Strides Shasun

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

Product Name : Qurled			
Generic Name : Sofosbuvir Tablets 400mg			
Batch No.	: 7233151	A.R. No. / Date	: 40000193767 / 31-May-2018
Batch Size	: 120000 Nos	Sample No.	: 574701
Mfg. Date	: 05-2018	Product Code	: 3009516
Exp. Date	: 04-2020	Specification No.	: 2004633/PRS/R2
Customer	: STRIDES SHASUN LTD Institution-Domestic		

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 ± 5.0 % and none deviates by more than ± 10.0 %	Lowest deviation: -1.0 % & Highest deviation: 1.5%
Water by KF	Not more than 3.5 % w/w	1.74 % w/w
Dissolution	Not less than 80.0 % (Q) of labeled amount of Sofosbuvir should dissolve in 15 minutes	96.3%, 94.9%, 95.3%, 97.8%, 96.5%, 97.0%, Avg. : 96.3%

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WORKS : 'KRS Gardens", Suragajakkanahalli, 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

REGD. OFF. : 201, Devavrata, Sector 17, Vashi, Navi Mumbai - 400 703. India. Tel: 91-22-27892924 / 968 / 27893199. Fax: 91-22-27892942

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Tests	Specifications	Results
Impurity by HPLC		
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%]
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: 1.6
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	99.9 %
Assay in mg	400.0 mg - 380.0 mg to 420.0 mg	399.6 mg

GQC/024/F-06/R2

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Tests	Specifications	Results

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

Remarks : Microbial limit test shall be performed on every 10th batch.

Checked by : Ravindra K.V	**Approved by** : B.Sivakumar
Designation : Sr. Team Leader - QA	**Designation** : Sr.Team Leader - QA
Date : 31-May-2018	**Date** : 31-May-2018

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