



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 L	B. No.: 1900146	
Generic Name : Ledipasvir and Sofosbuvir Tablets		
Batch size: 36551 Tablets	Sampling Date : 29/03/2016	Mfg. Date: 03/2016
Qty. Sampled: 28 Tablets	Analysis Date : 29/03/2016	Exp. Date: 02/2018
Sampled by: Bhargavi	Reporting Date: 31/03/2016	A.R. No.: FP/AR/109/16

S.No	TEST	SPECIFICATION	RESULT
1.	Description	Green coloured, oval shaped, film-coated tablets debossed with 'SL' on one side and plain on other side.	Complies
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.	Complies. Complies
3.	Uniformity of dosage units (By content uniformity)	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)	1.81 (Sofosbuvir) 4.55 (Ledipasvir)
4.	Average weight per tablet	1030.0 mg \pm 5.0 %	1041.04 mg
5.	Water content (by KF)	Not more than 5.0% w/w	1.7 %



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6.	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	Minimum = 98.4 % Maximum = 100.7 % Average = 99.8 %
	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Ledipasvir is dissolved in 45 minutes.	Minimum = 97.0 % Maximum = 99.7 % Average = 98.1 %
7.	Assay (By HPLC) Each film coated tablet contains Ledipasvir 90 mg	Not less than 95.0% and not more than 105.0% of the labeled amount of Ledipasvir.	97.0%
	Sofosbuvir 400 mg	Not less than 95.0% and not more than 105.0% of the labeled amount of Sofosbuvir.	100.16%
8.	Related impurities (By HPLC)		
	a) Sofosbuvir		
	Any individual impurity	Not more than 0.30 %	0.02%
	Total impurities	Not more than 1.0 %	0.10%
	b) Ledipasvir		
	Keto impurity	Not more than 0.8%	0.09%
	Any individual unspecified impurity	Not more than 0.20 %	0.09%
	Total impurities	Not more than 1.2 %	0.24%

Remarks: The product is complies as per Specification No. : FP/SPC/008-00

PREPARED BY

CHECKED BY

APPROVED BY

Page 2 of 2

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