wavelength as that of	wavelength as that of
		standard preparation.	standard preparation
3	Average Weight	1237.83 mg	1230.00 mg ± 3 % (1193.10
			mg - 1266.90 mg)
4	Uniformity of Weight		± 5.0% of Average Weight.
	, ·	Highest : 0.77 %	
	·	Lowest::-0.96 %	
5	Water Content (By KF)	2.12 % w/w	Not more than 6.0% w/w.
6	Dissolution (By UV)		Not less than 75% (D) of
		Tablet 1- : 97.4 %	labeled amount of
		Tablet 2- : 99.6 %	Sofosbuvir should dissolve in
		Tablet 3- : 100.8 %	15 minutes.
		Tablet 4- : 99.1 %	
		Tablet 5- : 97.7 %	
		Tablet 6-: 100.5 %	
		Average::99.2 %	
7	Related Substances (By		
	HPLC)		
7.1	Maximum Single Impurity	0.10 % w/w	Not more than 0.5% w/w

Remarks: APP	ROVED (Sample Conforms to a	bove Specification)	
Checked By	Nisha.Chandel	Approved By	D.S.N.Reddy
Date	10-07-2015 15:01	Date	10-07-2015 15:06
Printed by: D.S	i.N.Reddy	Printed on: 10-	07-2015 15:21
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CNo: C6003990			

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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7.2	Total Impurities	0.17 % w/w	Not more than 1.0% w/w
8	Assay (By HPLC) Each film	100.9 %	Not less than 95.0% and Not
	coated tablet contains:		more than 105.0%
	Sofosbuvir		
	(C22H29FN3O9P) (%)		
	Labeled amount		

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

Printed by: D.S.N.Reddy Printed on: 10-07-2015 15:21

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