

Quality Control Department
Certificate of Analysis

Product Code : 5028873
Product Description :
DACIHEP 60 MG TABLETS 28 TABLETS SALE DOMESTIC
DACLATASVIR DIHYDROCHLORIDE TABLETS

Batch No. : S704928

Inspection Lot No : 040000772680
Date of Manufacture: OCT 2017
Date of Expiry : SEP 2019
Specification No : QC/SPC/F/7609-00

SFG Batch No. : S704927
Batch Quantity : 10,037.000 PAC
Usage Decision Date: 11.11.2017

Remarks:

Evaluation:

The batch complies with the above specifications and accepted.

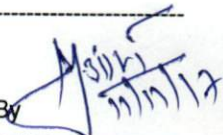
Prepared By



Checked By



Approved By



Plant Address : Unit-1 : Bhaghey Khola, N.H.No. 10, Majhitar, Rangpo, East Sikkim - 737 136, India. Phone : 8016099901 / 9733101465
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Sr.No.	Test	Specifications	Results
1	Description	Orange, round, biconvex, film coated tablets debossed with '60' on one side and 'D' on other side.	Orange, round, biconvex, film coated tablets debossed with '60' on one side and 'D' on other side.
2	Identification	In the Assay, the principal peak in the chromatogram obtained with the sample solution corresponds to the principal peak in the chromatogram obtained with the standard solution.	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%.	+1.7% & -1.4%
4	Dissolution	Not less than 70% (D) of the stated amount of Daclatasvir is dissolved in 30 minutes.	98.0% (Min. 97.1% & Max. 98.5%)
5	Related substances	Unidentified degradant ≤0.5%	LOQ
6	Related substances	Total degradants ≤2.0%	LOQ
7	Assay	Daclatasvir Dihydrochloride 57.0 to 63.0mg	59.29mg
8	Assay	Daclatasvir Dihydrochloride 95.0 to 105.0%	98.80%
9	Microbial enumeration test and test for	Total Aerobic Count ≤2000cfu/g	25.0cfu/g
10	Microbial enumeration test and test for	Total Fungai ≤200cfu/g	Less than 10cfu/g
11	Microbial enumeration test and test for	E. Coli : Should be absent in g.	Absent

Prepared By *B. Mittal*

Checked By *B. Mittal*

Approved By *M. Mittal*