



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.	3105979	A.R. No.	MLNFP19010117
Mfg. Date	Sep-2019	Market	Emerging
Exp. Date	Aug-2021	Batch Size	2,50,000 Tablets
Ref. Spec No.	FPSSFV195R-06	Date of Analysis	Oct 19, 2019

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 ₃ O ₉ P should be dissolved in 30 minutes.	(Tab-1) : 94 % (Tab-2) : 94 % (Tab-3) : 95 % (Tab-4) : 95 % (Tab-5) : 93 % (Tab-6) : 94 % Min : 93 % Max : 95 % Avg : 94 % RSD:0.7%
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	(Tab-1) : 93 % (Tab-2) : 93 % (Tab-3) : 93 % (Tab-4) : 94 %

Remarks: APPROVED

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Assay results are reported as per PR#2000039

Prepared By : Sandip.Lachake	Approved By : Ajitkumar.Desai
Prepared On : Oct 31 2019 9:28PM	Approved On : Oct 31 2019 9:35PM
Printed by: Sandip.Lachake	Printed on: Oct 31 2019 9:41PM
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CNo: C80000011297

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		O_8 should be dissolved in 30 minutes.	(Tab-5) : 92 % (Tab-6) : 94 % Min : 92 % Max : 94 % Avg : 93 % RSD:0.8%
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 : 97.9 % Sample-2 : 97.7 % Sample-3 : 97.8 % Sample-4 : 98.6 % Sample-5 : 98.9 % Sample-6 : 99.1 % Sample-7 : 98.1 % Sample-8 : 98.4 % Sample-9 : 99.6 % Sample-10 : 99.5 % Average : 98.6 % AV:1.7
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 : 97.9 % Sample-2 : 98.3 % Sample-3 : 98.3 % Sample-4 : 99.0 % Sample-5 : 99.3 % Sample-6 : 99.9 % Sample-7 : 98.6 % Sample-8 : 98.5 % Sample-9 : 100.3 % Sample-10 : 99.8 % Average : 99.0 % AV:1.9
5	Assay (By HPLC)		
5.1	Sofosbuvir 400 mg	Not less than 360.00 mg and not more than 440.00 mg of Sofosbuvir, $C_{22}H_{29}FN$ O_3P	In mg : 395.85 mg In %:99.0 % w/w

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		(90.0% w/w – 110.0% w/w of labeled amount of Sofosbuvir)	
5.2	Velpatasvir 100 mg	Not less than 90.00 mg and not more than 110.00 mg of Velpatasvir, C ₄₉ H ₅₄ N ₈ O ₈ (90.0% w/w – 110.0% w/w of labeled amount of Velpatasvir)	In mg : 98.32 mg In %:98.3 % 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	Not Detected
6.1.2	b.Lactone impurity	Not more than 1.0% w/w	0.021 % w/w
6.1.3	c. Any unknown impurity	Not more than 0.5% w/w	0.046 % 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	0.045 % w/w
6.3	C.Total impurities (A + B)	Not more than 3.5% w/w	0.155 % w/w
7	Residual solvents (By GC)		
7.1	Ethanol	Not more than 5000 ppm	294 ppm
8	Water (By KF)	Not more than 5.5% w/w	3.02 % w/w

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

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