HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

Product Name	DACLAHEP 60 (Daclatasvir Tablets 60mg)		
Product Code	4013090	A.R No.	H5FP18001740
Batch No.	31171630	Batch Size	0.749 Lac.
Mfg.Date	May-2018	Pack size/Type	Container
Exp.Date	APR-2020	Specification No.	FPS/B-3006904-1-01

S.No	TEST	SPECIFICATION	RESULT
1.0	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.
2.0*	Identification (By HPLC)	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.	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.
3.0	Average weight	309.00mg ± 3% (299.73mg to 318.27mg)	309.63 mg
4.0*	Uniformity of weight	± 5% of Average Weight	-1.00 % to 0.97 %
5.0*	Water content (By KF)	Not more than 5.0% w/w	2.07 % w/w
6.0*	Dissolution (By UV)	Not less than 75 % (D) of the labeled amount of Daclatasvir is dissolve in 45minutes.	Tablet 1 : 99.7 % Tablet 2 : 100.3 % Tablet 3 : 101.9 % Tablet 4 : 101.4 % Tablet 5 : 100.6 % Tablet 6 : 101.2 % Average: 100.9 %
7.0	Related Substances (By HPLC)		
7.1	Max single Impurity	Not more than 0.50 %	0.09 %
7.2	Total Impurities	Not more than 2.00 %	0.21 %
8.0*	Assay (By HPLC) Each Film coated tablet contains: Daclatasvir dihydrochloride eq. to Daclatasvir (%) Labeled amount	Not less than 95.0% and Not more than 105.0%	99.3 %

Remark: The product Complies as per above specification.

"*"These results are taken from A.R.No. H5FP18001409.

	Prepared by	Checked by	Approved by
Name	Dimple Raj	J.Sudhakar Reddy	D.S.N. Reddy
Designation	Executive – Q.C.	Dy.Manager – Q.C.	Sr. Manager - Q.C.
Sign	Dimple		
Date	22-04-2018	23-04-2018	23-04-2018

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