

Hypromellose Assay (Japanese Pharmacopeia)

This note shows the analysis of Hypromellose which was conducted under the assay method of the new 17th edition of the Japanese Pharmacopeia (JP17). This new method replaces the use of packed column, which was indicated in the old method, with a GC capillary column. Successful results were obtained due to the pretreatment and the analysis methods contained in this application.

Pre-treatment

Standard sample

Standard Sample weighing

- Adipic Acid 60-100 mg
(in this analysis 69 mg)
- Internal standard⁽¹⁾ 2.0 mL
- Hydriodic acid 2.0 mL

Close the standard tightly
and measure the mass

Add the standard
sample for the assay

- Iodomethane 45 μ L

Mass measurement

- Isopropyl iodide 15-22 μ L
(in this analysis 15 μ L)

Mass measurement

Mix and recover the
supernatant

GC/FID

Sample

Sample weighing

- Hypromellose approx. 65 mg
(in this analysis 65 mg)
- Adipic Acid 60-100 mg
(in this analysis 69 mg)
- Internal standard⁽¹⁾ 2.0 mL
- Hydriodic acid 2.0 mL

Close the standard tightly
and measure the mass

Stir and heat
(130°C, for 60 min) ⁽²⁾

Cool and measure the
mass

- Check if the quantity
decrease is less than 25 mg.

Mix and recover the
supernatant

GC/FID

⁽¹⁾ 3 mL of n-octane was diluted to volume in o-Xylene to 100m.

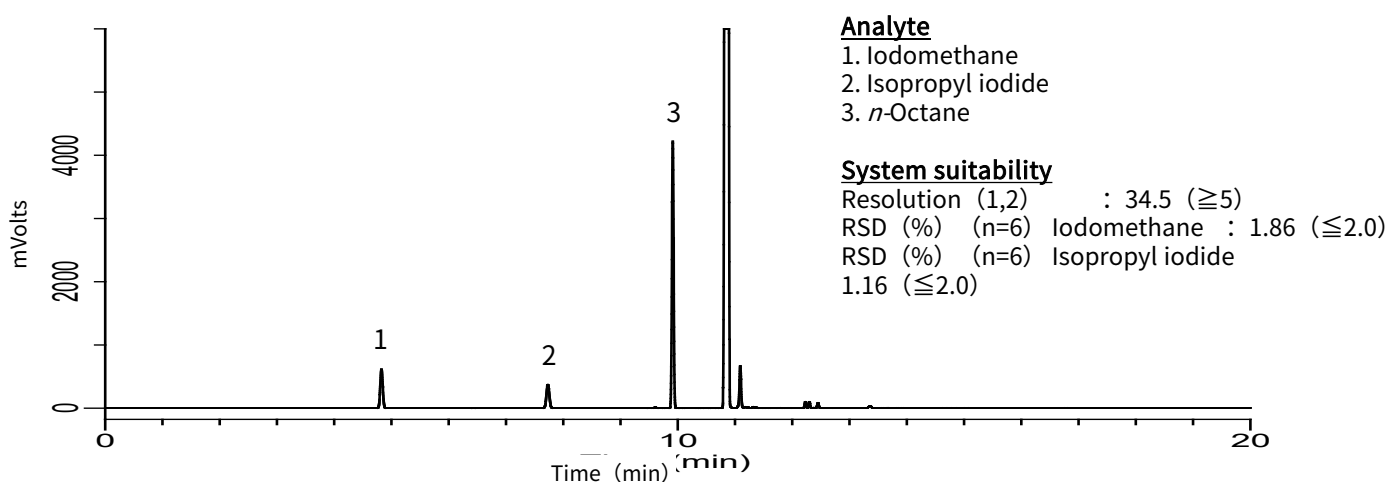
⁽²⁾ This procedure was conducted by using a Reacti-Therm Heating and Stirring Module.

Analysis Conditions and Results

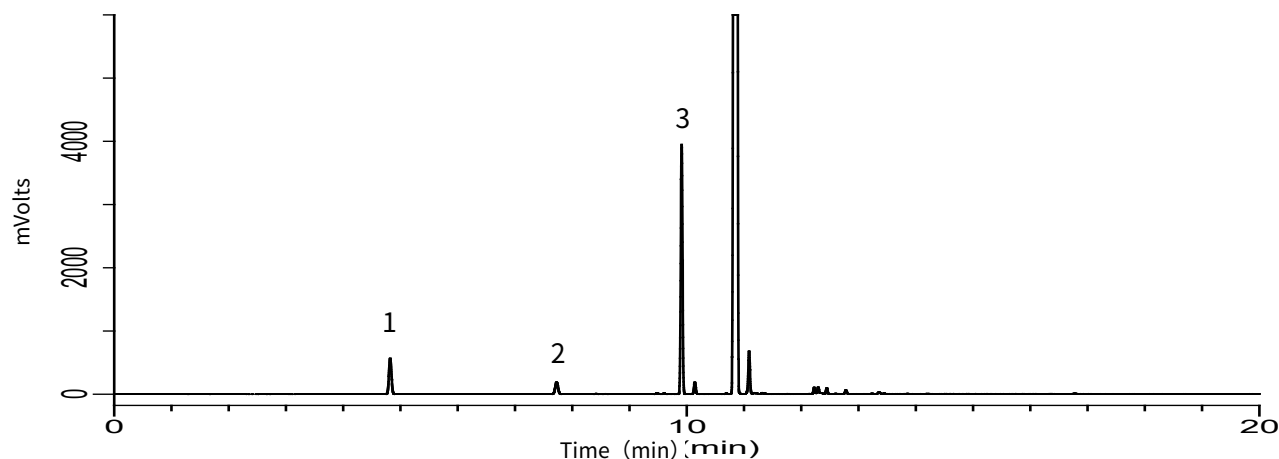
Conditions

System : GC-FID
Column : InertCap 1
 0.53 mm I.D. × 30 m df = 3.00 μm (Cat.No.: 1010-11448)
Col. Temp. : 50 °C (3 min) - 10 °C/min - 100 °C - 35 °C/min - 250 °C (8 min)
Carrier Gas : He 3 mL/min (Internal standard retention time 10 min)
Injection : Split 1:40
 250 °C
Detection : FID Auto Range
 280 °C
Sample Size : 1 μL

Standard sample chromatogram



Sample chromatogram



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