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

CERTIFICATE OF ANALYSIS

Product Name: Velakast Tablets		B.No. : 1901203
Generic Name : Sofosbuvir and Velpatasvir Tablets 400mg/100mg		Product Code : GVS23AZ
Batch size: 98,609 Tablets	Sampling Date: 13/05/2019	Mfg. Date: 04/2019
Qty. Sampled: 01 Container	Analysis Date: 13/05/2019	Exp. Date: 03/2021
Sampled by: Priyanka	Reporting Date: 13/05/2019	A.R. No.: FP/AR/179/19

S.No	TEST	SPECIFICATION	RESULT
1.	Description	Blue colored, oval shaped, film-coated tablets debossed with 'S' on one side and 'V' on other side.	Blue colored, oval shaped, film-coated tablets debossed with 'S' on one side and 'V' on other side.
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.	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.
	b) By UV	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelength.	The UV absorption spectrum of the sample solution and standard solution exhibits maxima at the same wavelength.
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)	L1 for Velpatasvir 2.21 L1 for Sofosbuvir 3.88

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	14/05/2019	14/05/2019	14/05/2019
Name	B N Patwari	Badan Kabita	Sanjay S Chandrain
Designation	Officer-QC	Asstt Manager	Sr Manager

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

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S.No	TEST	SPECIFICATION	RESULT
4.	Average weight	1030.0 mg ± 5.0 %	1035.29 mg
5.	Water content	Not more than 5.0% w/w	2.05 % w/w
6.	Dissolution (By HPLC)	Not less than 80% (Q) of the labeled amount of Velpatasvir is dissolved in 30 minutes.	Average = 99.5 % Minimum = 97.5 % Maximum =100.9 %
		Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.	Average = 100.9 % Minimum = 98.9 % Maximum = 102.3 %
7.	Assay (By HPLC) Each film coated tablet contains Sofosbuvir 400 mg	Not less than 95.0% and Not more than 105.0% of the labeled amount of Sofosbuvir.	102.4 %
	Velpatasvir 100 mg	Not less than 95.0% and Not more than 105.0% of the labeled amount of Velpatasvir.	100.3 %

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	14/05/2019	14/05/2019	14/05/2019
Name	B N Patwari	Badan Kabita	Sanjay S. Chandra
Designation	Officer - QC	Asstt Manager	Sr manager

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S.No	TEST	SPECIFICATION	RESULT
8.	Degradation Products (% w/w, By HPLC)		
	a) Sofosbuvir		
	Desphenyl impurity	Not more than 0.5	Below LOQ* (Limit:0.026)
	Any individual unspecified impurity	Not more than 0.2	0.02
	Total impurities	Not more than 1.0	0.05
	b) Velpatasvir		
	Methoxy methyl Pyrrolidine	Not more than 0.5	Not Detected
	Impurity- A	Not more than 0.5	0.06
	Impurity- E	Not more than 0.5	0.14
	Any individual unspecified impurity	Not more than 0.2	0.06
	Total impurities	Not more than 1.5	0.47

*LOQ = Limit of Quantification

Remarks: The product complies as per Specification No. : FP/SPC/014-02

	PREPARED BY	CHECKED BY	APPROVED BY
Sign	14/05/2019	14/05/2019	14/05/2019
Name	B N Patwari	Rachna Kashyap	Sanjay Srivastava
Designation	Officer-QC	Addl Manager	Sr manager

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