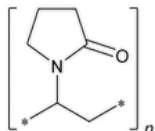


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Povidone

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2-Pyrrolidinone, 1-ethenyl-, homopolymer;

1-Vinyl-2-pyrrolidinone polymer;

Poly [(2-oxo-1-pyrrolidinyl)ethylene]

CAS RN®: 9003-39-8.

DEFINITION

Povidone is a chain polymer of 1-vinyl-2-pyrrolidone. It contains NLT 11.5% and NMT 12.8% of nitrogen (N: 14.01), calculated on the anhydrous basis. It has the nominal K-value of NLT 10 and NMT 120. The nominal K-value is shown on the label.

IDENTIFICATION

• A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#)

Sample: Dry at 105° for 6 h.

Acceptance criteria: Meets the requirements

• •B.

Sample solution: 20 mg/mL of Povidone

Analysis: To 10 mL of the *Sample solution*, add 20 mL of 1 N hydrochloric acid VS and 5 mL of [potassium dichromate TS](#).

Acceptance criteria: An orange-yellow precipitate is formed.

• •C.

Solution A: Dissolve 75 mg of [cobalt nitrate](#) and 300 mg of [ammonium thiocyanate](#) in 2 mL of water.

Sample solution: 20 mg/mL of Povidone

Analysis: Combine *Solution A* and 5 mL of the *Sample solution*, and render the resulting solution acidic by the addition of 3 N hydrochloric acid.

Acceptance criteria: A pale blue precipitate is formed.

• •D.

Sample solution: 5 mg/mL of Povidone

Analysis: To 5 mL of the *Sample solution*, add a few drops of [iodine TS](#).

Acceptance criteria: A deep red color is produced.

• E.

Sample solution: 50 mg/mL of Povidone in water

Acceptance criteria: The substance dissolves.

ASSAY

• NITROGEN DETERMINATION

Sample: 0.1 g of Povidone

Analysis: Weigh the *Sample* accurately and place in a Kjeldahl flask. Add 5 g of a powdered mixture of 33 g of [potassium sulfate](#) and 1 g of titanium dioxide. Wash down any adhering sample from the neck of the flask with a small amount of water. Add 7 mL of

sulfuric acid allowing it to flow down the inside wall of the flask. Heat the flask gradually until the solution has a clear, yellow-green color and the inside wall of the flask is free from any carbonized material and then heat for an additional 45 min. After cooling, cautiously add 20 mL of water, and connect the flask to the distillation apparatus previously washed by passing steam through it. To the absorption flask add 30 mL of a solution of boric acid (1 in 25), 3 drops of [bromocresol green-methyl red TS](#), and sufficient water to immerse the lower end of the condenser tube. Add 30 mL of a solution of sodium hydroxide (2 in 5) through the funnel, rinse the funnel cautiously with 10 mL of water, immediately close the clamp attached to the rubber tube, and then start the distillation with steam to obtain 80–100 mL of the distillate. Remove the absorption flask from the lower end of the condenser tube, rinsing the end part with a small quantity of water, and titrate the distillate with [0.025 mol/L sulfuric acid VS](#) until the color of the solution changes from green through pale grayish blue to pale grayish red-purple. Perform a blank determination in the same manner, and make any necessary correction.

Each milliliter of [0.025 mol/L sulfuric acid VS](#) equals 0.700 mg of nitrogen.

Acceptance criteria: 11.5%–12.8% on the anhydrous basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Change to read:

- [▲LEAD \(251\), Procedures, Procedure 1 ▲](#) (CN 1-JUN-2023)

Test preparation: 1.0 g in 25 mL of water

Acceptance criteria: NMT 10 ppm*

• LIMIT OF ALDEHYDES

Solution A: Transfer 8.3 g of [potassium pyrophosphate](#) to a 500-mL volumetric flask and dissolve in 400 mL of water. Adjust, if necessary, with 1 N hydrochloric acid VS to a pH of 9.0, and dilute with water to volume.

Solution B: Transfer a quantity of lyophilized [aldehyde dehydrogenase](#), equivalent to 70 units, to a glass vial, and dissolve in 10.0 mL of water. [NOTE—This solution is stable for 8 h at 4°.]

Solution C: Transfer 40 mg of [nicotinamide adenine dinucleotide](#) to a glass vial, and dissolve in 10.0 mL of *Solution A*. [NOTE—This solution is stable for four weeks at 4°.]

Standard solution: Dissolve 0.140 g of acetaldehyde ammonia trimer trihydrate in water to make 200.0 mL. Dilute 1.0 mL of the solution with *Solution A* to 100.0 mL.

Sample solution: 10 mg/mL of Povidone in *Solution A*. Insert a stopper into the flask, heat at 60° for 1 h, and cool to room temperature.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelength: 340 nm

Cell: 1 cm

Analysis

Samples: *Standard solution*, *Sample solution*, and water

Pipet 0.5 mL each of the *Standard solution*, *Sample solution*, and water (used for blank test) into separate cells. Add 2.5 mL of *Solution A* and 0.2 mL of *Solution C* to each cell. Cover the cells to exclude oxygen. Mix by inversion and allow to stand for 2–3 min at 22 ± 2°.

Determine the absorbances of the solutions using the water as the reference. Add 0.05 mL of *Solution B* to each cell. Cover the cells to exclude oxygen. Mix by inversion and allow to stand for 5 min at 22 ± 2°. Determine the absorbances of the solutions, using the water as the reference.

Calculate the percentage of aldehydes, expressed as acetaldehyde, in the portion of Povidone taken:

$$\text{Result} = 100 \times (C_s/C_u) \times \{[(A_{U2} - A_{U1}) - (A_{B2} - A_{B1})]/[(A_{S2} - A_{S1}) - (A_{B2} - A_{B1})]\}$$

C_s = concentration of acetaldehyde in the *Standard solution*, calculated from the weight of the acetaldehyde ammonia trimer trihydrate with the factor 0.72 (mg/mL).

[NOTE—The molar mass of acetaldehyde is 44.05 g/mol, and the molar mass of acetaldehyde ammonia trimer trihydrate is 183.26 g/mol. $(44.05 \times 3)/183.26 = 0.72$]

C_u = concentration of the *Sample solution* (mg/mL), calculated on the anhydrous basis

A_{U2} = absorbance of the solution from the *Sample solution*, after addition of *Solution B*

A_{U1} = absorbance of the solution from the *Sample solution*, before addition of *Solution B*

A_{B2} = absorbance of the solution from the blank, after addition of *Solution B*