

**Quality Control Department
Certificate of Analysis**

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

Batch No. : S800539

Inspection Lot No : 040000800926
Date of Manufacture: FEB 2018
Date of Expiry : JAN 2020
Specification No : QC/SPC/F/6961-00

SFG Batch No. : S800538
Batch Quantity : 5,286.000 PAC
Usage Decision Date: 12.02.2018

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%.	+1.9% & -2.9%
4	Dissolution	Not less than 70% (D) of the labeled amount of Sofosbuvir is dissolved in 45 minutes.	98.2%(Min. 95.2% & Max. 100.6%)
5	Related substances	Unidentified degradant <=0.5%	Below LOQ
6	Related substances	Total Degradants <=2.0%	Below LOQ
7	Assay	Sofosbuvir 360.00 to 440.00mg /tablet	404.800mg /tablet
8	Assay	Sofosbuvir 90.0 to 110.0% of the labeled claim	101.20% 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]* 12/02/18

Checked By *[Signature]* 12/02/18

Approved By *[Signature]* 12/02/18

Plant Address : Unit-1 : Bhaghey Khola, N.H.No. 10, Majhitar, Rangpo, East Sikkim - 737 136, India. Phone : 8016099901 / 9733104465
Unit-2 : Kamarey Bhasmay, Duga Circle, Rorathang Road, Kumrek, Rangpo, East Sikkim 737132

Regd. Office : 'Zydus Tower', Satellite Cross Road, Ahmedabad - 380015, India.
Phone : +91-79-2686 8100 (20 Lines) Fax : +91-79-2686 2365 www.zyduscadila.com CIN : U51900GJ1989PLC079501

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Remarks:

Evaluation:

The batch complies with the above specifications and accepted.

Prepared By

12/02/18

Checked By

12/02/18

Approved By

12/02/18

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