



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg)			
Product Code	4013090	A.R. No.	H5FP19000357
Specification ID	FPS/B-3006904-1-02	Batch No.	31172195
Mfg. Date	01/2019	Batch Size	2.0 Lac.
Exp. Date	12/2020	Date Of Release	25-01-2019

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	311.65 mg	309.00mg \pm 3% (299.73mg to 318.27mg)
4	Uniformity of weight	Highest : 1.02 % Lowest:-1.35 %	\pm 5% of Average weight
5	Water content (By KF)	2.77 %w/w	Not more than 5.0 %w/w
6	Dissolution (By UV)	Tablet 1- : 97.4 % Tablet 2- : 98.1 % Tablet 3- : 97.4 % Tablet 4- : 96.5 % Tablet 5- : 97.2 % Tablet 6- : 97.7 % Average::97.4 %	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	0.08 %	Not more than 0.50 %
7.2	Total Impurities	0.26 %	Not more than 2.00 %
8	Assay (By HPLC) Each Film coated tablet contains Daclatasvir dihydrochloride IP eq. to	99.2 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Rameshvar.Dhakedey	Approved By	D.S.N.Reddy
Date	25-01-2019 17:02	Date	25-01-2019 17:03
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	Daclatasvir (%) Labeled amount		

Remarks: APPROVED (Sample Conforms to above Specification)			
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