MYLAN LABORATORIES LIMITED
F-4 & F-12, Malegaon MIDC, Sinnar,
Nashik - 422 113, Maharashtra, India.

CERTIFICATE OF ANALYSIS

Name of the Product: MyHEP ALL (Sofosbuvir and Velpatasvir Film-coated Tablets 400 mg / 100 mg)			
Batch No.	3117178	**A.R. No.**	MLNFP20005623
Mfg. Date	May-2020	**Market**	Emerging
Exp. Date	Apr-2022	**Batch Size**	2,50,000 Tablets
Ref. Spec No.	FPSSFV195R-06	**Date of Analysis**	Jun 17, 2020

S. No.	TEST	SPECIFICATION	RESULT
1	**Description**	Light green to green colored, modified capsule shaped biconvex beveled edge film coated tablet debossed with M on one side and SFV on the other side.	Light green colored, modified capsule shaped biconvex beveled edge film coated tablet debossed with M on one side and SFV on the other side.
2	**Identification**		
2.1	**A. By HPLC**	The retention time of the Sofosbuvir and Velpatasvir peaks in the chromatogram of the test preparation should corresponds to that in the chromatogram of the standard preparation as obtained in the test “Assay (By HPLC)”.	The retention time of the Sofosbuvir and Velpatasvir peaks in the chromatogram of the test preparation corresponds to that in the chromatogram of the standard preparation as obtained in the test “Assay (By HPLC)”.
2.2	**B. By HPLC (With PDA detector)**	Compare the spectrums of the Sofosbuvir and Velpatasvir peaks from the test solution chromatogram with that of the standard solution chromatogram from the PDA data. The test spectrum should match with that of standard spectrum due to Sofosbuvir and Velpatasvir peaks.	Compared the spectrums of the Sofosbuvir and Velpatasvir peaks from the test solution chromatogram with that of the standard solution chromatogram from the PDA data. The test spectrum matches with that of standard spectrum due to Sofosbuvir and Velpatasvir peaks
3	**Dissolution (By HPLC)**		
3.1	**Sofosbuvir 400 mg**	Complies with Ph. Eur. General Chapter 2.9.3 Not less than 80% (Q = 75%) of the labeled amount of Sofosbuvir, $C_{22}H_{29}FN_3O_9P$ should be dissolved in 30 minutes.	(Tab-1) : 95 % (Tab-2) : 96 % (Tab-3) : 96 % (Tab-4) : 96 % (Tab-5) : 95 % (Tab-6) : 96 % Min : 95 % Max : 96 % Avg : 96 % RSD:0.3%
3.2	**Velpatasvir 100 mg**	Complies with Ph. Eur. General Chapter 2.9.3 Not less than 80% (Q = 75%) of the labeled amount of Velpatasvir, $C_{49}H_{54}N_8O_8$ should be dissolved in 30 minutes.	(Tab-1) : 95 % (Tab-2) : 95 % (Tab-3) : 96 % (Tab-4) : 96 % (Tab-5) : 95 % (Tab-6) : 97 %

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By : Sandip.Lachake	Approved By : Kamalnayan.Pandey
Prepared On : Jun 18 2020 8:32AM	Approved On : Jun 18 2020 9:59AM

Printed by: Sandip.Lachake	**Printed on: Jun 18 2020 10:39AM**	**Copy No.: 1** **Page No.: 1 of 3**

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S. No.	TEST	SPECIFICATION	RESULT
			Min : 95 % Max : 97 % Avg : 96 % RSD:0.7%
4	**Uniformity of dosage units (By Content Uniformity)**		
4.1	**Sofosbuvir 400 mg**	Complies with Ph. Eur. General Chapter 2.9.40 The Acceptance Value (AV) should be not more than 15.0.	Sample-1 : 98.9 % Sample-2 : 100.5 % Sample-3 : 100.6 % Sample-4 : 102.3 % Sample-5 : 100.8 % Sample-6 : 101.9 % Sample-7 : 101.6 % Sample-8 : 102.0 % Sample-9 : 101.0 % Sample-10 : 99.4 % Average : 100.9 % AV:2.7
4.2	**Velpatasvir 100 mg**	Complies with Ph. Eur. General Chapter 2.9.40 The Acceptance Value (AV) should be not more than 15.0.	Sample-1 : 97.8 % Sample-2 : 99.9 % Sample-3 : 99.3 % Sample-4 : 101.5 % Sample-5 : 99.8 % Sample-6 : 100.6 % Sample-7 : 100.6 % Sample-8 : 101.2 % Sample-9 : 100.4 % Sample-10 : 99.1 % Average : 100.0 % AV:2.6
5	**Assay (By HPLC)**		
5.1	**Sofosbuvir 400 mg**	Not less than 360.00 mg and not more than 440.00 mg of Sofosbuvir, $C_{22}H_{29}FN_3O_9P$ (90.0% w/w – 110.0% w/w of labeled amount of Sofosbuvir)	In mg : 399.90 mg In %:100.0% w/w
5.2	**Velpatasvir 100 mg**	Not less than 90.00 mg and not more	

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S. No.	TEST	SPECIFICATION	RESULT
		than 110.00 mg of Velpatasvir, $C_{49}H_{54}N_8O_8$ (90.0% w/w – 110.0% w/w of labeled amount of Velpatasvir)	In mg : 99.93 mg In %:99.9% w/w
6	**Related Substances (By HPLC)**		
6.1	**A.Velpatasvir impurities:**		
6.1.1	**a.Amine free base**	Not more than 1.0% w/w	Below LOQ
6.1.2	**b.Lactone impurity**	Not more than 1.0% w/w	0.026 % w/w
6.1.3	**c. Any unknown impurity**	Not more than 0.5% w/w	0.060 % w/w
6.2	**B.Sofosbuvir impurities:**		
6.2.1	**a.Fluoro uridine impurity**	Not more than 0.5% w/w	Not Detected
6.2.2	**b. Any unknown impurity**	Not more than 0.5% w/w	Below disregard limit
6.3	**C.Total impurities (A + B)**	Not more than 3.5% w/w	0.126 % w/w
7	**Residual solvents (By GC)**		
7.1	**Ethanol**	Not more than 5000 ppm	266 ppm
8	**Water (By KF)**	Not more than 5.5% w/w	3.12 % w/w

Storage: Do not store above 30 °C, store in original container.

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