

Quality Control Department
Certificate of Analysis

Bhaghey Khola,
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Material No : 3012019

Batch No. : ZHS1398

Material Description:

SOVIHEP

SOFOSBUVIR TABLETS 400 MG

Inspection Lot No : 040000610937

Sample Quantity : 68.000 NOS

Date of Manufacture: FEB 2016

Batch Quantity : 145,913 NOS

Date of Expiry : JAN 2018

Usage Decision Date: 22.02.2016

Specification No : QC/SPC/F/6961-00

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%.	+1.4% & -2.3%
4	Dissolution	Not less than 70% (D) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	99.1% (Min. 98.8% & Max. 99.4%)
5	Related substances	Unidentified degradant <=0.5%	0.14%
6	Related substances	Total Degradants <=2.0%	0.1%
7	Assay	Sofosbuvir 360.00 to 440.00mg /tablet	395.000mg /tablet
8	Assay	Sofosbuvir 90.0 to 110.0% of the labeled claim	98.75% of the labeled claim
9	Microbial limit Test	Total Aerobic count <=2000cfu/g	20.0cfu/g
10	Microbial limit Test	Total Fungal count <=200cfu/g	Less than 10cfu/g
11	Microbial limit Test	E.Coli : Should be absent per g	Absent

Prepared By

[Signature]
22/02/16

Checked By

[Signature]
22/02/16

Approved By

[Signature]
22/02/16

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Remarks:

Evaluation:

The batch complies with the above specifications and accepted.

Prepared By *[Signature]* 22/02/16

Checked By *[Signature]* 22/02/16

Approved By *[Signature]* 22/02/16