

Bhaghey Khola,  
N.H. No. 10, Majhitar, Rangpo,  
East Sikkim - 737 136, India.  
Phone : 8016099901, 9733101465  
CIN : U51900GJ1989PLC079501

**Quality Control Department  
Certificate of Analysis**

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

Batch No. : S604502

Inspection Lot No : 040000669927  
Date of Manufacture: OCT 2016  
Date of Expiry : SEP 2018  
Specification No : QC/SPC/F/6961-00

SFG Batch No. : S604501  
Batch Quantity : 5,243.000 PAC  
Usage Decision Date: 21.10.2016

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 than 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 ≤2000cfu/g	Under Observation
10	Microbial limit Test	Total Fungal count ≤200cfu/g	Under Observation
11	Microbial limit Test	E.Coli : Should be absent per g	Under Observation

Prepared By

*[Signature]*  
21/10/16

Checked By

*[Signature]*  
21/10/16

Approved By

*[Signature]*  
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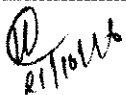
SFG Batch No. : S604501  
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Remarks:

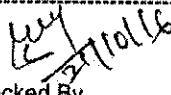
Evaluation:

The batch complies with the above specifications and accepted.

Prepared By



Checked By



Approved By

