

Certificate of Analysis

Product Name : VIRSO	A.R. No./Date : 40000114029 / 06-SEP-2017
Generic Name : Sofosbuvir Tablets 400mg	Sample No. : 387523
Batch No : 7230922	Product Code : 307429
Batch Size : 120 000 Nos	Specification No. : 2004723/PRS/R1
Mfg. Date : 09-2017	
Exp. Date : 08-2019	

Sr. No.	Test	Specifications	Results
1	Appearance	Blue colored, capsule shaped, biconvex bevel edged film coated tablets debossed with "400" on the side and plain on other side	Blue colored, capsule shaped, biconvex bevel edged film coated tablets debossed with "400" on the side and plain on other side
2	Identification A	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.	Complies
3	Identification B	By UV absorption: The UV spectrum of the sample should be consistent with that of the standard spectrum	Complies
4	Uniformity of weight	Not more than 2 of the individual masses deviate from the average mass by more than $\pm 5\%$ and none deviates by more than $\pm 10\%$	Lowest deviation: -1.8 % & Highest deviation: 2.4 %
5	Water by KF	Not more than 3.5 % w/w	1.58 % w/w
6	Dissolution	Not less than 80% (Q) of the labeled amount of Sofosbuvir should dissolve in 15 minutes.	98.3 %, 99.7%, 95.3%, 96.7%, 95.5%, 97.6%, Avg.: 97.2%
7	Impurity by HPLC	Not more than 0.3 %	BDL [LOD = 0.028%]
8	Assay	Sofosbuvir 90.0% to 110.0% of the labeled claim	99.95% of the labeled claim
9	Microbial Limit Test	Total Aerobic count ≤ 2000 cfu/g	Under Observation
10	Microbial Limit Test	Total Fungal count ≤ 200 cfu/g	Under Observation
11	Microbial Limit Test	E.Coli: Should be absent per g	Under Observation

GQC/024/F-06/R0

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Page No: 1 of 1

Prepared by:



Reviewed by:



Approved:

