Standard solution\(^1\)
(0.1 mg/mL Lansoprazole,
0.05 mg/mL 4'-Ethoxyacetophenone)

<table>
<thead>
<tr>
<th>System suitability requirement</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resolution (1, 2)</td>
<td>≥ 10</td>
</tr>
<tr>
<td>Relative standard deviation of the peak area ratio of 1 to 2 (n=6)</td>
<td>≤ 1.0%</td>
</tr>
</tbody>
</table>

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Column : YMC-Triart C18 (5 µm, 12 nm)
250 X 4.6 mml.D.
Eluent : acetonitrile/water/TEA\(^2\) (40/60/1) adjusted to pH 7.0 with phosphoric acid
Flow rate : 1.5 mL/min (adjust the flow rate so that the retention time of Lansoprazole is about 7 min)
Temperature : 25°C
Detection : UV at 285 nm
Injection : 10 µL

(The draft for the Japanese Pharmacopoeia; Assay)

\(^1\) Standard solution was prepared from Lansoprazole supplied as a reagent for laboratory use.
\(^2\) triethylamine
(A) Standard solution \(^1\)
(0.0025 mg/mL Lansoprazole)

<table>
<thead>
<tr>
<th>System suitability requirement</th>
<th>Result</th>
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</thead>
<tbody>
<tr>
<td>Theoretical plate number (Lansoprazole)</td>
<td>( \geq 150000 )</td>
</tr>
<tr>
<td>Tailing factor (Lansoprazole)</td>
<td>( \leq 1.5 )</td>
</tr>
<tr>
<td>Relative standard deviation of the peak area (n=6) (Lansoprazole)</td>
<td>( \leq 3.0% )</td>
</tr>
<tr>
<td>Peak area ratio of test solution for required detectability (0.125 µg/mL) to standard solution (Lansoprazole)</td>
<td>4-6%</td>
</tr>
</tbody>
</table>

(B) Sample solution \(^1\)
(0.25 mg/mL Lansoprazole)

Column : YMC-Triart C18 (5 µm, 12 nm)
150 X 4.6 mm I.D.

Eluent : A) water
B) acetonitrile/water/TEA \(^2\) (160/40/1) adjusted to pH 7.0 with phosphoric acid
10-80%B (0-40 min), 80%B (40-50 min)

Flow rate : 0.65 mL/min (adjust the flow rate so that the retention time of Lansoprazole is about 29 min)

Temperature : 25°C
Detection : UV at 285 nm
Injection : 40 µL

(The draft for the Japanese Pharmacopoeia; Related substances)

\(^1\) All standard and sample solutions were prepared from Lansoprazole supplied as a reagent for laboratory use.

\(^2\) triethylamine
(A) Standard solution\(^1\)
(0.0025 mg/mL Lansoprazole)

![Chromatogram](image1)

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<td>4-6%</td>
</tr>
</tbody>
</table>

(B) Sample solution\(^1\)
(0.25 mg/mL Lansoprazole)

![Chromatogram](image2)

Column : YMC-Triart C18 (5 µm, 12 nm)
150 X 4.6 mm I.D.

Eluent : A) water
B) acetonitrile/water/TEA\(^2\) (160/40/1) adjusted to pH 7.0 with phosphoric acid
10-80%B (0-30 min), 80%B (30-40 min)

Flow rate : 0.65 mL/min (adjust the flow rate so that the retention time of Lansoprazole is about 24 min)

Temperature : 25°C

Detection : UV at 285 nm

Injection : 40 µL

(The draft for the Japanese Pharmacopoeia; Related substances)

\(^1\) All standard and sample solutions were prepared from Lansoprazole supplied as a reagent for laboratory use.

\(^2\) triethylamine