



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: HEPCFIX 60 (Daclatasvir Tablets 60mg)			
Product Code	4013167	A.R. No.	H5FP18001821
Specification ID	FPS/B-3006904-1-01	Batch No.	HPM80405
Mfg. Date	04/2018	Batch Size	0.51 Lac.
Exp. Date	03/2020	Date Of Release	24-04-2018

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	313.65 mg	309.00mg \pm 3% (299.73mg to 318.27mg)
4	Uniformity of weight	Highest : 3.34 % Lowest:-1.93 %	\pm 5% of Average weight
5	Water content (By KF)	2.47 %w/w	Not more than 5.0 %w/w
6	Dissolution (By UV)	Tablet 1- : 99.2 % Tablet 2- : 101.1 % Tablet 3- : 98.9 % Tablet 4- : 98.1 % Tablet 5- : 100.5 % Tablet 6- : 99.4 % Average::99.5 %	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	0.25 %	Not more than 2.00 %
8	Assay (By HPLC) Each Film coated tablet contains Daclatasvir dihydrochloride eq. to	98.7 %	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	24-04-2018 12:17	Date	24-04-2018 12:18
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	Daclatasvir (%) Labeled amount		
9	Thickness	4.66 mm	4.30 mm-5.10 mm
10	Hardness	11.1 Kp	Not Less than 4.00 Kp and Not more than 22.0 Kp
11	Disintegration Time	Time : 8 Minutes 46 Seconds	Not more than 15 minutes.

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Rameshvar.Dhakedey	Approved By	D.S.N.Reddy
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