



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: HEPCFIX 60 (Daclatasvir Tablets 60mg)			
Product Code	4013167	A.R. No.	H5FP18000939
Specification ID	FPS/B-3006904-1-01	Batch No.	HPM80506
Mfg. Date	05/2018	Batch Size	1.3 Lac.
Exp. Date	04/2020	Date Of Release	13/05/2018

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	311.93 mg	309.00mg \pm 3% (299.73mg to 318.27mg)
4	Uniformity of weight	Highest : 1.53 % Lowest:-2.23 %	\pm 5% of Average weight
5	Water content (By KF)	2.94 %w/w	Not more than 5.0 %w/w
6	Dissolution (By UV)	Tablet 1- : 99.4 % Tablet 2- : 98.7 % Tablet 3- : 98.5 % Tablet 4- : 96.4 % Tablet 5- : 96.4 % Tablet 6- : 94.2 % Average:97.3 %	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	0.12 %	Not more than 0.50 %
7.2	Total Impurities	0.15 %	Not more than 2.00 %
8	Assay (By HPLC) Each Film coated tablet contains Daclatasvir dihydrochloride eq. to	99.4 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Nisha.Chandel	Approved By	D.S.N.Reddy
Date	13/05/2018	Date	13/05/2018
Printed by: D.S.N.Reddy		Printed on:13/05/2018	
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	Daclatasvir (%) Labeled amount		
9	Thickness	4.57 mm	4.30 mm-5.10 mm
10	Hardness	8.8 Kp	Not Less than 4.00 Kp and Not more than 22.0 Kp
11	Disintegration Time	Time : 8 Minutes 25 Seconds	Not more than 15 minutes.
12	Microbial Limits		
12.1	Total viable aerobic count		
12.1.1	Total aerobic microbial count	Less than 10 cfu/g	Not more than 1000 cfu per g.
12.1.2	Total molds and yeast count	Less than 10 cfu/g	Not more than 100 cfu per g.
12.2	Test for specified micro organisms		
12.2.1	Bile-Tolerant Gram Negative bacteria	Absent in 1g	Absent in 1g
12.2.2	Escherichia coli	Absent in 1g	Absent in 1g
12.2.3	Salmonella Species	Absent in 10g	Absent in 10g
12.2.4	Staphylococcus aureus	Absent in 1g	Absent in 1g
12.2.5	Pseudomonas aeruginosa	Absent in 1g	Absent in 1g

Remarks: APPROVED (Sample Conforms to above Specification)

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