Acetaminophen Drug Substance by HPLC

Method Conditions

Column: Cogent Bidentate™, 4µm, 100Å
Catalog No.: 40018-75P
Dimensions: 4.6 x 75 mm
Mobile phase:
Solvent A: 100% DI water + 0.1% acetic acid + 0.005% TFA
Solvent B: 100% acetonitrile + 0.1% acetic acid + 0.005% TFA
Gradient:

<table>
<thead>
<tr>
<th>Time</th>
<th>%B</th>
<th>Time</th>
<th>%B</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>0</td>
<td>6.0</td>
<td>30</td>
</tr>
<tr>
<td>1.0</td>
<td>0</td>
<td>6.01</td>
<td>0</td>
</tr>
<tr>
<td>4.0</td>
<td>30</td>
<td>10.0</td>
<td>0</td>
</tr>
</tbody>
</table>

Flow rate: 1.0 mL/min.
Peaks: 1: Impurity
2: Acetaminophen
Injection Volume: 2 µL
Sample: 1 mg of the compound dissolved in 1 mL of 50% A/50%B solution. Sample for injection diluted 1:15 with 100% A.
Detection: UV 254 nm

Discussion

A high-performance liquid chromatography (RP-HPLC) method has been developed for determination of acetaminophen: drug substance. The chromatographic separation was achieved on a Cogent Bideante™C-18 column using a gradient elution. The method shown here has excellent stability and reproducibility (RT of acetaminophen for 5 consecutive injections were: 4.122, 4.122, 4.121, 4.119, 4.121 min : 0.03% RSD).

For more information visit www.MTC-USA.com

Note: Acetaminophen (n-acetyl-p-aminophenol, APAP) is an anti-inflammatory valuable drug (non-steroidal). The drug is widely used for the management of pain and fever. Safety concerns require analyzing the composition of the pharmaceutical formulations. The proposed method can be used for the routine quality control of acetaminophen.

<table>
<thead>
<tr>
<th>Cat. No.</th>
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<tbody>
<tr>
<td>40018-75P</td>
<td>Cogent Bidentate™ C18 HPLC Column, 4µm, 100Å 4.6mm x 75mm</td>
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