

**CERTIFICATE OF ANALYSIS : FINISHED PRODUCT**
**STRIDES SHASUN LIMITED , ODF, Bangalore**

<b>Product Name</b> : VIRSO	
<b>Generic Name</b> : Sofosbuvir Tablets 400mg	
Batch No. : 7228521	A.R. No. / Date : 40000120284 / 23-Oct-2016
Batch Size : 120000 Nos	Sample No. : 399436
Mfg. Date : 10-2016	Product Code : 3007429
Exp. Date : 07-2018	Specification No. : 2004633/PRS/R2
Customer : DOMESTIC	Page 1 of 3

Tests	Specifications	Results
Appearance	Blue colored, capsule shaped, biconvex bevel edged film coated tablets debossed with "400" on one side and plain on other side	Blue colored, capsule shaped, biconvex bevel edged film coated tablets debossed with "400" on one side and plain on other side
Identification A	By HPLC: The retention time of the major peak in the chromatogram of the sample preparation should correspond to those in the chromatogram of the standard preparation, as obtained in Assay	Complies
Identification B	By UV absorption: The UV spectrum of sample should be consistent with that of the standard spectrum	Complies
Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5.0\%$ and none deviates by more than $\pm 10.0\%$	Lowest deviation: $-0.7\%$ & Highest deviation: $0.7\%$
Water by KF	Not more than $3.5\%$ w/w	$1.36\%$ w/w
Dissolution	Not less than $80.0\%$ (Q) of labeled amount of Sofosbuvir should dissolve in 15 minutes	94.1%, 94.9%, 94.9%, 95.5%, 93.4%, 92.2%, Avg. : $94.1\%$
Impurity by HPLC		

GQC/024/F-06/R1

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**WORKS** : 'KRS Gardens', Surajajakkanahalli, Indlawadi Cross, Anekal Taluk, Bangalore South - 562 106.

**CORP. OFF. :** 'STRIDES HOUSE', Bilekahalli, Bannerghatta Road, Bangalore - 560 076. India. Tel.: 91-80-67840000. Fax: 91-80-67840700 / 800. E-mail: info@stridesarco.com. www.stridesarco.com

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Tests	Specifications	Results
i) GS-606965	Not more than 0.30 %	BDL [ LOD = 0.028% ]
ii) GS-331007	Not more than 0.30 %	BDL [ LOD = 0.009% ]
iii) GS-566500	Not more than 0.30 %	BDL [ LOD = 0.016% ]
iv) GS-607669	Not more than 0.30 %	BDL [ LOD = 0.009% ]
v) GS-607670	Not more than 0.30 %	BDL [ LOD = 0.012% ]
vi) Phenol	Not more than 0.30 %	BDL [ LOD = 0.024% ]
vii) Any unspecified degradation product	Not more than 0.20 %	BQL [ LOQ = 0.060% ]

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Tests	Specifications	Results
viii) Total degradation product	Not more than 0.6 %	BQL
Uniformity of dosage units by weight variation	The acceptance value of 10 dosage units should be less than or equal to L1 [L1 is 15.0]	L1: 2.1
Assay by HPLC	Each film coated tablet contains: Sofosbuvir Label claim - Limits	
Assay in %	400.0 mg - 95.0 % to 105.0 % of label claim	102.4 %
Assay in mg	400.0 mg - 380.0 mg to 420.0 mg	409.6 mg

**Conclusion:** The sample complies with above standards as per IH Specifications

**Remarks :** Microbial limit test shall be performed on every 10th batch. Average weight of tablet is 1.240g.

<b>Checked by</b> : Ravindra K.V	<b>Approved by</b> : B.Sivakumar
<b>Designation</b> : Sr. Team Leader - QA	<b>Designation</b> : Team Leader - QA
<b>Date</b> : 29-Oct-2016	<b>Date</b> : 29-Oct-2016

**Note :** This document is produced electronically and is valid without handwritten signature

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