Calculate the percentage of 2-pyrrolidinone in the sample taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of 2-pyrrolidinone from the *Sample solution*
r_S = peak response of 2-pyrrolidinone from the *Standard solution*
C_S = concentration of 2-pyrrolidinone in the *Standard solution* (mg/mL)
C_U = concentration of Povidone in the *Sample solution* (mg/mL), calculated on the anhydrous basis

Acceptance criteria: NMT 3.0%

- **PEROXIDES**

Sample solution: 40 mg/mL of Povidone in water, calculated on the anhydrous basis
Blank: To 25 mL of the *Sample solution*, add 2 mL of 13% sulfuric acid.
Instrumental conditions
(See *Ultraviolet-Visible Spectroscopy* ⟨857⟩.)
Mode: UV-Vis
Analytical wavelength: 405 nm
Cell: 1 cm
Analysis
Sample: *Sample solution*
To 25 mL of the *Sample solution*, add 2 mL of titanium trichloride–sulfuric acid TS, and allow to stand for 30 min. Measure the absorbance of a portion of this solution against the *Blank*.
Acceptance criteria: NMT 0.35, corresponding to NMT 400 ppm, expressed as H_2O_2

- **FORMIC ACID**

Mobile phase: Diluted perchloric acid (1 in 700)
Standard solution: 10 µg/mL of formic acid in water
Sample stock solution: 20 mg/mL of Povidone in water
Sample solution: Transfer a suspension of strongly acidic ion-exchange resin (use the hydrogen form of ion-exchange resin) in water to a column of about 8 mm in inside diameter to give a packing depth of about 20 mm in length. Keep the strongly acidic ion-exchange resin layer constantly immersed in water. Pour 5 mL of water and adjust the flow rate so that water drops at a rate of about 1 mL/min. When the level of the water is near the top of the strongly acidic ion-exchange resin layer, introduce 100 mL of the *Sample stock solution* into the column. Disregard the first 2 mL of the eluate, then collect 1.5 mL of the solution, and use this as the *Sample solution*.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 210 nm
Column: 7.8-mm × 30-cm; 9-µm packing L17
Column temperature: 35°
Flow rate: 1.0 mL/min
[NOTE—The retention time of formic acid is about 8 min.]
Injection volume: 50 µL
System suitability
Sample: *Standard solution*
Suitability requirements
Column efficiency: NLT 1000 theoretical plates for the formic acid peak
Symmetry factor: 0.5–1.5 for the formic acid peak
Relative standard deviation: NMT 2.0% of formic acid for six injections
Analysis
Samples: *Standard solution* and *Sample solution*
Record the chromatograms and measure the responses for the formic acid peak.

Calculate the percentage of formic acid in the sample taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of formic acid from the *Sample solution*
r_S = peak response of formic acid from the *Standard solution*
C_S = concentration of formic acid in the *Standard solution* (mg/mL)
C_U = concentration of Povidone in the *Sample solution* (mg/mL), calculated on the anhydrous basis

Acceptance criteria: NMT 0.5%

SPECIFIC TESTS

- **pH** ⟨791⟩

Sample solution: 50 mg/mL in water
Acceptance criteria: 3.0–5.0 for Povidone having a nominal K-value of 30 or less; 4.0–7.0 for Povidone having a nominal K-value greater than 30

- **WATER DETERMINATION** ⟨921⟩, *Method I*: NMT 5.0%
- **K-VALUE**

Sample solution: Weigh a quantity of undried Povidone, equivalent on the anhydrous basis, to the amount specified in *Table 1*.

Table 1

Nominal K-value	Quantity (g)
≤18	5.00
>18 to ≤95	1.00
>95	0.10

Dissolve it in 50 mL of water in a 100-mL volumetric flask, and dilute to volume. Allow to stand for 1 h.
Analysis
Samples: *Sample solution* and water
Determine the viscosity of the *Sample solution* and the water, using a capillary-tube viscometer (see *Viscosity—Capillary Methods* ⟨911⟩), at 25 ± 0.2°.
Calculate the K-value of Povidone:

$$\text{Result} = \left[\sqrt{300c\log z + (c + 1.5c\log z)^2} + 1.5c\log z - c\right] \Big/ (0.15c + 0.003c^2)$$

c = weight, on the anhydrous basis, of the specimen tested in each 100.0 mL of solution (g)
z = viscosity of the *Sample solution* relative to that of water

Acceptance criteria
K-value of Povidone having a stated (nominal) K-value of NMT 15: 85.0%–115.0% of the stated values
K-value of Povidone having a stated K-value or a stated K-value range with an average of more than 15: 90.0%–108.0% of the stated value or of the average of the stated range

ADDITIONAL REQUIREMENTS

- **•PACKAGING AND STORAGE:•** Preserve in tight containers.
- **LABELING:** Label it to state, as part of the official title, the K-value or K-value range of Povidone.
- **•USP REFERENCE STANDARDS•** ⟨11⟩
USP Povidone RS