



Natco Pharma Limited

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

CERTIFICATE OF ANALYSIS

Product Name: SofoKem Generic Name : Sofosbuvir Tablets	B. No.: 1900132	
Batch size: 35168 Tablets	Sampling Date : 30/03/2016	Mfg. Date: 02/2016
Qty. Sampled: 1 X 28 Tablets	Analysis Date : 30/03/2016	Exp. Date: 01/2018
Sampled by: Bhargavi	Reporting Date: 31/03/2016	A.R. No.: FP/AR/110/16

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.	Complies
2.	Identification a) By HPLC	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.	Complies.
	b) By UV	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.	Complies
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)	Complies (Acceptance value is 1.4)
4.	Average weight per tablet	1236.0 mg \pm 3.0 %	1248.54 mg
5.	Water content (by KF)	Not more than 4.0% w/w	1.7 %



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CERTIFICATE OF ANALYSIS

6.	Dissolution (%w/w, By UV)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.	Minimum = 99.39 % Maximum = 100.44 % Average = 99.95 %
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.	102.19 %
8.	Related impurities (By HPLC)		
	a) Single maximum impurities	Not more than 0.5 %	0.04 %
	b) Total impurities	Not more than 2.0 %	0.13 %

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
	<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 is complies as per Specification No. : FP/SPC/004-00

PREPARED BY

CHECKED BY

APPROVED BY