Morphine Sulfate Injection – BP 2018

These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.


1  Blank
2  System suitability test 0.05 % w/v morphine sulfate & codeine phosphate
3  0.05 % w/v morphine sulfate
4 - 9 Injection 0.05 % w/v solution
10 - 11 Granules for Oral Suspension 0.05 % w/v solution (also ran on the same plate)

TLC plate  Merck TLC silica gel 60 Plate, 20 cm × 20 cm
Plate preconditioning N/A
Diluent  1:1 mixture of ethanol (96 %) and water
Mobile Phase  13.5 M ammonia : acetone : ethanol (70 % v/v) : toluene (2.5:32.5:35:35 v/v/v/v)
Mobile Phase volume  100 mL
Band application  3 mm band size with a spotting volume of 10 µL
Chamber saturation Minimum 60 minutes at room temperature
Development  150 mm
Development time  35 minutes
Drying time  10 minutes in air
Derivatisation  Sprayed with potassium iodobismuthate (R2 Soln.).
Visualisation Derivatised plates examined under white light


Column: Waters Symmetry C18 (150 mm × 4.6 mm, 5 μm)
Mobile Phase A: Mobile phase A: 0.101 % w/v sodium heptanesulfonate adjusted to pH 2.6 with 50 % v/v orthophosphoric acid
Mobile Phase B: Methanol
Gradient:

<table>
<thead>
<tr>
<th>Time (min)</th>
<th>Mobile Phase A (%)</th>
<th>Mobile Phase B (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2</td>
<td>85</td>
<td>15</td>
</tr>
<tr>
<td>2-35</td>
<td>85–50</td>
<td>15-50</td>
</tr>
<tr>
<td>35-40</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>40-42</td>
<td>50-85</td>
<td>50-15</td>
</tr>
<tr>
<td>42-50</td>
<td>85</td>
<td>15</td>
</tr>
</tbody>
</table>

Diluent: 1% v/v acetic acid
Flow Rate: 1.5 mL/min
Column Temp: 35°C
Injection Volume: 20 μL
Detection: UV, 230 nm
Typical chromatogram for solution (3) in the Assay test for Morphine Sulfate Injection as published in BP 2018.

Peak ID: 1: Morphine sulfate; 2: Codeine phosphate

Column : Nucleosil C18 (100 mm X 4.6 mm, 5 μm)
Mobile Phase : A solution of 0.005 M diocetyl sodium sulfosuccinate and 0.01 M sodium acetate in methanol (60 %) adjusted to pH 5.5 with glacial acetic acid
Diluent : Methanol (60 %, v/v)
Flow Rate : 2.0 mL/min
Column Temp : 25°C
Injection Volume : 20 µL
Detection : UV, 285 nm