



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:: Velakast Tablets

Generic Name:	Sofosbuvir and Velpatasvir Tablets 400mg/100mg	Product Code:	GVS41AZ
Batch No.:	1903237	LIMS A.R. No.:	1900FPG22000476
Batch Size:	99258 Tablets	Sampled By:	Mozibul
Sampling Date:	21/12/2022	Sampling Quantity:	28 Tablets
Date Of Release:	22/12/2022 14:24	Mfg. Date:	11/2022
Specification No:	FP/SPC/014-02	Exp. Date:	10/2025

S. No.	TEST	RESULT	SPECIFICATION
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		
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 wavelength.	The UV absorption spectrum of the sample solution and standard solution shall exhibit maxima at the same wavelength.
3	Uniformity of dosage units (By content uniformity)	Sofosbuvir AV value: 1.33 Velpatasvir AV value: 1.58	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	1032.03 mg	1030.0 mg $\pm$ 5.0 %
5	Water content	3.25% w/w	Not more than 5.0% w/w
6	Dissolution (By HPLC)		
6.1	Velpatasvir	Velpatasvir minimum: 96.6% Velpatasvir maximum:	Not less than 80% (Q) of the labeled amount of Velpatasvir is dissolved in 30 minutes.

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

Checked By: badan.kalita Checked On: 22/12/2022 10:27

Approved By: Pandalaneni.Murali Mohan Rao Approved On: 22/12/2022 12:14

Approved By: Bidyut.Das Approved On: 22/12/2022 14:24

Printed by: Bidyut.Das Printed on: 22/12/2022 14:25

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		99.3% Velpatasvir average: 98.2%	
6.2	Sofosbuvir	Sofosbuvir minimum: 95.8% Sofosbuvir maximum: 98.0% Sofosbuvir average: 97.1%	Not less than 80% (Q) of the labeled amount of Sofosbuvir is dissolved in 30 minutes.
7	Assay (By HPLC)		
7.1	Each film coated tablet contains: Sofosbuvir 400 mg	100.6%	Not less than 95.0% and Not more than 105.0% of the labeled amount of Sofosbuvir
7.2	Velpatasvir 100 mg	101.2%	Not less than 95.0% and Not more than 105.0% of the labeled amount of Velpatasvir.
8	Degradation Products (%w/w, By HPLC)		
8.1	a) Sofosbuvir		
8.1.1	Desphenyl impurity	Below LOD (Limit:0.009%)	Not more than 0.5 % w/w
8.1.2	Any individual unspecified impurity	0.02% w/w	Not more than 0.2 % w/w
8.1.3	Total impurities	0.03% w/w	Not more than 1.0 % w/w
8.2	b) Velpatasvir		
8.2.1	Methoxy methyl Pyrrolidine	Below LOD (Limit:0.017%)	Not more than 0.5% w/w
8.2.2	Impurity- A	0.04% w/w	Not more than 0.5% w/w
8.2.3	Impurity- E	0.06% w/w	Not more than 0.5% w/w
8.2.4	Any individual unspecified	0.07% w/w	Not more than 0.2% w/w

Remarks: APPROVED (Sample Conforms to above Specification)

Comment(s): Approved

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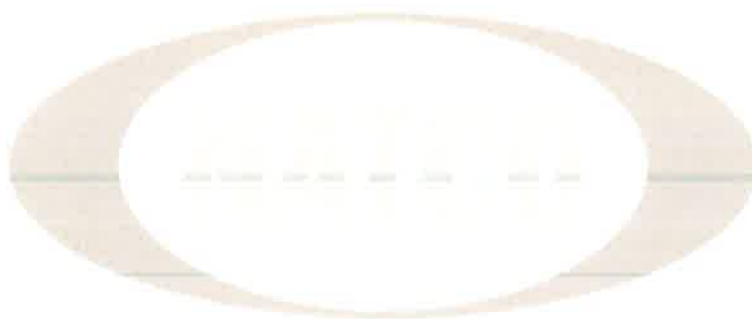
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8.2.5	impurity Total impurities	0.39% w/w	Not more than 1.5% w/w
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