

**Quality Control Department
Certificate of Analysis**

Material No : 5022606
Material Description:
SOVIHEP TABLET- SALE-1X28T
SOFOSBUVIR TABLETS

Batch No. : S705636

Inspection Lot No : 040000786231
Date of Manufacture : DEC 2017
Date of Expiry : NOV 2019
Specification No : QC/SPC/F/6961-00

SFG Batch No : S705635
Batch Quantity : 5,272,000 PAC
Usage Decision Date : 26.12.2017

Sr.No.	Test	Specifications	Results
1	Description	Brick red colored, capsule shaped, biconvex, film coated tablets, debossed with 'Z' on one side and '400' on other side.	Brick red colored, capsule shaped, biconvex, film coated tablets, debossed with 'Z' on one side and '400' on other side.
2	Identification	The retention time of the major peak in the chromatogram of the sample preparation corresponds to that of the standard preparation obtained as directed in the essay.	Complies
3	Uniformity of weight	Not more than 2 tablets out of 20 tablets should deviate from the average weight by more than 5% and none should deviate by more than 10%.	+6.0% & -4.8%
4	Dissolution	Not less than 70%(D) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	97.6% (Min. 96.4% & Max. 98.6%)
5	Related substances	Unidentified degradant ≤0.5%	0.09%
6	Related substances	Total Degradants ≤2.0%	0.09%
7	Assay	Sofosbuvir 360.00 to 440.00mg/tablet	393.050mg/tablet
8	Assay	Sofosbuvir 90.0 to 110.0% of the labeled claim	98.30% of labeled claim
9	Microbial limit test	Total Aerobic count ≤2000cfu/g	20 cfu/g
10	Microbial limit test	Total Fungal count ≤200cfu/g	Less than 10 cfu/g
11	Microbial limit test	E.Coli : Should be absent per g	Absent.

Remarks:

Evaluation:

The batch complies with the above specifications and accepted.

Prepared By

Checked By

Approved By

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