(A) System suitability test solution
(1.0 μg/mL 1-Vinyl-2-pyrrolidone, 50 μg/mL Vinyl acetate)

Column: YMC-Triart C18 (5 μm, 12 nm)
[Pre-column] 20 X 4.0 mmI.D.
[Separation column] 250 X 4.0 mmI.D.
Eluent: acetonitrile/water (1/9)
Flow rate: 1.0 mL/min
Temperature: 40°C
Detection: UV at 235 nm
Injection: 50 μL

Modified conditions of The Japanese Pharmacopoeia 17th; Purity (3) 1-Vinyl-2-pyrrolidone

(B) Standard solution
(0.25 μg/mL 1-Vinyl-2-pyrrolidone)

Relative standard deviation of the peak area (n=6)
(1-Vinyl-2-pyrrolidone) ≤2.0% 0.62%
Column: YMC-Triart C18 (5 μm, 12 nm)
  [Pre-column] 33 X 4.6 mm I.D.
  [Separation column] 250 X 4.0 mm I.D.
Eluent: acetonitrile/water (2/23)
Flow rate: 1.0 mL/min
Temperature: 40°C
Detection: UV at 205 nm
Injection: 20 μL

(System suitability requirement) Results

<table>
<thead>
<tr>
<th>Elution order</th>
<th>Resolution (1, 2)</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1, 2</td>
<td>≥2.0</td>
<td>9.76</td>
</tr>
</tbody>
</table>

(1) vinyl-2-pyrrolidone and vinyl acetate)
System suitability test solution (each 5.0 µg/mL)

<table>
<thead>
<tr>
<th></th>
<th>System suitability requirement</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elution order</td>
<td>1, 2</td>
<td>1, 2</td>
</tr>
<tr>
<td>Resolution (1, 2)</td>
<td>≥5.0</td>
<td>7.22</td>
</tr>
<tr>
<td>Relative standard deviation of the peak area (n=6) (1-Vinyl-2-pyrrolidone)</td>
<td>≤2.0%</td>
<td>0.50%</td>
</tr>
</tbody>
</table>

Column: YMC-Triart C18 (5 µm, 12 nm)  
250 X 4.0 mmL.D.

Eluent: A) acetonitrile/methanol/water (1/1/18)  
B) acetonitrile/methanol/water (9/1/10)  
0%B (0-2 min), 0-15%B (2-40 min), 15-100%B (40-42 min)

Flow rate: 1.0 mL/min  
Temperature: 30°C  
Detection: UV at 205 nm  
Injection: 10 µL  

(Japanese Pharmaceutical Excipients 2018; Purity (3) Vinyl acetate)
Polyvinyl Alcohol (Japanese Pharmaceutical Excipients)

**Column**: YMC-Pack ODS-AL (5 μm, 12 nm)

- 250 X 4.0 mmL.D.

**Eluent**

- A) acetonitrile/methanol/water (1/1/38)
- B) acetonitrile/methanol/water (9/1/10)

  - 0%B (0-2 min), 0-15%B (2-40 min), 15-100%B (40-42 min), 100%B (42-48 min), 100-0%B (48-51 min)

**Flow rate**: 1.0 mL/min

**Temperature**: 30°C

**Detection**: UV at 205 nm

**Injection**: 10 μL

(Modified conditions of Japanese Pharmaceutical Excipients 2018; Purity (4) Vinyl acetate)