

Quality Control Department
Certificate of Analysis

Bhaghey Khola,
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Material No : 3012019
Material Description:
SOVIHEP
SOFOSBUVIR TABLETS 400 MG

Batch No. : ZHS1222

Inspection Lot No : 040000608927
Date of Manufacture : JAN 2016
Date of Expiry : DEC 2017
Specification No : QC/SPC/F/6961-00

Sample Quantity : 60.000 NOS
Batch Quantity : 143,471 NOS
Usage Decision Date: 12.02.2016

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%.	+3.8% & -2.4%
4	Dissolution	Not less than 70% (D) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	96.9% (Min. 95.8% & Max. 97.6%)
5	Related substances	Unidentified degradant ≤ 0.5%	0.116%
6	Related substances	Total Degradants ≤ 2.0%	0.258%
7	Assay	Sofosbuvir 360.00 to 440.00mg /tablet	401.505mg /tablet
8	Assay	Sofosbuvir 90.0 to 110.0% of labeled claim	100.40% of labeled claim
9	Microbial Limit Test	Total Aerobic count ≤ 2000cfu/g	30cfu/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

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Remarks:

Evaluation:

The batch complies with the above specifications and accepted.

Prepared By

Shree Singh
12/02/16

Checked By

12/02/16

Approved By

M. Singh
12/02/16

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