



# 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](mailto:info@natcopharma.co.in)

## CERTIFICATE OF ANALYSIS

Product Name: Sofokast Tablets	B.No. : 1901146
Generic Name : Sofosbuvir 400 mg Tablets	Product Code : GSF41AZ
Batch size: 90969 Tablets	Sampling Date: 25/02/2019
Qty. Sampled: 01 Container	Mfg. Date: 02/2019
Sampled by: Priyanka	Analysis Date: 25/02/2019
	Exp. Date: 01/2021
	Reporting Date: 28/02/2019
	A.R. No.: FP/AR/076/19

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	<p>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.</p> <p>The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.</p>	<p>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.</p> <p>The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelengths.</p>
3.	Uniformity of dosage units (By weight variation)	The acceptance value of the first 10 dosage units is less than or equal to L1 (L1 is 15.0 and L2 is 25.0)	Acceptance value = 2.66

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	<i>RA 01/03/2019</i>	<i>RA 01/03/2019</i>	<i>Sanyam S. Chandra</i>
Name	B N Bhatnagar	Rustam Alam	Sanyam S. Chandra
Designation	Officer-ec	Officer a.c.	Senior manager-ec



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S.No	TEST	SPECIFICATION	RESULT
4.	Average weight per tablet	1236.0 mg $\pm$ 3.0 %	1241.00 mg
5.	Water content (By KF)	Not more than 4.0% w/w	1.89 % w/w
6.	Dissolution (By UV)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.	Minimum = 99.9 % Maximum = 101.7 % Average = 101.0 %
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.	100.1 %
8.	Related impurities (By HPLC)		
	a) Individual unknown impurity	Not more than 0.5 %	0.02 %
	b) Total impurities	Not more than 2.0 %	0.04%

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Name	B N Satish	Rustam Alam	Sanjay S. Chandra
Designation	Officer-CC	Officer Q.C.	Sr manager

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WORKS : PHARMA DIVISION, Kokjhar, Mirza, Kamrup (R),  
Guwahati, Assam, 781125, Office : + 91-362-3230 470, 471, 472, 473



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## CERTIFICATE OF ANALYSIS

Product Name: Sofokast Tablets	B.No. : 1901146
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Qty. Sampled: 01 Container	Analysis Date: 25/02/2019
Sampled by: Priyanka	Reporting Date: 28/02/2019
	A.R. No.: FP/AR/076/19

S.No	TEST	SPECIFICATION	RESULT
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
	<i>Escherichia coli</i>	Should be absent/g	Absent
	<i>Salmonella species</i>	Should be absent/10 g	Absent
	<i>Staphylococcus aureus</i>	Should be absent/g	Absent
	<i>Pseudomonas aeruginosa</i>	Should be absent/g	Absent

**Remarks:** The product complies as per Specification No. : FP/SPC/004-01

	PREPARED BY	CHECKED BY	APPROVED BY
Sign			
Name	B N Balwani	Rastan Alan	Sanyas Chandra
Designation	Officer-in-charge	Officer in charge	Sr manager