



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.	3112906	A.R. No.	MLNFP20002187
Mfg. Date	Feb-2020	Market	Emerging
Exp. Date	Jan-2022	Batch Size	2,50,000 Tablets
Ref. Spec No.	FPSSFV195R-06	Date of Analysis	Mar 23, 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 to 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) : 99 % (Tab-2) : 97 % (Tab-3) : 97 % (Tab-4) : 96 % (Tab-5) : 97 % (Tab-6) : 97 % Min : 96 % Max : 99 % Avg : 97 % RSD:0.8%
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 ₈ O ₈ should be dissolved in 30 minutes.	(Tab-1) : 98 % (Tab-2) : 97 % (Tab-3) : 97 % (Tab-4) : 96 % (Tab-5) : 97 % (Tab-6) : 97 %

Remarks: APPROVED (Sample Conforms to above Specification)

Prepared By : VISHWAJEET.KONGLE	Approved By : Rajendra.Adavkar
Prepared On : Mar 23 2020 5:24PM	Approved On : Mar 23 2020 5:43PM
Printed by: VISHWAJEET.KONGLE	Printed on: Mar 23 2020 5:47PM
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CNo: C9000002719

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			Min : 96 % Max : 98 % Avg : 97 % 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 : 100.6 % Sample-2 : 99.4 % Sample-3 : 100.3 % Sample-4 : 99.9 % Sample-5 : 100.6 % Sample-6 : 99.1 % Sample-7 : 100.5 % Sample-8 : 99.4 % Sample-9 : 100.1 % Sample-10 : 100.2 % Average : 100.0 % AV:1.3
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 : 100.7 % Sample-2 : 99.9 % Sample-3 : 100.6 % Sample-4 : 100.2 % Sample-5 : 100.9 % Sample-6 : 99.8 % Sample-7 : 100.5 % Sample-8 : 99.3 % Sample-9 : 100.5 % Sample-10 : 100.5 % Average : 100.3 % AV:1.1
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 ₃ O ₉ P (90.0% w/w – 110.0% w/w of labeled amount of Sofosbuvir)	In mg : 398.82 mg In %:99.7% 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 ${}^{49}_{15}\text{H}$ ${}^{54}_{14}\text{N}$ ${}^{8}_{16}\text{O}$ (90.0% w/w – 110.0% w/w of labeled amount of Velpatasvir)	In mg : 99.58 mg In %:99.6% 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	0.025 % w/w
6.1.3	c. Any unknown impurity	Not more than 0.5% w/w	0.044 % 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	0.018 % w/w
6.3	C.Total impurities (A + B)	Not more than 3.5% w/w	0.344 % w/w
7	Residual solvents (By GC)		
7.1	Ethanol	Not more than 5000 ppm	397 ppm
8	Water (By KF)	Not more than 5.5% w/w	2.73 % w/w
9	Microbiological Test		
9.1	A.Microbial enumeration tests a.Total aerobic microbial count (TAMC)	Complies with Ph. Eur. General Chapter 5.1.4. Not more than 1000 CFU/g	Less than 10 cfu/g
9.2	b.Total combined yeasts / moulds count (TYMC)	Not more than 100 CFU/g	Less than 10 cfu/g
9.3	B.Test for specified Micro-organisms Escherichia coli	Must be absent / g	Absent/g

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

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