# Certificate of Analysis

**Product Name**: DACLAHEP 60 (Daclatasvir Tablets 60mg)

<table>
<thead>
<tr>
<th>S. No.</th>
<th>TEST</th>
<th>RESULT</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Description</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>
</tr>
<tr>
<td>2</td>
<td>Identification (By HPLC)</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 correspond to that in the chromatogram of the standard solution, as obtained in the assay.</td>
</tr>
<tr>
<td>3</td>
<td>Average weight</td>
<td>311.11 mg</td>
<td>309.00mg ± 3% (299.73mg to 318.27mg)</td>
</tr>
</tbody>
</table>
| 4      | Uniformity of weight | Highest: 0.82 %  
Lowest: -0.68 % | ±5% of Average weight |
| 5      | Water content (By KF) | 2.75 %w/w | Not more than 5.0 %w/w |
| 6      | Dissolution (By UV) | Tablet 1- : 102.3 %  
Tablet 2- : 101.9 %  
Tablet 3- : 99.9 %  
Tablet 4- : 100.1 %  
Tablet 5- : 99.5 %  
Tablet 6- : 100.3 %  
Average::100.7 % | Not less than 75 % (D) of the labeled amount of Daclatasvir is dissolve in 45minutes. |
| 7      | Related Substances (By HPLC) | 0.15 % | Not more than 0.50 % |
| 7.1    | Max single Impurity | 0.21 % | Not more than 2.00 % |
| 7.2    | Total Impurities | 99.9 % | Not less than 95.0% and Not more than 105.0% |

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By: Anand Singh  
Approved By: D.S.N Reddy  
Date: 2019-10-18  
Printed on: 2019-10-18

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CNo: C100004424
CERTIFICATE OF ANALYSIS

Product Name: DACLAHEP 60 (Daclatasvir Tablets 60mg)
Product Code 4013090
Specification ID FPS/B-3006904-1-02
Mfg. Date 09/2019
Exp. Date 08/2021
A.R. No. H5FP19004245
Batch No. 31172804
Batch Size 20000 Tablets
Date Of Release 18-10-2019

Remarks: APPROVED (Sample Conforms to above Specification)

Checked By: Anand Singh
Approved By: D.S.N. Reddy
Date: 18-10-2019 17:52
Printed by: D.S.N. Reddy
Printed on: 18-10-2019 17:55
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