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# Purified Cotton

## DEFINITION

Purified Cotton is the hair of the seed of cultivated varieties of *Gossypium hirsutum* L. or other species of *Gossypium* (Family Malvaceae), freed from adhering impurities, deprived of fatty matter, bleached, and sterilized in its final container.

## IDENTIFICATION

Add the following:

▲ **A. [AUXILIARY PACKAGING COMPONENTS \(670\)](#), [Pharmaceutical Coil](#), [Cotton Pharmaceutical Coil](#):** Meets the requirements ▲ (USP 1-Dec-2020)

Add the following:

▲ **B. FLUORESCENCE:** No intense blue with UV ▲ (USP 1-Dec-2020)

## IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#).

**Sample:** 5 g of Purified Cotton

**Analysis:** Place the *Sample* in a porcelain or platinum dish, and moisten with 2 N sulfuric acid. Gently heat the cotton until it is charred, then ignite more strongly until the carbon is completely consumed.

**Acceptance criteria:** NMT 0.20% of residue remains.

• **ORGANIC IMPURITIES: FATTY MATTER**

**Sample:** 10 ± 0.01 g of Purified Cotton

**Analysis:** Pack the *Sample* in a Soxhlet extractor provided with a tared receiver, and extract with ether for 5 h at a rate such that the ether siphons over NLT 4 times/h. The ether solution in the flask shows no trace of blue, green, or brownish color. Evaporate the extract to dryness, and dry at 105° for 1 h.

**Acceptance criteria:** The weight of the residue is NMT 70 mg (0.7%).

## SPECIFIC TESTS

• **ACIDITY OR ALKALINITY**

**Sample:** 10 g of Purified Cotton

**Analysis:** Thoroughly saturate the *Sample* with 100 mL of recently boiled and cooled water, then with the aid of a glass rod, press out two 25-mL portions of the water into white porcelain dishes. To one portion add 3 drops of [phenolphthalein TS](#), and to the other portion add 1 drop of [methyl orange TS](#).

**Acceptance criteria:** No pink color develops in either portion.

Add the following:

▲ **LOSS ON DRYING**

[AUXILIARY PACKAGING COMPONENTS \(670\)](#), [Pharmaceutical Coil](#), [Cotton Pharmaceutical Coil](#): Meets the requirements ▲ (USP 1-Dec-2020)

• [STERILITY TESTS \(71\)](#): Meets the requirements

• **WATER-SOLUBLE SUBSTANCES**

**Sample:** 10 g of Purified Cotton

**Analysis:** Place the *Sample* in a beaker containing 1000 mL of water and boil gently for 30 min, adding water as required to maintain the volume. Pour the water through a funnel into another vessel, and press out the excess water from the cotton with a glass rod. Wash the cotton in the funnel with two 250-mL portions of boiling water, pressing the cotton after each washing. Filter the combined extract and washings, and wash the filter thoroughly with hot water. Evaporate the combined extract and washings to a small volume, transfer to a tared porcelain or platinum dish, evaporate to dryness, and dry the residue at 105° to constant weight.

**Acceptance criteria:** The residue weighs NMT 35 mg (0.35%).

Add the following:

▲ • **FIBER LENGTH**

**Sample:** Remove Purified Cotton from its wrappings, and condition it for NLT 4 h in a standard atmosphere of  $65 \pm 2\%$  relative humidity at  $21 \pm 1^\circ$  before determining the fiber length.

**Analysis:** Determine the fiber length using a suitable method.

**Acceptance criteria:** NMT 10% of the fibers by weight are 6.25 mm or less in length. ▲ (USP 1-Dec-2020)

**Add the following:**

▲ • **ABSORBENCY**

**Sample:** Remove Purified Cotton from its wrappings, and condition it for NLT 4 h in a standard atmosphere of  $65 \pm 2\%$  relative humidity at  $21 \pm 1^\circ$  before determining the absorbency.

**Analysis:** Prepare a test basket, weighing NMT 3 g, from copper wire approximately 0.4 mm in diameter (No. 26, B. & S. gauge) in the form of a cylinder approximately 5 cm in diameter and 8 cm deep, with spaces of about 2 cm between the wires. Take portions of cotton weighing  $1 \pm 0.05$  g from five different parts of the package by pulling, not cutting, the specimens. Combine the portions in the basket and weigh. Hold the basket on its side approximately 12 mm above the surface of water at  $25 \pm 1^\circ$  and drop it into the water. Determine, preferably by use of a stopwatch, the time in seconds required for complete submersion. Remove the basket from the water, allow it to drain for 10 s in the same horizontal position, then place it immediately in a tared, covered vessel, and weigh, deducting the weight of the test basket and of the cotton to determine the weight of water absorbed.

**Acceptance criteria:** Submersion is complete in 10 s at a temperature of  $25^\circ$ , and the cotton retains NLT 24 times its weight of water. ▲ (USP 1-Dec-2020)

**Delete the following:**

▲ • **COTTON (691), Fiber Length** and **Absorbency Test:** Remove it from its wrappings, and condition it for NLT 4 h in a standard atmosphere of  $65 \pm 2\%$  relative humidity at  $21 \pm 1.1^\circ$  ( $70 \pm 2^\circ\text{F}$ ), before determining the *Fiber length* and *Absorbency*.

**Fiber length**

**Analysis:** Determine the fiber length of Purified Cotton as directed under [Cotton \(691\), Fiber Length](#).

**Acceptance criteria:** NLT 60% of the fibers by weight are 12.5 mm or greater in length, and NMT 10% of the fibers by weight are 6.25 mm or less in length.

**Absorbency**

**Analysis:** Proceed as directed under [Cotton \(691\), Absorbency Test](#).

**Acceptance criteria:** Submersion is complete in 10 s at a temperature of  $25^\circ$ , and the cotton retains NLT 24 times its weight of water. ▲ (USP 1-Dec-2020)

• **DYES**

**Sample:** 10 g of Purified Cotton

**Analysis:** Pack the *Sample* in a narrow percolator, and extract slowly with alcohol until the percolate measures 50 mL.

**Acceptance criteria:** When observed downward through a column 20 cm in depth, the percolate may show a yellowish color but neither a blue nor a green tint.

**Change to read:**

• **OTHER FOREIGN MATTER:** The ▲samples▲ (USP 1-Dec-2020) of Purified Cotton taken for the determination of fiber length in the test for *Fiber Length* contain no oil stains or metallic particles ▲on visual inspection.▲ (USP 1-Dec-2020)

**ADDITIONAL REQUIREMENTS**

• **PACKAGING AND STORAGE:** Package Purified Cotton in rolls of NMT 500 g of a continuous lap, with a lightweight paper running under the entire lap, the paper being of such width that it may be folded over the edges of the lap to a distance of at least 25 mm, the two together being tightly and evenly rolled, enclosed, and sealed in a well-closed container. It also may be packaged in other types of containers if these are so constructed that the sterility of the product is maintained.

• **LABELING:** Its label bears a statement to the effect that the sterility cannot be guaranteed if the package bears evidence of damage or if the package has been opened previously.

**Auxiliary Information** - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PURIFIED COTTON	<a href="#">Leslie Furr</a> Associate Scientific Liaison	GCDF2020 General Chapters - Dosage Forms 2020

**Chromatographic Database Information:** [Chromatographic Database](#)

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