## HETERO LABS LIMITED (UNIT-II)

(Formulations Division)

### CERTIFICATE OF ANALYSIS

- **Product Name:** DACLAHEP 60 (Daclatasvir Tablets 60mg)
- **Product Code:** 4013090
- **A.R. No.:** H5FP19000357
- **Specification ID:** FPS/B-3006904-1-02
- **Batch No.:** 31172195
- **Batch Size:** 2.0 Lac.
- **Mfg. Date:** 01/2019
- **Exp. Date:** 12/2020
- **Date Of Release:** 25-01-2019

### Table: Analysis Results

<table>
<thead>
<tr>
<th>S. No.</th>
<th>TEST Description</th>
<th>RESULT</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Light yellow round bevel edged biconvex film coated tablets debossed with 'H' on one side and 'D19' on the other side.</td>
<td>Light yellow round bevel edged biconvex film coated tablets debossed with 'H' on one side and 'D19' on the other side.</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>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.</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>311.65 mg</td>
<td>309.00mg ± 3% (296.73mg to 318.27mg)</td>
<td></td>
</tr>
</tbody>
</table>
| 4      | Highest : 1.02 %
Lowest: -1.35 % | ±5% of Average weight |
| 5      | 2.77 %w/w | Not more than 5.0 %w/w |
| 6      | Tablet 1: 97.4 %
Tablet 2: 98.1 %
Tablet 3: 97.4 %
Tablet 4: 96.5 %
Tablet 5: 97.2 %
Tablet 6: 97.7 %
Average: 97.4 % | Not less than 75 % (D) of the labeled amount of Daclatasvir is dissolve in 45minutes. |
| 7      | Max single Impurity: 0.08 % | Not more than 0.50 % |
| 7.1    | Total Impurities: 0.26 % | Not more than 2.00 % |
| 8      | 99.2 % | Not less than 95.0% and Not more than 105.0% |

### Remarks: APPROVED (Sample Conforms to above Specification)

- **Checked By:** Rameshvar.Dhakedey
- **Approved By:** D.S.N Reddy
- **Date:** 25-01-2019 17:02
- **Date:** 25-01-2019 17:03
- **Printed by:** D.S.N.Reddy
- **Printed on:** 25-01-2019 17:43
- **Copy No.:** 1
- **Page No.:** 1 of 2

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# CERTIFICATE OF ANALYSIS

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<tr>
<th>Daclatasvir (%) Labeled amount</th>
</tr>
</thead>
</table>

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By | Rameshwar Dhakedev | Approved By | D.S.N. Reddy |
Date | 25-01-2019 17:02 | Date | 25-01-2019 17:03 |
Printed by | D.S.N. Reddy | Printed on | 25-01-2019 17:43 |
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