



# HETERO LABS LIMITED (UNIT-II)

## (Formulations Division)

### CERTIFICATE OF ANALYSIS

<b>Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg)</b>			
<b>Product Code</b>	4013090	<b>A.R. No.</b>	H5FP19004245
<b>Specification ID</b>	FPS/B-3006904-1-02	<b>Batch No.</b>	31172804
<b>Mfg. Date</b>	09/2019	<b>Batch Size</b>	200000 Tablets
<b>Exp. Date</b>	08/2021	<b>Date Of Release</b>	18-10-2019

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	311.11 mg	309.00mg $\pm$ 3% (299.73mg to 318.27mg)
4	Uniformity of weight	Highest : 0.82 % Lowest::-0.68 %	$\pm$ 5% of Average weight
5	Water content (By KF)	2.75 %w/w	Not more than 5.0 %w/w
6	Dissolution (By UV)	Tablet 1- : 102.3 % Tablet 2- : 101.9 % Tablet 3- : 99.9 % Tablet 4- : 100.1 % Tablet 5- : 99.5 % Tablet 6- : 100.3 % Average::100.7 %	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	0.15 %	Not more than 0.50 %
7.2	Total Impurities	0.21 %	Not more than 2.00 %
8	Assay (By HPLC) Each Film coated tablet contains Daclatasvir dihydrochloride IP eq. to Daclatasvir (%) Labeled	99.9 %	Not less than 95.0% and Not more than 105.0%

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By	Anand.Singh	Approved By	D.S.N.Reddy
Date	18-10-2019 17:52	Date	18-10-2019 17:53
Printed by: D.S.N.Reddy		Printed on: 18-10-2019 17:55	
Copy No.: 1		Page No.: 1 of 2	
<b>Note : This document has been generated electronically and is valid without signature.</b>			
CNo: C100004424			

