

Official Monographs For Part II, JPXIV

Absorbent Cotton

脱脂綿

Absorbent Cotton is the hair of the seed of *Gossypium hirsutum* Linné, or of other species of the same genus (*Malvaceae*), deprived of fatty matter, and bleached.

Description Absorbent Cotton occurs as white, soft, fine filament-like hairs. It is odorless and tasteless.

Under a microscope, Absorbent Cotton occurs as hollow, flattened and twisted bands, striate, and slightly thickened at the edges.

It dissolves in ammonia copper TS, and does not dissolve in ordinary solvents.

Purity Obtain certain amount of Absorbent Cotton from different 10 parts of the same package, and combine them to the required amount. Use this as the sample for Purity.

(1) Acid or alkali—Add 100 mL of freshly boiled and cooled water to 10 g of Absorbent Cotton, digest, and add 3 drops of phenolphthalein TS to 25 mL of the extract: no red color develops. Add 1 drop of methyl orange TS to 25 mL of the extract: no red color develops.

(2) Water-soluble substances—To 5 g of Absorbent Cotton add 500 mL of water, and boil gently for 30 minutes, while adding water to maintain the original volume. Pour the extract through a funnel into another vessel, transfer the cotton to the funnel, and press out the water absorbed therein with a glass rod. Wash the cotton with two 150-mL portions of hot water, pressing the cotton after each washing. Filter the combined extracts and washings. Evaporate to concentrate the filtrate, transfer to a weighing bottle, and dry at 105°C to constant mass: the amount of the residue is not more than 14.0 mg. Perform a blank determination, and make any necessary correction.

(3) Dyes—Digest 10 g of Absorbent Cotton with 100 mL of ethanol (95), press out, and transfer 50 mL of the extracts to a Nessler tube. Observe downward: a yellow color develops, but neither a blue nor a green color develops.

(4) Fluorescent whitening agents—Irradiate Absorbent Cotton with ultraviolet rays in a dark place: no fluorescence is perceptible on the surface.

(5) Submersion rate—Prepare a test basket, weighing 3.0 g, from copper wire 0.44 mm in diameter in the form of a cylinder 50.0 mm in diameter and 80.0 mm in depth, with spaces of 20 mm between the wires. Place 5 g of Absorbent Cotton in the basket, hold the basket on its side 12 mm above the surface of water between 24°C and 26°C, and drop the basket gently into the water, which is 200 mm

deep: the time required for complete submersion is not more than 8 seconds.

(6) Absorbency—Leave the submerged basket at the bottom of the water in (5) as it is for 3 minutes. Lift the basket gently from the water, keeping its side horizontal, and allow to drain for 1 minute on the wire gauze of a sieve No. 10 in the same horizontal position. Then place in a beaker and weigh: the mass of water absorbed is not less than 100.0 g.

(7) Other filaments—Dip 1.0 g of Absorbent Cotton in 0.5 mol/L iodine TS for 0.5 minute, and wash well with water: no colored filament is found.

(8) Neps and adhering impurities—Spread evenly about 1 g of Absorbent Cotton between two 10 cm-square, colorless, transparent plates, and examine neps and adhering impurities (fragments of rinds and seeds): the total number of the fragments more than 2.5 mm in diameter is not more than 5.

Total ash Not more than 0.25% (5 g, proceed as directed in the Total ash under Crude Drugs).

Containers and storage Containers—Well-closed containers.

Purified Absorbent Cotton

精製脱脂綿

Purified Absorbent Cotton is the hair of the seed of *Gossypium hirsutum* Linné, or of other species of the same genus (*Malvaceae*), carefully selected, free from adhering impurities, deprived of fatty matter, and bleached.

Description Purified Absorbent Cotton occurs as white, soft, fine filament-like hairs. It is odorless and tasteless.

Under a microscope, Purified Absorbent Cotton occurs as hollow, flattened and twisted bands, striate and slightly thickened at the edges.

It dissolves in ammonia copper TS, and does not dissolve in ordinary solvents.

Purity Obtain certain amount of Purified Absorbent Cotton from different 10 parts of the same package, and combine them to the required amount. Use this as the sample for Purity.

(1) Acid or alkali—Add 100 mL of freshly boiled and cooled water to 10 g of Purified Absorbent Cotton, digest, and add 3 drops of phenolphthalein TS to 25 mL of the extract: no red color develops. Add 1 drop of methyl orange TS to 25 mL of the extract: no red color develops.

(2) Water-soluble substances—To 5 g of Purified Absorbent Cotton add 500 mL of water, and boil gently for 30 minutes, while adding water to maintain the original volume. Pour the extract through a funnel into another vessel, transfer the cotton to the funnel, and press out the water absorbed therein with a glass rod. Wash the cotton with two 150-mL portions of hot water, pressing the cotton after each washing. Filter the combined extracts and washings. Evaporate to concentrate the filtrate, transfer to a weighing bottle, and dry at 105°C to constant mass: the amount of the residue is not more than 14.0 mg. Perform a blank determination, and make any necessary correction.

(3) Dyes—Digest 10 g of Purified Absorbent Cotton with 100 mL of ethanol (95), press out, and transfer 50 mL of the extracts to a Nessler tube. Observe downward: a yellow color develops, but neither a blue nor a green color develops.

(4) Fluorescent whitening agents—Irradiate Purified Absorbent Cotton under ultraviolet rays in a dark place: no fluorescence is perceptible on the surface.

(5) Submersion rate—Prepare a test basket, weighing 3.0 g, form copper wire 0.44 mm in diameter in the form of a cylinder 50.0 mm in diameter and 80.0 mm in depth, with spaces of 20 mm between the wires. Place 5 g of Purified Absorbent Cotton in the basket, hold the basket on its side 12 mm above the surface of water between 24°C and 26°C, and drop the basket gently into the water, which is 200 mm deep: the time required for complete submersion is not more than 8 seconds.

(6) Absorbency—Leave the submerged basket at the bottom of the water in (5) as it is for 3 minutes. Lift the basket gently from the water, keeping its side horizontal, and allow to drain for 1 minute on the wire gauze of a sieve No. 10 in the same horizontal position. Then place in a beaker and weigh: the mass of water absorbed is not less than 100.0 g.

(7) Other filaments—Dip 1.0 g of Purified Absorbent Cotton in 0.5 mol/L iodine TS for 1 minute, and wash well with water: no colored filament is found.

(8) Neps and adhering impurities—Spread evenly about 1 g of Purified Absorbent Cotton between two 10 cm-square, colorless, transparent plates, and examine neps and adhering impurities (fragments of rinds and seeds): the total number of the fragments more than 2.5 mm in diameter is not more than 5.

(9) Short fibers—Take 0.10 g of Purified Absorbent Cotton, separate the fibers into two groups, one consisting of fibers not exceeding 6.0 mm in length (short fibers) and the other consisting of fibers exceeding 6.0 mm in length, weigh both groups, and determine the content (%) of the short fibers: not more than 10%.

$$\begin{aligned} & \text{Percentage (\%)} \text{ of the short fibers} \\ & = \frac{W_2}{W_1 + W_2} \times 100 \end{aligned}$$

W_1 : Mass of the group of fibers exceeding 6.0 mm in length

W_2 : Mass of the group of fibers not exceeding 6.0 mm in length

Total ash Not more than 0.25% (5 g, proceed as directed in the Total ash under Crude Drugs).

Containers and storage Containers—Well-closed containers.

Sterile Absorbent Cotton

滅菌脫脂綿

Sterile Absorbent Cotton is sterilized Absorbent Cotton.

Description Apply the Description under Absorbent Cotton.

Purity Proceed as directed in the Purity under Absorbent Cotton.

Total ash Proceed as directed in the Total ash under Absorbent Cotton.

Sterility Take Sterile Absorbent Cotton from package abacterially under an aseptic circumstances, sample about 0.5 g of it (whole content in the case of less than 0.5 g) evenly from 5 different parts around the center portion, put the samples in a test tube of 25 mm × 200 mm containing 60 mL each of fluid thioglycollate medium I for the Sterility Test for the growth of bacteria and fungi: it meets the requirements of the Sterility Test. In the case of the test for the growth of fungi, a 200-mL Erlenmeyer flask can also be used. In this connection, perform an efficient test of the medium under a condition without the samples: the medium supports the substantial growth of the incubated microorganisms.

Sample number used in the Sterility Test is indicated in the following table.

Number of products of the same kind sterilized simultaneously	Number of products used for test
Not more than 100	4
100 to not more than 500	10
Not less than 500	20

Containers and storage Containers—Tight containers impervious to any microbe.

Sterile Purified Absorbent Cotton

滅菌精製脫脂綿

Sterile Purified Absorbent Cotton is sterilized Purified Absorbent Cotton.

Description Apply the Description under Purified Absorbent Cotton.

Purity Proceed as directed in the Purity under Purified Absorbent Cotton.

Total ash Proceed as directed in the Total ash under Purified Absorbent Cotton.

Sterility Take Sterile Purified Absorbent Cotton from package abacterially under an aseptic circumstances, sample about 0.5 g of it (whole content in the case of less than 0.5 g) evenly from 5 different parts around the center portion, put