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Gellan Gum

CAS RN®: 71010-52-1.

DEFINITION

Gellan Gum is a high-molecular-weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Pseudomonas elodea*, purified by recovery with isopropyl alcohol, and then dried and milled. It is a heteropolysaccharide comprising a tetrasaccharide repeating unit of one rhamnose, one glucuronic acid, and two glucose units. The glucuronic acid is neutralized to mixed potassium, sodium, calcium, and magnesium salts. It may contain acyl (glyceryl and acetyl) groups as the *O*-glycosidically linked esters. It yields NLT 3.3% and NMT 6.8% of carbon dioxide, calculated on the dried basis.

IDENTIFICATION

• **A.**

Sample solution: Hydrate 1 g of Gellan Gum in 99 mL of deionized water. Stir the mixture for 2 h, using a motorized stirrer and a propeller-type stirring blade.

Analysis: Draw a small amount of the solution obtained into a wide-bore pipet, and transfer it to a 10% calcium chloride solution. [NOTE—Reserve the remaining portion of this solution for *Identification* test *B*.]

Acceptance criteria: A tough, wormlike gel will form instantly.

• **B.**

Sample solution: The remaining *Sample solution* from *Identification* test *A*

Analysis: Add 0.5 g of sodium chloride, heat the solution to 80°, stirring constantly, and hold at 80° for 1 min. Stop heating and stirring the solution, and allow it to cool to room temperature.

Acceptance criteria: A firm gel will form.

ASSAY

• **Alginates Assay ⟨311⟩**

Sample: 1.2 g of undried Gellan Gum

Analysis: Proceed as directed for the *Procedure* in the chapter.

Acceptance criteria: 3.3%–6.8% of carbon dioxide on the dried basis

IMPURITIES

Change to read:

• ▲**Lead ⟨251⟩, *Procedures, Procedure 1***▲ (CN 1-Jun-2023)

Test preparation: Prepare as directed, using a 2.0-g portion of Gellan Gum. Use 4 mL of *Diluted Standard Lead Solution* (4 µg of Pb) for the test.

Acceptance criteria: NMT 2.0 µg/g

Change to read:

• ▲**Arsenic ⟨211⟩, *Procedures, Procedure 2***▲ (CN 1-Jun-2023) **:** NMT 3.0 µg/g

• **Limit of Isopropyl Alcohol**

Internal standard solution: 1 mg/mL of tertiary butyl alcohol

Standard stock solution: 1 mg/mL of isopropyl alcohol

Standard solution: Pipet 4 mL of the *Standard stock solution* and 4 mL of the *Internal standard solution* into a 100-mL volumetric flask, dilute with water to volume, and mix.

Sample solution: Disperse 1 mL of a suitable antifoam emulsion in 200 mL of water contained in a 1000-mL, round-bottom distilling flask having a 24/40 standard taper ground joint. Add 5 g of Gellan Gum, and shake for 1 h on a wrist-action mechanical shaker. Connect the

flask to a fractionating column, and distill about 100 mL, adjusting the heat so that foam does not enter the column. Add by pipet 4 mL of the *Internal standard solution*, and mix.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 3.2-mm × 1.8-m stainless steel; packed with 80- to 100-mesh surface silanized packing S3, or equivalent

Temperatures

Column: 165°

Detector: 200°

Injection port: 200°

Carrier gas: Helium

Injection volume: 4–5 µL

Analysis

Samples: *Standard solution* and *Sample solution*

[Note—The retention time of tertiary butyl alcohol is 1.5 relative to that of isopropyl alcohol.]

Calculate the amount of isopropyl alcohol in the portion of Gellan Gum taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of isopropyl alcohol to the internal standard from the *Sample solution*

R_S = peak response ratio of isopropyl alcohol to the internal standard from the *Standard solution*

C_S = concentration of isopropyl alcohol in the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.075%

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*. The total aerobic microbial count is NMT 10^3 cfu/g, and the total combined molds and yeasts count is NMT 10^2 cfu/g.

• **Articles of Botanical Origin,** *Total Ash* **⟨561⟩:** 4.0%–14.0% on the dried basis

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 2.5 h.

Acceptance criteria: NMT 15.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers, and store at room temperature.

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

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

Chromatographic Database Information: Chromatographic Database

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