

# CERTIFICATE OF ANALYSIS

HEPCVIR TABLETS				
INSPECTION LOT NO. : 40000386665		DATE OF RELEASE : 12.09.2017		
BATCH NO.	: PB70868	MFG. DT.	: Aug 2017	
QTY	: 3981 EA	EXP. DT.	: Jul 2019	
		LIMS LOT NO.	: 2282807	
TEST	REFERENCE	UNIT	STANDARD	RESULT
DESCRIPTION	INHOUSE			Meets the requirement
Observation		-	Pink colored, film coated , Oval shaped, tablets debossed with 'SFV' on one side and plain on other side.	Complies
IDENTIFICATION (By HPLC)	INHOUSE			Meets the requirement
Observation		-	The retention time of the peak due to Sofosbuvir in the chromatogram obtained with the sample solution is similar to that in the chromatogram obtained with standard solution in the test for Assay.	Complies
WATER	INHOUSE			Meets the requirement
Water		% wt/wt	NMT 5.00	1.71
DISSOLUTION (BY UV)	INHOUSE			Meets the requirement
Dissolution		-		Pass
Average		%	Meets the requirement of the final stage executed.	99
Minimum		%	Meets the requirement of the final stage executed.	98
Maximum		%	Meets the requirement of the final stage executed.	100

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Mfg. Site :

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TEST	REFERENCE	UNIT	STANDARD	RESULT
DISSOLUTION (BY UV)	INHOUSE			Meets the requirement
Stage 1		-	Each unit is not less than 70 % (Q) + 5 % which is equivalent to 75 % of the labeled amount released in 45 minutes.	Pass
Stage 2		-	Average of 12 units (S1+S2) is equal to or greater than 70 % (Q). No unit is less than 55 % (Q-15 %).	Not Applicable
Stage 3		-	Average of 24 units (S1+S2+S3) is equal to or greater than 70 % (Q). Not more than 2 units are less than 55 % (Q-15 %). No unit is less than 45 % (Q-25 %).	Not Applicable
RELATED SUBSTANCES (BY HPLC)	INHOUSE			Meets the requirement
H-SFBRC01		%	NMT 1.0	Below 0.1 %
Single maximum unknown impurity		%	NMT 0.5	Below 0.1 %
Total impurities		%	NMT 2.0	Below 0.1 %
ASSAY (BY HPLC)	INHOUSE			Meets the requirement

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TEST	REFERENCE	UNIT	STANDARD		RESULT
ASSAY (BY HPLC)	INHOUSE				Meets the requirement
Content of Sofosbuvir in mg/tablet		mg/tablet	NLT 360.0	NMT 440.0	397.6
Content of Sofosbuvir in %		%	NLT 90.0	NMT 110.0	99.4

REMARK : COMPLIES WITH INHOUSE STANDARDS. ANALYSIS AS PER SPECIFICATION NUMBER 1035  
-32018006/1.0, DATED 19.02.2016.

### QUALITY CONTROL

Name : Sachin Kedari (51132)  
(Head Quality Control)

Date : 11.09.2017 12:09:57

### QUALITY ASSURANCE

Name : Hemant There (39696)  
(Head Quality Assurance)

Date : 12.09.2017 13:37:56

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