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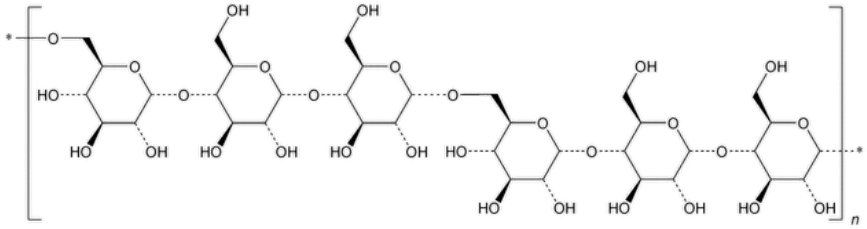
Pullulan



$(C_{36}H_{60}O_{30})_n$

Poly[6)-α-D-glucopyranosyl-(1→4)-α-D-glucopyranosyl-(1→4)-α-D-glucopyranosyl-(1→]

CAS RN®: 9057-02-7.

DEFINITION

Pullulan is a neutral, simple polysaccharide produced by the growth of *Aureobasidium pullulans*. It has a chain structure of repeated α-1,6-bonds of maltotriose composed of three glucoses in α-1,4-bonds. It may contain some maltotetraosyl units. It contains NLT 90% of glucan, calculated on the dried basis.

IDENTIFICATION

- **A.**

  Sample: 10 g

  Analysis: Dissolve the *Sample* in 100 mL of water by adding in small portions with stirring.

  Acceptance criteria: A viscous solution is produced.

- **B.**

  Pullulanase sample solution: 10 units/mL of pullulanase

  Sample solution: The viscous solution obtained in *Identification* test *A*

  Analysis: Mix 10 mL of the *Sample solution* with 0.1 mL of *Pullulanase sample solution*, and allow to incubate at 25° for 20 min.

  Acceptance criteria: A substantial loss of viscosity is observed.

- **C.**

  Sample solution: 20 mg/mL

  Analysis: To 10 mL of the *Sample solution* add 2 mL of polyethylene glycol 600.

  Acceptance criteria: A white precipitate is formed immediately.

ASSAY

- **Content of Monosaccharide, Disaccharide, and Oligosaccharides**

  Sample stock solution: 8 mg/mL, on previously dried material

  Sample solution: To 1.0 mL of the *Sample stock solution* add 0.1 mL of saturated potassium chloride solution, and shake vigorously with 3 mL of methyl alcohol. Centrifuge, and use the supernatant.

  Standard solution: Dilute 1.0 mL of the *Sample stock solution* with water to 50 mL.

  Blank: Water

  Instrumental conditions

  (See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)

  Mode: Vis

  Analytical wavelength: 620 nm

  Analysis

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

Transfer 0.2 mL each of the *Standard solution*, *Sample solution*, and *Blank* to a test tube containing 5 mL of a 1-in-500 solution of anthrone in 75% (v/v) sulfuric acid, with the test tube placed in ice water. Mix each tube immediately, and then heat the test tube at 90° for 10 min. Remove the tube, and allow it to cool in cold running water.

Determine the absorbances of the resulting solutions at the specified wavelength.

Determine the percentage of monosaccharide, disaccharide, and oligosaccharides in the portion of the sample taken:

$$\text{Result} = (D_U/D_S) \times (A_U - A_B)/(A_S - A_B) \times 100$$

D_U = dilution factor for the *Sample solution*, 4.1

D_S = dilution factor for the *Standard solution*, 50

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

A_B = absorbance of the *Blank*

Acceptance criteria: The total content of monosaccharide, disaccharide, and oligosaccharides is NMT 10.0%, corresponding to NLT 90% of glucan on the dried basis.

IMPURITIES

• **Residue on Ignition ⟨281⟩**
Sample: 2.0 g
Acceptance criteria: NMT 0.3%

• **Nitrogen Determination, *Method II*⟨461⟩**
Sample: 3 g, previously dried
Analysis: Proceed as directed in the chapter, replacing the 7 mL of sulfuric acid with 12 mL of sulfuric acid for the decomposition and replacing the 30 mL of sodium hydroxide solution (2 in 5) with 40 mL of a solution of sodium hydroxide (2 in 5).
Acceptance criteria: NMT 0.05%

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined molds and yeasts count does not exceed 10^2 cfu/g.

• **pH ⟨791⟩**
Sample: 1.0 g
Analysis: Dissolve the *Sample* in 10 mL of freshly boiled and cooled water.
Acceptance criteria: 4.5–6.5

• **Loss on Drying ⟨731⟩**
Analysis: Dry at 90° under vacuum for 6 h.
Acceptance criteria: NMT 6.0%

• **Viscosity—Capillary Methods ⟨911⟩**
Sample: Exactly 10.0 g, previously dried
Analysis: Dissolve the *Sample* in water to make exactly 100 g, and perform the test at 30 ± 0.1° using a Ubbelohde-type viscometer.
Acceptance criteria: The kinematic viscosity is 100–180 $mm^2 \cdot s^{-1}$.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. No storage requirements specified.

• **Labeling:** Label it to indicate the viscosity, giving the type of viscosity parameter, concentration of the solution, and the type of equipment used.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PULLULAN	Documentary Standards Support	CE2020 Complex Excipients

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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