



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 Plus Tablets

Generic Name:	Daclatasvir and Sofosbuvir Tablets, 60mg/400mg	Product Code:	GSD23AZ
Batch No.:	1903245	LIMS A.R. No.:	1900FPG22000482
Batch Size:	88796 Tablets	Sampled By:	Mriganka
Sampling Date:	27/12/2022	Sampling Quantity:	28 Tablets
Date Of Release:	28/12/2022 15:11	Mfg. Date:	11/2022
Specification No:	FP/SPC/010-01	Exp. Date:	10/2024

S. No.	TEST	RESULT	SPECIFICATION
1	Description	White colored, oval shaped, film-coated tablets, debossed with 'SD' on one side and '460' on another side.	White colored, oval shaped, film-coated tablets, debossed with 'SD' on one side and '460' on another 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 USP<905> (By content uniformity)	Sofosbuvir AV value:2.65 Daclatasvir AV value:2.37	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	1237.51 mg	1236.0 mg $\pm$ 5.0 %
5	Water content (%w/w, By KF) USP<921>	2.49 % w/w	Not more than 5.0% w/w
6	Dissolution (By HPLC) USP<711> Appartus-II		

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Checked By	RUSTAM.ALAM	Checked On	28/12/2022 09:33
Approved By:	Pandalaneni.Murali Mohan Rao	Approved On	28/12/2022 14:48
Approved By:	Bidyut.Das	Approved On	28/12/2022 15:11
Printed by: Bidyut.Das		Printed on: 28/12/2022 15:11	
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	(Paddle) Medium -0.01 N HCl, 900ml, RPM-75		
6.1	Sofosbuvir	Sofosbuvir Average:100.1% Sofosbuvir Minimum:98.2% Sofosbuvir Maximum:102.2%	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.
6.2	Daclatasvir	Daclatasvir Average:99.1% Daclatasvir Minimum:97.4% Daclatasvir Maximum:100.8%	Not less than 80% (Q) of the labeled amount of Daclatasvir is dissolved in 45 minutes.
7	Assay (By HPLC) Each film coated tablet contains Sofosbuvir 400 mg and Daclatasvir 60 mg		
7.1	Daclatasvir	Daclatasvir:99.4%	Not less than 95.0% and not more than 105.0% of the labeled amount of Daclatasvir.
7.2	Sofosbuvir	Sofosbuvir:101.3%	Not less than 95.0% and not more than 105.0% of the labeled amount of Sofosbuvir.
8	Related impurities (% w/w, By HPLC)		
8.1	a) Sofosbuvir		
8.1.1	Desphenyl impurity	0.02 %w/w	Not more than 0.2% w/w
8.1.2	Any individual unspecified	0.02 %w/w	Not more than 0.2% w/w

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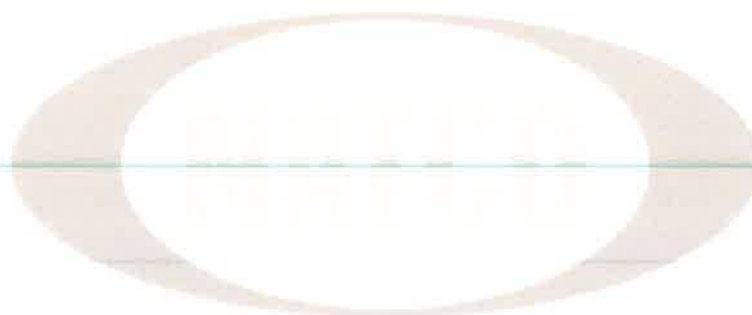
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	impurity		
8.1.3	Total impurities	0.06 %w/w	Not more than 2.0% w/w
8.2	b) Daclatasvir		
8.2.1	Any individual impurity	0.02 %w/w	Not more than 0.3% w/w
8.2.2	Total impurities	0.04 %w/w	Not more than 1.5% w/w



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