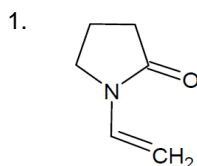
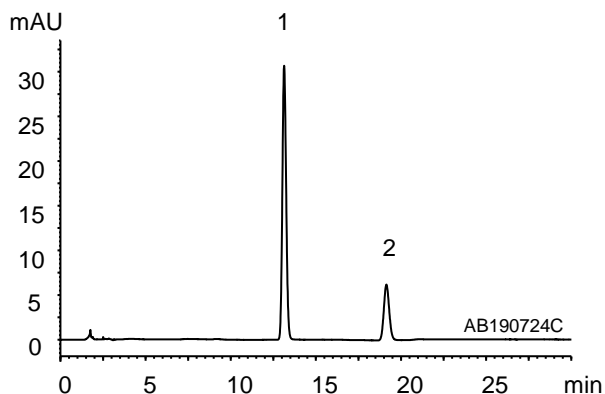


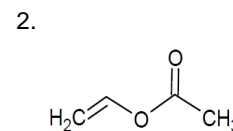
クロスポビドン (日本薬局方記載条件)
Crosopovidone (The Japanese Pharmacopoeia)

AB190727A

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



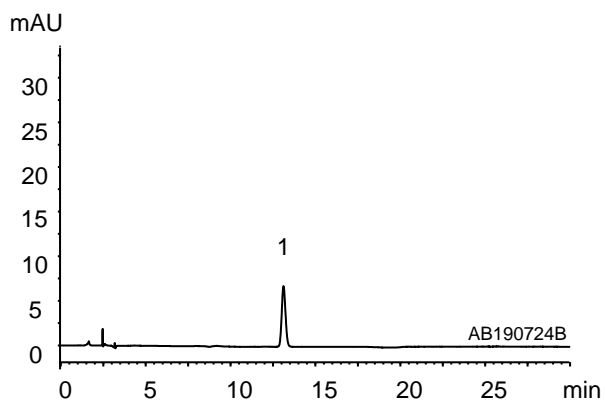
1-Vinyl-2-pyrrolidone



Vinyl acetate

	System suitability requirement	Result
Elution order	1, 2	1, 2
Resolution (1,2)	≥2.0	12.0

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



	System suitability requirement	Result
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] 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

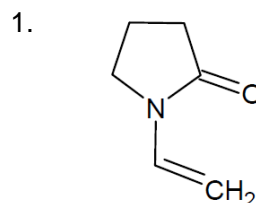
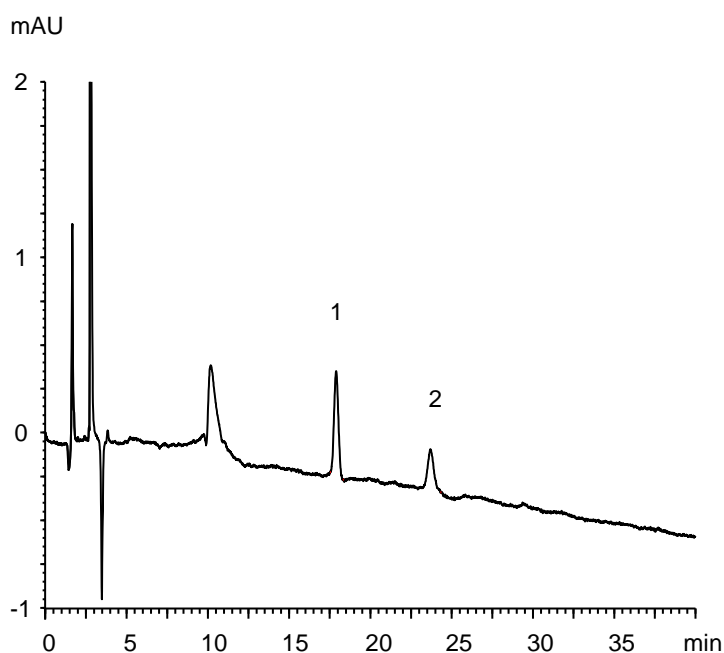
Injection : 50 µL

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

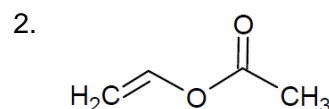
コポビドン (日本薬局方記載条件)
Copovidone (The Japanese Pharmacopoeia)

AB190726A

Standard solution (each 0.25 µg/mL)



1-Vinyl-2-pyrrolidone



Vinyl acetate

	System suitability requirement	Result
Elution order	1, 2	1, 2
Resolution (1, 2)	≥2.0	9.76

Column : YMC-Triart C18 (5 µm, 12 nm)
[Pre-column] 33 X 4.6 mmI.D.
[Separation column] 250 X 4.0 mmI.D.

Eluent : acetonitrile/water (2/23)

Flow rate : 1.0 mL/min

Temperature : 40°C

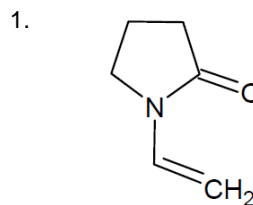
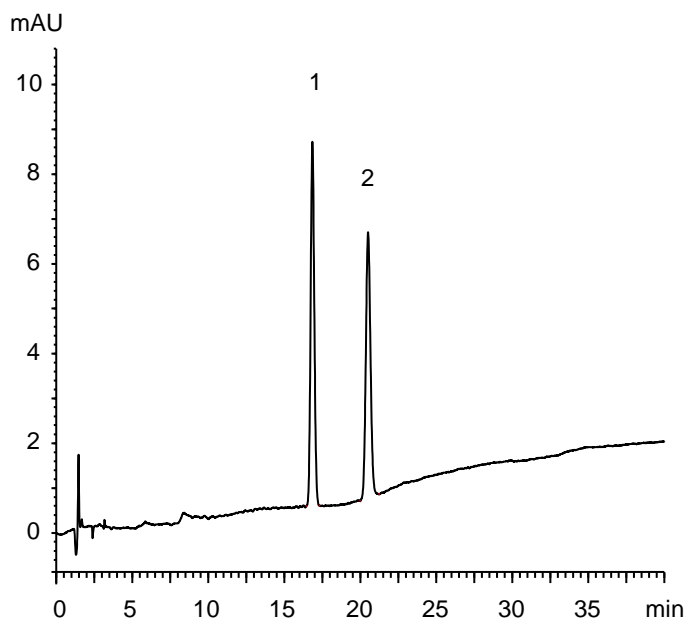
Detection : UV at 205 nm

Injection : 20 µL

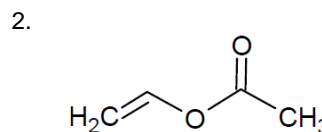
(Modified conditions of the draft for The Japanese Pharmacopoeia 18th; Purity (4) 1-Vinyl-2-pyrrolidone and vinyl acetate)

酢酸ビニル樹脂30%分散液 (医薬品添加物規格記載条件)
Poly (vinyl acetate) dispersion 30 percent (Japanese Pharmaceutical Excipients) AB190719A

System suitability test solution
(each 5.0 µg/mL)



1-Vinyl-2-pyrrolidone



Vinyl acetate

	System suitability requirement	Result
Elution order	1, 2	1, 2
Resolution (1, 2)	≥5.0	7.22
Relative standard deviation of the peak area (n=6) (1-Vinyl-2-pyrrolidone)	≤2.0%	0.50%

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

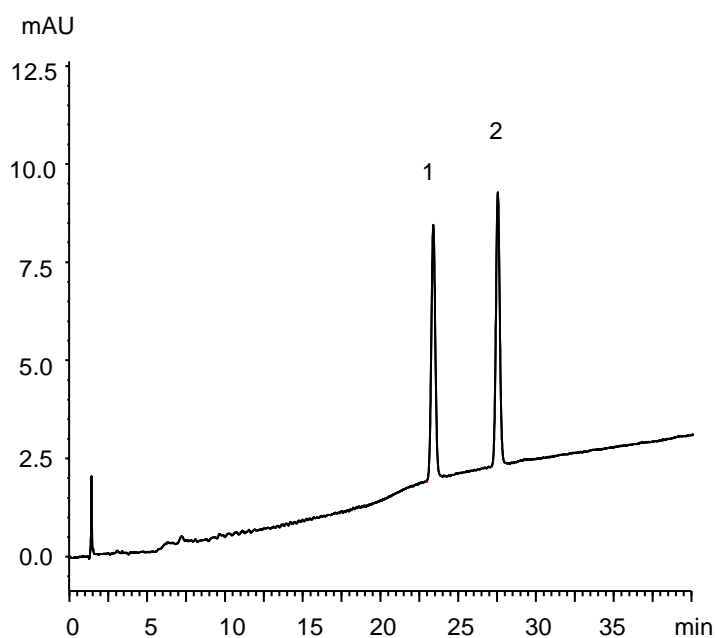
Injection : 10 µL

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

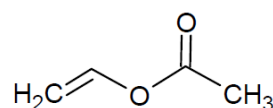
ポリビニルアルコール・ポリエチレングリコール・グラフトコポリマー(医薬品添加物規格記載条件)
Polyvinyl Alcohol・Polyethylene Glycol Graft Copolymer
(Japanese Pharmaceutical Excipients)

AB190821C

System suitability test solution
(each 5.0 µg/mL)

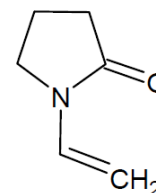


1.



Vinyl acetate

2.



1-Vinyl-2-pyrrolidone

	System suitability requirement	Result
Elution order	1, 2	1, 2
Resolution (1, 2)	≥5.0	8.79

Column : YMC-Pack ODS-AL (5 µm, 12 nm)
250 X 4.0 mmI.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)