



# HETERO LABS LIMITED (UNIT-II)

## (Formulations Division)

### CERTIFICATE OF ANALYSIS

Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg)			
Product Code	4013090	A.R. No.	H5FP16003207
Specification ID	FPS/B-3006904-1-01	Batch No.	31172103
Mfg. Date	11/2018	Batch Size	2.0 Lac.
Exp. Date	10/2020	Date Of Release	20/11/2018

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Light yellow round bevel edged biconvex film coated tablets debossed with 'H' on one side and 'D19' on the other side.	Light yellow round bevel edged biconvex film coated tablets debossed with 'H' on one side and 'D19' on the other side.
2	Identification (By HPLC)	The retention time of the major peak in the chromatogram of the sample solution corresponds to that in the chromatogram of the standard solution, as obtained in the assay.	The retention time of the major peak in the chromatogram of the sample solution should corresponds to that in the chromatogram of the standard solution, as obtained in the assay.
3	Average weight	313.36 mg	309.00mg $\pm$ 3% (299.73mg to 318.27mg)
4	Uniformity of weight	Highest : 1.92 % Lowest:-1.67 %	$\pm$ 5% of Average weight
5	Water content (By KF)	2.51 %w/w	Not more than 5.0 %w/w
6	Dissolution (By UV)	Tablet 1- : 98.2 % Tablet 2- : 98.2 % Tablet 3- : 97.7 % Tablet 4- : 98.9 % Tablet 5- : 99.5 % Tablet 6- : 98.8 % Average::98.6 %	Not less than 75 % (D) of the labeled amount of Daclatasvir is dissolve in 45minutes.
7	Related Substances (By HPLC)		
7.1	Max single Impurity	0.10 %	Not more than 0.50 %
7.2	Total Impurities	0.28 %	Not more than 2.00 %
8	Assay (By HPLC) Each Film coated tablet contains Daclatasvir dihydrochloride eq. to Daclatasvir (%)	99.7 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Ramanuj.Mishra	Approved By	D.S.N.Reddy
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