HETERO LABS LIMITED (UNIT-II)
(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg)			
Product Code	4013090	**A.R.No.**	H5FP16003682
Specification ID	FPS/B-3006904-1-01	**Batch No.**	31171546
Mfg. Date	APR.2018	**Batch Size**	2.0 Lac
Exp. Date	MAR.2020	**Date Of Release**	06-04-2018

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 corresponds to that in the chromatogram of the standard solution, as obtained in the assay.
3	Average weight	311.24 mg	309.00mg±3.0% (299.73mg to 318.27mg)
4	Uniformity of Weight	Highest: 1.72% Lowest: -1.29%	±5.0% of Average Weight
5	Water content (by KF)	3.02 % w/w	Not more than 5.0% w/w
6	Dissolution (%w/w, By UV)	Tablet 1 - 99.8% Tablet 2 - 100.4% Tablet 3 - 101.2% Tablet 4 - 98.7% Tablet 5 - 100.9% Tablet 6 - 101.1 % Average - 100.4%	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	0.06 %	Not more than 0.50%
7.2	Total Impurities	0.25 %	Not more than 2.0%
8	Assay (By HPLC) Each film coated tablet contains Daclatasvir digydrochloride eg. to Daclatasvir (%)	101.7 %	Not less than 95% and not more than 105%

Remarks: APPROVED (Sample Conforms to above Specifications)

Checked By	Ramanuj.Mishra	Approved By	D.S.N. Reddy.
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Office: 7-2-2A, 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