



NATCO PHARMA LIMITED

Regd. Off: 'NATCO HOUSE', Road No. 2, Banjara Hills, Hyderabad-500 034,
Telangana, INDIA. Tel : +91 40 23547532, Fax : +91 40 23548243
CIN : L24230TG1981PLC003201, www.natcopharma.co.in

CERTIFICATE OF ANALYSIS (FINISHED PRODUCT (UNIT-9))

PRODUCT NAME:: Sofokast Tablets

Generic Name:	Sofosbuvir 400 mg Tablets	Product Code:	GSF51AZ
Batch No.:	1903128	LIMS A.R. No.:	1900FPG22000277
Batch Size:	93944 Tablets	Sampled By:	Saiful
Sampling Date:	29/08/2022	Sampling Quantity:	28 Tablets
Date Of Release:	30/08/2022 16:15	Mfg. Date:	08/2022
Specification No:	FP/SPC/004-01	Exp. Date:	07/2025

S. No.	TEST	RESULT	SPECIFICATION
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		
2.1	By HPLC	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 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.
2.2	By UV	The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelengths.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelengths.
3	Uniformity of dosage units (by weight variation)	1.40	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)
4	Average Weight per tablet	1237.89 mg	1236.0 mg $\pm$ 3.0 %
5	Water content (By KF)	1.81% w/w	Not more than 4.0% w/w
6	Dissolution (By UV)	Minimum:98.6% Maximum:100.8% Average:99.6%	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.
7	Assay (By HPLC) Each film	100.0%	Not less than 90.0% and not more than

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Checked By	badan.kalita	Checked On	30/08/2022 15:16
Approved By:	Pandalaneni.Murali Mohan Rao	Approved On	30/08/2022 15:42
Approved By:	Bidyut.Das	Approved On	30/08/2022 16:15
Printed by: Bidyut.Das		Printed on: 30/08/2022 16:15	
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	coated tablet contains 400 mg of Sofosbuvir.		110.0% of the labeled amount of Sofosbuvir.
8	Related impurities (By HPLC)		
8.1	Individual unknown impurity	0.01%	Not more than 0.5 %
8.2	Total impurities	0.05%	Not more than 2.0 %
9	Microbial Enumeration tests & test for specified microorganisms USP <61> & <62>		
9.1	Total aerobic microbial count	<10 cfu/g	Not more than 1000 cfu/g
9.2	Total combined molds and Yeasts	<10 cfu/g	Not more than 100 cfu/g
9.3	Escherichia coli	Absent/g	Should be Absent/g
9.4	Salmonella species	Absent/10g	Should be Absent/10 g
9.5	Staphylococcus aureus	Absent/g	Should be Absent/g
9.6	Pseudomonas aeruginosa	Absent/g	Should be Absent/g

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

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