

Quality Control Department  
Certificate of Analysis

Bhaghey Khola,  
N.H. No. 10, Majhitar, Rangpo,  
East Sikkim - 737 136, India.  
Phone : 8016099901, 9733101465  
CIN : U51900GJ1889PLC079501

Product Code: 5022606  
Product Description:  
SOVIHEP TABLET - SALE - 1X28T  
SOFOSBUVIR TABLETS

Batch No. S701022

Inspection lot No: 040000669927  
Date of Manufacture: FEB 2017  
Date of Expiry: JAN 2019  
Specification No: QC/SPC/F-6961-00

SFG Batch No: S700535  
Batch Quantity: 5,243.000 PAC  
Usage Decision date: 21.02.2017

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 assay	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%	+5.1% & -6.9%
4	Dissolution	Not less 70% (D) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	101.7% (Min. 100.5% & Max. 103.2%)
5	Related Substances	Unidentified degradant <=0.5%	Below Disregard Limit
6	Related Substances	Total degradants <=2.0%	Below Disregard Limit
7	Assay	Sofosbuvir 360.00 to 440.00mg/tablet	399.800mg/tablet
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

Prepared By 

Checked By 

Approved By 

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Remarks:

Evaluation:

The Batch complies with the above specifications and accepted.

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