



HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

CERTIFICATE OF ANALYSIS

| | | | |
|---|--------------------|------------------------|--------------|
| Product Name: DACTOVIN 60 (Daclatasvir Tablets 60mg) | | | |
| Product Code | 4013090 | A.R.No. | H5FP16003652 |
| Specification ID | FPS/B-3006904-1-01 | Batch No. | BM17007 |
| Mfg. Date | 07/2017 | Batch Size | 2.0 Lac |
| Exp. Date | 06/2019 | Date Of Release | 06-07-2017 |

| S. No. | TEST | RESULT | SPECIFICATION |
|--------|---|---|---|
| 1 | Description | Light yellow round bevel edged biconvex film coated tablets | Light yellow round bevel edged biconvex film coated tablets |
| 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 | 310.76 mg | 309.00mg±3.0% (299.73mg to 318.27mg) |
| 4 | Uniformity of Weight | Highest: 1.74% Lowest: -1.34% | ±5.0% of Average Weight |
| 5 | Water content (by KF) | 3.11 % w/w | Not more than 5.0% w/w |
| 6 | Dissolution (%w/w, By UV) | Tablet 1 - 99.5% Tablet 2 - 99.9% Tablet 3 - 97.8% Tablet 4 - 99.7% Tablet 5 - 99.9% Tablet 6 - 100.2 % Average - 99.6% | 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 (%) | 100.9 % | Not less than 95% and not more than 105% |

Remarks: APPROVED (Sample Conforms to above Specifications)

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| Checked By | Ramanuj.Mishra | Approved By | D.S.N. Reddy. |
| Date | 06-07-2017 17:45 | Date | 06-07-2017 17:47 |
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