Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Jun-2023
Document Type: NF Monographs
DocId: GUID-19CE56D5-FD93-4814-A4E4-8A232ED922F6_4_en-US
DOI: https://doi.org/10.31003/USPNF_M89160_04_01
DOI Ref: 5yb25

Xanthan Gum

DEFINITION

Xanthan Gum is a high molecular weight polysaccharide gum produced by a pure-culture fermentation of a carbohydrate with *Xanthomonas campestris*, then purified by recovery with Isopropyl Alcohol, dried, and milled. It contains D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid, and is prepared as the sodium, potassium, or calcium salt. It yields NLT 4.2% and NMT 5.0% of carbon dioxide, calculated on the dried basis, corresponding to NLT 91.0% and NMT 108.0% of Xanthan Gum.

IDENTIFICATION

• **A.**

Sample: Prepare a dry blend of 1.5 g of Xanthan Gum and 1.5 g of locust bean gum.

Control: 3.0 g of Xanthan Gum

Analysis

Samples: *Sample* and *Control*

To two separate 400-mL beakers add 300 mL of water, and heat to 80°. Stir rapidly by mechanical means. Add the *Sample* to one of the beakers and the *Control* to the other beaker at the point of maximum agitation. Stir until the mixtures dissolve, and then continue stirring for 30 min longer. Do not allow the temperature of the mixtures to drop below 60° during the stirring. Discontinue stirring, and allow the mixtures to cool at room temperature for NLT 2 h.

Acceptance criteria: A firm, rubbery gel forms with the *Sample* after the temperature drops below 40°, but no such gel forms with the *Control*.

ASSAY

• **Procedure**

Sample: 1.2 g

Analysis: Proceed as directed in *Alginates Assay* ⟨311⟩.

Acceptance criteria: 4.2%–5.0% of carbon dioxide on the dried basis, corresponding to 91.0%–108.0% of Xanthan Gum

IMPURITIES

Change to read:

• ▲*Arsenic* ⟨211⟩, *Procedures, Procedure 2*▲ (CN 1-Jun-2023) **:** NMT 3 µg/g

Change to read:

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

Sample: Prepare a *Test Preparation* as directed in the chapter

Control: Use 5 mL of *Diluted Standard Lead Solution* (5 µg of Pb).

Analysis: Proceed as directed in the chapter.

Acceptance criteria: NMT 5 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, and dilute with water to volume.

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 Xanthan Gum, and shake for 1 h on a wrist-action mechanical shaker. Connect the flask to a fractionating column, and distill 100 mL, adjusting the heat so that foam does not enter the column. Add by pipet 4 mL of the *Internal standard solution*.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 3.2-mm × 1.8-m stainless steel column 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 percentage of isopropyl alcohol in the portion of Xanthan Gum taken:

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

R_U = peak response ratio of isopropyl alcohol to tertiary butyl alcohol from the *Sample solution*

R_S = peak response ratio of isopropyl alcohol to tertiary butyl alcohol 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%

• **Pyruvic Acid**

Solution A: 5 mg/mL of 2,4-dinitrophenylhydrazine in 2 N hydrochloric acid

Standard stock solution: 90 µg/mL of pyruvic acid

Standard solution: Transfer 10.0 mL of the *Standard stock solution* to a glass-stoppered, 50-mL flask. Add 20.0 mL of 1 N hydrochloric acid, weigh the flask, and reflux for 3 h, taking precautions to prevent loss of vapors. Cool, and add water to make up for any weight loss during refluxing. Transfer 2.0 mL of this solution to a 30-mL separator containing 1.0 mL of *Solution A*. Mix, and allow to stand for 5 min. Extract the mixture with 5 mL of ethyl acetate, and discard the aqueous layer. Extract the hydrazone from the ethyl acetate with three 5-mL portions of sodium carbonate TS, collect the extracts in a 50-mL volumetric flask, and dilute with sodium carbonate TS to volume.

Sample stock solution: 6 mg/mL of Xanthan Gum

Sample solution: Transfer 10.0 mL of the *Sample stock solution* to a glass-stoppered, 50-mL flask. Proceed as directed in the *Standard solution*, beginning with "Add 20.0 mL of 1 N hydrochloric acid…".

Blank: Sodium carbonate TS

Instrumental conditions

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

Mode: Spectrophotometry

Analytical wavelength: 375 nm

Cell: 1 cm

Analysis

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

Acceptance criteria: The absorbance of the *Sample solution* is NLT that of the *Standard solution*, corresponding to NLT 1.5% of pyruvic acid.

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for *Salmonella* species and *Escherichia coli*.

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 2.5 h.

Acceptance criteria: NMT 15.0%

• **Ash**

Sample: Weigh 3 g in a tared crucible.

Analysis: Incinerate the *Sample* at 650° until free from carbon. Cool the crucible and its contents in a desiccator, and weigh.

Acceptance criteria: The weight of the ash is between 6.5%–16.0%, calculated on the dried basis.

- **Viscosity—Rotational Methods ⟨912⟩**

Sample: Prepare a dry blend of 3.0 g of Xanthan Gum and 3.0 g of potassium chloride.

Instrumental conditions

Instrument: Rotational viscometer

Spindle cylinder dimensions

Diameter: 1.27 cm

Height: 0.16 cm

Shaft diameter: 0.32 cm

Distance from top of cylinder to lower lip of shaft: 2.54 cm

Immersion depth: 5.00 cm (No. 3 spindle)

Spindle rotation speed: 60 rpm

Analysis: To a 400-mL beaker add 250 mL of water. Add the *Sample* slowly while stirring at 800 rpm, using a low-pitched, propeller-type stirrer. Add 44 mL of water, rinsing the walls of the beaker. Approximately 10 min after the addition of the *Sample* to the water, remove the beaker from the propeller-type stirrer, and vigorously stir the solution by hand to ensure that all the particles around the edge of the beaker are in solution. Return the beaker to the stirrer, and agitate at 800 rpm for a total mixing time of 2 h. Adjust the temperature to 24 ± 1°, and stir by hand in a vertical motion to eliminate any thixotropic effects or layering. Each hand mixing should be NMT 15–30 s, and the last hand mixing should occur immediately before measuring the viscosity. With the spindle rotating at 60 rpm, immediately observe and record the scale reading. Convert the scale readings to centipoises by multiplying the readings by the constant for the viscometer spindle and speed used.

Acceptance criteria: NLT 600 centipoises at 24°

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers.

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(6)

Current DocID: GUID-19CE56D5-FD93-4814-A4E4-8A232ED922F6_4_en-US

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