HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg)			
Product Code	4013090	**A.R. No.**	H5FP17004791
Specification ID	FPS/B-3006904-1-01	**Batch No.**	31171132
Mfg. Date	10/2017	**Batch Size**	1.72 Lac.
Exp. Date	09/2019	**Date Of Release**	31-10-2017

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**	313.37 mg	309.00mg ± 3% (299.73mg to 318.27mg)
4	**Uniformity of weight**	Highest : 1.25 % Lowest::-2.38 %	±5% of Average weight
5	**Water content (By KF)**	2.92 %w/w	Not more than 5.0 %w/w
6	**Dissolution (By UV)**	Tablet 1- : 100.8 % Tablet 2- : 101.2 % Tablet 3- : 101.2 % Tablet 4- : 101.9 % Tablet 5- : 99.9 % Tablet 6- : 100.4 % Average::100.9 %	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**	0.15 %	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	31-10-2017 16:54	Date	31-10-2017 16:55
Printed by: D.S.N.Reddy		**Printed on: 31-10-2017 16:55**	
Copy No.: 1		**Page No.: 1 of 2**	
Note : This document has been generated electronically and is valid without signature.			
CNo: C8005081			

Office : 7-2-A/2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad-18, INDIA. Tel : 040-23704923/24/25, Fax : 040-23704926
Factory : Village : Kalyanpur, Chakkan Road, BADDI, Tehsil : Baddi, Distt. Solan, H.P. - 173 205 INDIA.

HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg)			
Product Code	4013090	**A.R. No.**	H5FP17004791
Specification ID	FPS/B-3006904-1-01	**Batch No.**	31171132
Mfg. Date	10/2017	**Batch Size**	1.72 Lac.
Exp. Date	09/2019	**Date Of Release**	31-10-2017

	Daclatasvir (%) Labeled amount		

Remarks: APPROVED (Sample Conforms to above Specification)			
Checked By	Nisha.Chandel	Approved By	D.S.N.Reddy
Date	31-10-2017 16:54	Date	31-10-2017 16:55
Printed by: D.S.N.Reddy		**Printed on: 31-10-2017 16:55**	
Copy No.: 1		**Page No.: 2 of 2**	
Note : This document has been generated electronically and is valid without signature.			
CNo: C8005081			

Office : 7-2-A/2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad-18, INDIA. Tel : 040-23704923/24/25, Fax : 040-23704926
Factory : Village : Kalyanpur, Chakkan Road, BADDI, Tehsil : Baddi, Distt. Solan, H.P. - 173 205 INDIA.