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Oxidized Regenerated Cellulose

DEFINITION

Oxidized Regenerated Cellulose contains NLT 18.0% and NMT 24.0% of carboxyl groups (COOH), calculated on the dried basis. It is sterile.

IDENTIFICATION

• **A.**

Sample solution: 200 mg in 10 mL of 0.25 N sodium hydroxide

Analysis 1: Shake the *Sample solution* for 1 min. Add 10 mL of water, and shake.

Acceptance criteria 1: The *Sample solution* shows no more than a slight haze and is substantially free from fibers and foreign particles.

Analysis 2: Allow the resulting solution to stand for 10 min.

Acceptance criteria 2: Any swollen fibers initially present are no longer visible.

Analysis 3: Acidify the resulting solution with 3 N hydrochloric acid.

Acceptance criteria 3: A flocculent white precipitate is formed.

ASSAY

• **Procedure**

Sample: 1 g of Oxidized Regenerated Cellulose, previously dried at 90° for 2 h

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.1 N hydrochloric acid VS

Endpoint detection: Visual

Analysis: Place the *Sample* in a 250-mL conical flask, add 10 mL of 0.5 N sodium hydroxide VS, swirl to dissolve, and add 100 mL of water. Immediately titrate with *Titrant* to a phenolphthalein endpoint. Perform a blank determination, and note the difference in volumes required. Each mL of the difference in volumes of 0.1 N hydrochloric acid consumed is equivalent to 4.50 mg of carboxyl groups (COOH).

Acceptance criteria: 18.0%–24.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.15%

• **Limit of Nitrogen**

Solution A: 40 mg/mL of boric acid

Solution B: Methyl red TS and bromocresol green TS (1:4)

Sample: 1 g, previously dried

Titrimetric system

(See *Titrimetry ⟨541⟩*.)

Mode: Direct titration

Titrant: 0.02 N sulfuric acid VS

Endpoint detection: Visual

Analysis: Place a 125-mL conical flask, containing 30 mL of *Solution A* and 6 drops of *Solution B*, beneath the condenser of the distillation apparatus so that the tip of the condenser is well below the surface of the resulting solution. To a 500-mL Kjeldahl flask add the *Sample*, and add 1 g of Devarda's alloy, 100 mL of recently boiled water, a small lump of paraffin, and 100 mL of 1 N sodium hydroxide. Connect the Kjeldahl flask to the condenser by a suitable trap bulb. Heat the mixture in the flask until 45–50 mL of distillate has collected in the receiver. Rinse the condenser, and titrate the resulting solution with *Titrant* to a pale pink endpoint that persists for 30 s. Perform a blank determination, and make any necessary correction. Each mL of *Titrant* is equivalent to 0.2801 mg of nitrogen.

Acceptance criteria: NMT 0.5%

• **Limit of Formaldehyde**

Solution A: Formaldehyde in water (1 in 40,000)

Standard: 0.50 mL of *Solution A*

Sample: 500 mg

Instrumental conditions

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

Mode: Vis

Analytical wavelength: 570 nm

Blank: Mixture of 0.5 mL of water and 10 mL of chromotropic acid TS

Analysis: Transfer the *Sample* to a 500-mL iodine flask. Add 250 mL of water, and allow to stand for NLT 2 h with intermittent shaking. Pipet 0.50 mL each of the supernatant from the resulting solution and the *Standard* into two separate glass-stoppered test tubes. To each test tube add 10 mL of chromotropic acid TS. Stopper the tubes loosely, and heat in a boiling water bath for 30 min. Cool, and determine the absorbance of each solution against the *Blank*.

Acceptance criteria: 0.5% CH_2O; the absorbance of the *Sample* is NMT the *Standard*.

SPECIFIC TESTS

• **Sterility Tests ⟨71⟩**

Sample: 250 mg

Analysis: Proceed as directed in the chapter, adding 0.5 mL of 0.1 N sodium hydroxide to the portions of media used.

Acceptance criteria: Meets the requirements

• **Loss on Drying ⟨731⟩**

Sample: 150 mg

Analysis: Dry at 90° for 2 h.

Acceptance criteria: NMT 15.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*, protected from direct sunlight. Store at controlled room temperature.

• **Labeling:** The package bears a statement to the effect that the sterility of Oxidized Regenerated Cellulose cannot be guaranteed if the package bears evidence of damage, or if the package has been previously opened. Oxidized Regenerated Cellulose meets the requirements for *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

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

Topic/Question	Contact	Expert Committee
OXIDIZED REGENERATED CELLULOSE	Leslie Furr Associate Scientific Liaison	GCDF2020 General Chapters - Dosage Forms 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	GCDF2020 General Chapters - Dosage Forms 2020

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