Natco Pharma Limited

Regd. Off: 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034, INDIA
Tel: +91 40 23547532, Fax: +91 40 23548243

Email: info@natcopharma.co.in

CERTIFICATE OF ANALYSIS

Product Name: SoviHep		B.No. : S705636
Generic Name: Sofosbuvir 400mg Tablets		Product Code: GSF512Z Y
Batch size: 91,218 Tablets	Sampling Date: 08/02/2019	Mfg. Date: 02/2019
Qty. Sampled: 01 Container	Analysis Date: 08/02/2019	Exp. Date: 01/2021
Sampled by: Ch. Bhargavi	Reporting Date: 09/02/2019	A.R. No.: M/446/07

S.No	TEST	SPECIFICATION	RESULT
1.	Description	Brick red coloured, capsule shaped, film coated tablets debossed with '400' on one side and plain on other side.	Brick red coloured, capsule shaped, film coated tablets debossed with '400' on one side and plain on other side.
2.	Identification a) By HPLC b) By UV	The retention time of the major peak in the chromatogram of the sample preparation should correspond to that in the chromatogram of the standard preparation, as obtained in the Assay. The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation, as obtained in the Assay. The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelengths
3.	Uniformity of dosage units (By weight variation)	The acceptance value of the first 10 dosage units is less than or equal to LI (LI is 15.0 and L2 is 25.0)	Complies (Acceptance value is 0.8)

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	Aamir Hasan	Dasn	Amol Puri
Designation	A.R. Officer	Q.C. Officer	Senior Manager

WORKS: PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
Guwahati, Assam, 781125, Office: + 91-362-3230471, 472, 473

Natco Pharma Limited

Regd. Off: 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034, INDIA
Tel: +91 40 23547532, Fax: +91 40 23548243

Email: info@natcopharma.co.in

CERTIFICATE OF ANALYSIS

Product Name: SoviHep		B.No. : S705636
Generic Name: Sofosbuvir 400mg Tablets		Product Code: GSF512Z Y
Batch size: 91,218 Tablets	Sampling Date: 08/02/2019	Mfg. Date: 02/2019
Qty. Sampled: 01 Container	Analysis Date: 08/02/2019	Exp. Date: 01/2021
Sampled by: Ch. Bhargavi	Reporting Date: 09/02/2019	A.R. No.: M/446/07

S.No	TEST	SPECIFICATION	RESULT
4.	Average weight per tablet	1236.0 mg ±3.0%	1237.45 mg
5.	Water content	Not more than 4.0% w/w	2.32%
6.	Dissolution (%w/w, By UV)	Dissolution (%w/w, By UV) Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.	Minimum = 99.5 % Maximum = 100.5 % Average = 100.0 %
7.	Assay (By HPLC) Each film coated tablet contains 400 mg of Sofosbuvir	Not less than 90.0% and not more than 110.0% of the labeled amount of Sofosbuvir.	99.3 %
8.	Related impurities (By HPLC)		
	a) Single maximum impurities b) Total impurities	Not more than 0.5 % Not more than 2.0 %	0.04 % 0.13 %

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	Jamir Hassan	Devgn	Amol Puri
Designation	A.R. Officer	Q.C. Officer	Senior Manager

WORKS: PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
Guwahati, Assam, 781125, Office: + 91-362-3230471, 472, 473

Natco Pharma Limited

Regd. Off: 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034, INDIA
Tel: +91 40 23547532, Fax: +91 40 23548243

Email: info@natcopharma.co.in

CERTIFICATE OF ANALYSIS

Product Name: SoviHep		B.No. : S705636
Generic Name: Sofosbuvir 400mg Tablets		Product Code: GSF512Z Y
Batch size: 91,218 Tablets	Sampling Date: 08/02/2019	Mfg. Date: 02/2019
Qty. Sampled: 01 Container	Analysis Date: 08/02/2019	Exp. Date: 01/2021
Sampled by: Ch. Bhargavi	Reporting Date: 09/02/2019	A.R. No.: M/446/07

S.No	TEST	SPECIFICATION	RESULT
ADDITIONAL TESTS			
9.	Microbial Enumeration tests & test for specified microorganisms USP <61> & <62> #		
	Total aerobic microbial count	Not more than 1000 cfu/g	<10 cfu/g
	Total combined molds and Yeasts	Not more than 100 cfu/g	<10 cfu/g
	Escherichia coli	Should be absent/g	Absent
	Salmonella species	Should be absent/10 g	Absent
	Staphylococcus aureus	Should be absent/g	Absent
	Pseudomonas aeruginosa	Should be absent/g	Absent

Remarks: The product complies as per Specification No FP/SPC/004-00

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	Samir Hasan	Devan	Amol Puri
Designation	A.R. Officer	Q.C. Officer	Senior Manager

WORKS: PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),
Guwahati, Assam, 781125, Office: + 91-362-3230471, 472, 473