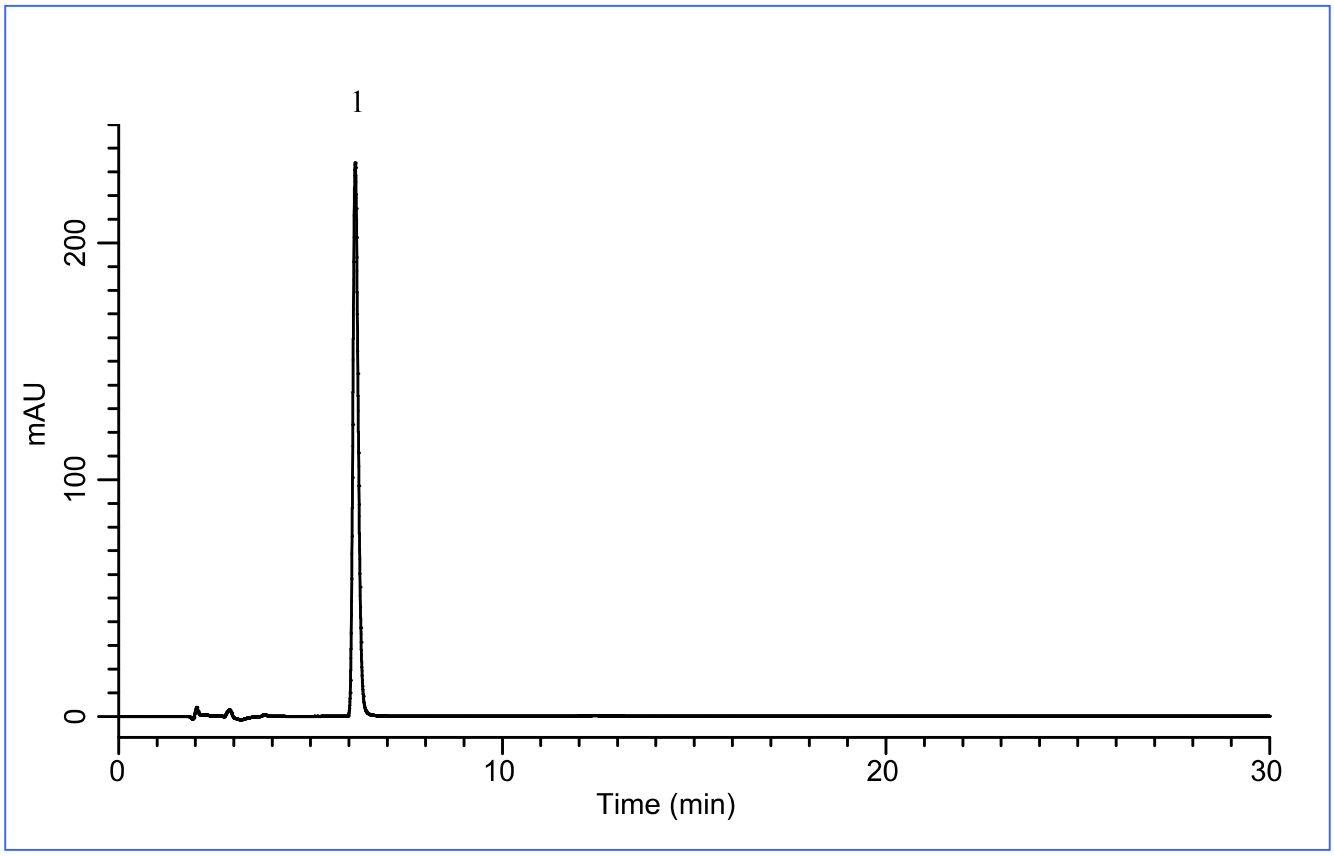
Analysis of Copovidone - Under the Condition of the EP 10th ed.

The Pharmacopoeial Discussion Group agreed on the international harmonization of copovidone, a pharmaceutical additive. Following this agreement, the tests of copovidone in European Pharmacopoeia (EP) have been revised in the 10th edition, which was implemented on the 1st of January, 2020.

The revision consists of the change of the analytical conditions of Impurity A (2-pyrrolidone) and newly added Impurities B and C (1-vinylpyrrolidin-2-one and vinyl acetate, respectively) tests. This technical note describes representative examples of these tests obtained with Inertsil ODS-4, which is opted for these tests.

EP: Impurity A



Conditions

Guard Column : Inertsil ODS-4 (5 µm, 10 x 4.0 mm I.D.)
Column : Inertsil ODS-4 (5 µm, 150 x 4.6 mm I.D.)
Eluent : A) CH_3OH
B) H_2O
A/B = 5/95, v/v
Flow Rate : 0.8 mL/min
Col. Temp. : 40 ℃
Detection : UV 205 nm
Injection Vol. : 20 µL
Sample : Standard

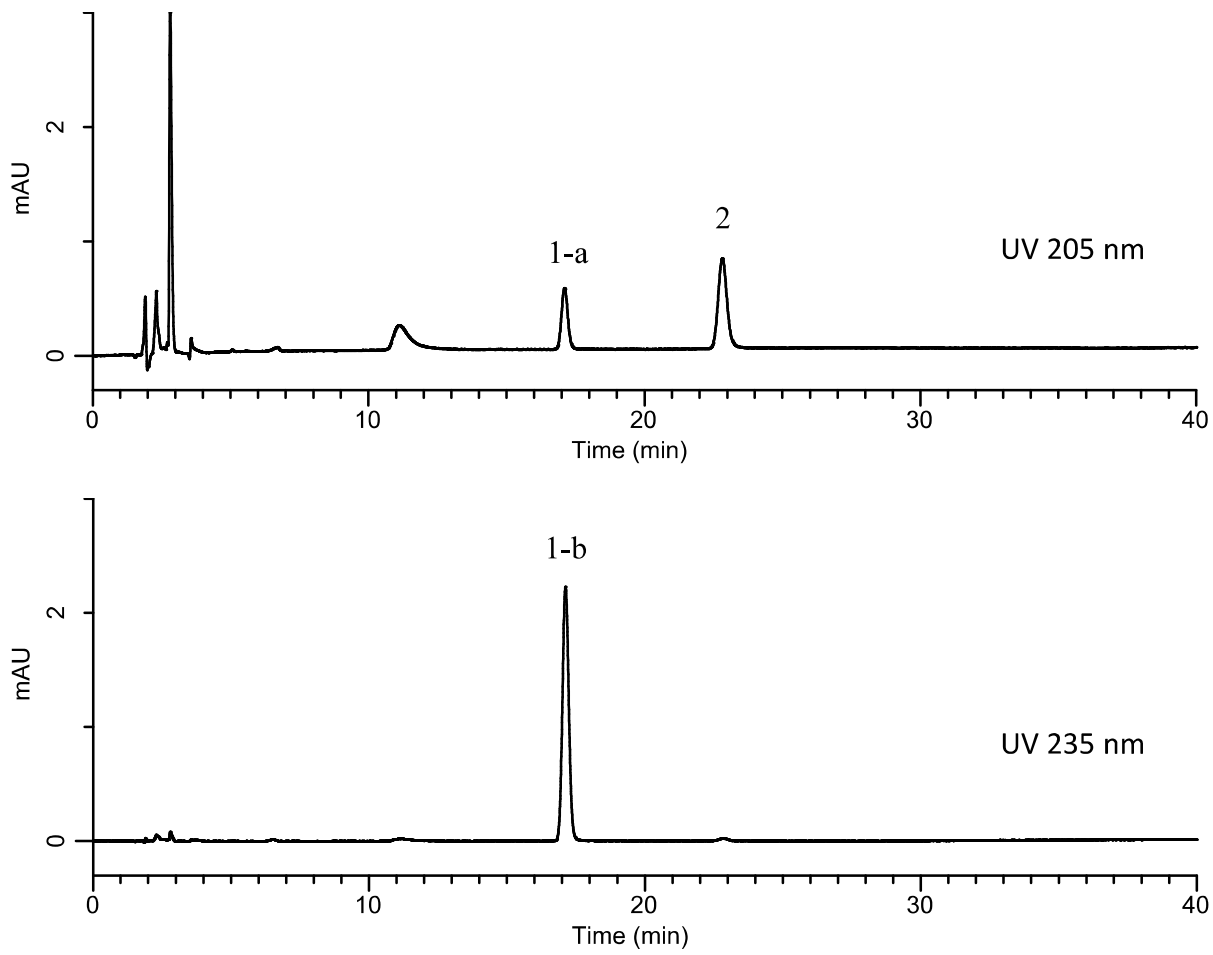
Analyte:

1. 2-Pyrrolidone 45 mg/L
(Impurity A)

Symmetry factor : 1.27 (≦ 1.5)*
RSD of the peak area (%)(n=6)
: 0.10 (≦ 2.0)*

* ( ) : pharmacopeia standard values

EP : Impurities B and C



Conditions

Guard Column : Inertsil ODS-4
(5 µm, 33 x 4.0 mm I.D.)
Column : Inertsil ODS-4
(5 µm, 250 x 4.0 mm I.D.)
Eluent : A) CH_3CN
B) H_2O
A/B = 8/92, v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 40 ℃
Detection : UV 205 or 235 nm
Injection Vol. : 20 µL
Sample : Standard

Analyte:

1. 1-Vinyl-2-pyrrolidone (Impurity B) 0.25 mg/L
2. Vinyl acetate (Impurity C) 0.25 mg/L

Resolution (1-a,2) : 11.75 (≧ 2.0)*
RSD of the peak area of 1-b (%)(n=6)
: 1.33 (≦ 2.0)
RSD of the peak area of 2 (%)(n=6)*
: 0.50 (≦2.0)

* ( ) : pharmacopeia standard values

Note: After each injection of the test solution, elute and wash away the remaining sample by passing the mobile phase through the column backwards for about 30 min at the same flow rate as applied in the test. This process may be replaced by washing the precolumn only.

Product Information

Columns for Impurity A test

Column (EP 10th ed.) :
Precolumn:
-size: l=0.010 m, Φ=4.0 mm;
-stationary phase:base-deactivated end-capped octadecylsilyl silica gel for chromatography R (5 µm).
Analytical Column:
-size: l=0.15 m, Φ=4.6 mm;
-stationary phase:base-deactivated end-capped octadecylsilyl silica gel for chromatography R (5 µm).

●Precolumn: Inertsil ODS-4 5 µm, 10 x 4.0 mm I.D.
Cat.No. 5020-03651

●Analytical column: Inertsil ODS-4 5 µm, 150 x 4.6 mm I.D.
Cat.No. 5020-03945

Columns for Impurities B and C test

Column (EP 10th ed.) :
Precolumn:
-size: l=0.033 m, Φ=4.0 mm;
-stationary phase:base-deactivated end-capped octadecylsilyl silica gel for chromatography R (5 µm).
Analytical Column:
-size: l=0.25 m, Φ=4.0 mm;
-stationary phase:base-deactivated end-capped octadecylsilyl silica gel for chromatography R (5 µm).

●Precolumn: Inertsil ODS-4 5 µm, 33 x 4.0 mm I.D.
Cat.No. 5020-04251

●Analytical column: Inertsil ODS-4 5 µm, 250 x 4.0 mm I.D.
Cat.No. 5020-03936

●Connection between the guard and analytical columns
PEEK tubing of 1/16" O.D., 0.25 mm I.D. was cut to 5 cm and connected by PEEK tough fittings.

●Related connection products
・PEEK tubing (1/16" O.D., 0.25 mm I.D., 5 m long)
Cat.No.6010-37305
・PEEK tough fitting, 5/pk
Cat.No.6010-48600
・Pre-column coupler W 0.25 mm I.D.
Cat.No.6010-49251

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