



# HETERO LABS LIMITED (UNIT-II)

## (Formulations Division)

### CERTIFICATE OF ANALYSIS

<b>Product Name: HEPCFIX 60 (Daclatasvir Tablets 60mg)</b>			
<b>Product Code</b>	4013167	<b>A.R.No.</b>	H5FP17003025
<b>Specification No.</b>	FPS/B-3006904-1-01	<b>Batch No.</b>	HPM71104
<b>Mfg. Date</b>	NOV.2017	<b>Batch Size</b>	2.0 Lac
<b>Exp. Date</b>	OCT.2019	<b>Pack Size/Type</b>	Container

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 corresponds to that in the chromatogram of the standard solution, as obtained in the assay.
3	Average weight	311.90 mg	309.00mg±3.0% (299.73mg to 318.27mg)
4	Uniformity of Weight	-1.41% to 1.08%	±5.0% of Average Weight
5	Water content (by KF)	3.21 % w/w	Not more than 5.0% w/w
6	Dissolution (%w/w, By UV)	Tablet 1 - 99.5% Tablet 2 - 99.9% Tablet 3 - 97.8% Tablet 4 - 99.7% Tablet 5 - 99.9% Tablet 6 - 100.2 % Average - 99.6%	Not less than 75% (D) of the labeled amount of Daclatasvir are dissolved in 45 minutes.
7	Related Substances (by HPLC)		
7.1	Max single Impurity	0.13 %	Not more than 0.50%
7.2	Total Impurities	0.18 %	Not more than 2.0%
8	Assay (By HPLC) Each film coated tablet contains Daclatasvir digydrochloride eg. to Daclatasvir	100.9 %	Not less than 95% and not more than 105%
9	Thickness	4.77mm	4.30mm - 5.10mm
10	Hardness	9.3Kp	Not less than 4.00Kp and not more 22.00Kp
11*	Total Impurities	0.18 %	Not more than 2.0%

Remark: The product Complies as per above specification.

\*Test is included as per Customer requirement

Checked By	J.Sudhakar Reddy	Approved By	D.S.N. Reddy.
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