



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

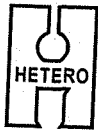
CERTIFICATE OF ANALYSIS

| | | | |
|--|--------------------|-----------------|--------------|
| Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg) | | | |
| Product Code | 4013090 | A.R. No. | H5FP16003652 |
| Specification ID | FPS/B-3006904-1-01 | Batch No. | 3116480 |
| Mfg. Date | 07/2016 | Batch Size | 2.0 Lac. |
| Exp. Date | 06/2018 | Date Of Release | 25-07-2016 |

| 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 | 310.76 mg | 309.00mg \pm 3% (299.73mg to 318.27mg) |
| 4 | Uniformity of weight | Highest : 1.74 % Lowest:-1.34 % | \pm 5% of Average weight |
| 5 | Water content (By KF) | 3.11 %w/w | Not more than 5.0 %w/w |
| 6 | Dissolution (By UV) | Tablet 1- : 99.5 % Tablet 2- : 99.9 % Tablet 3- : 97.8 % Tablet 4- : 99.7 % Tablet 5- : 99.7 % Tablet 6- : 100.2 % Average::99.5 % | 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 | 0.06 % | Not more than 0.50 % |
| 7.2 | Total Impurities | 0.25 % | Not more than 2.00 % |
| 8 | Assay (By HPLC) Each Film coated tablet contains Daclatasvir dihydrochloride eq. to Daclatasvir (%) | 100.9 % | Not less than 95.0% and Not more than 105.0% |

Remarks: APPROVED (Sample Conforms to above Specification)

| | | | |
|--|------------------|------------------------------|------------------|
| Checked By | Ramanuj.Mishra | Approved By | D.S.N.Reddy |
| Date | 25-07-2016 18:00 | Date | 25-07-2016 18:02 |
| Printed by: D.S.N.Reddy | | Printed on: 25-07-2016 18:05 | |
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| Labeled amount | | |
|----------------|--|--|
| | | |

Remarks: APPROVED (Sample Conforms to above Specification)

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