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.

Absorbent Gauze

ガーゼ

Absorbent Gauze consists of non-fatty and well-bleached cotton cloth of plain weave using pure cotton threads obtained from hairs of the seed of *Gossypium hirsutum* Linné or other species of the same genus (*Malvaceae*). The amount of Absorbent Gauze is expressed in terms of its type, length and width.

Description Absorbent Gauze occurs as white cotton cloth. It is odorless and tasteless.

Purity (1) Water-soluble substances—Place 20 g of Absorbent Gauze in 500 mL of water, and boil gently for 15 minutes, while adding water to maintain the original volume. Pour the extract through a funnel into a 1000-mL flask, transfer the Absorbent Gauze to the funnel, press out the water absorbed therein with a glass rod, and wash Absorbent Gauze with two 250-mL portions of boiling water, pressing after each washing. Combine the extract and the washings, filter, and add water to make 1000 mL. Transfer 400 mL of the filtrate to a beaker, evaporate to concentrate, and place the residue in a weighing bottle. Wash the beaker with a small amount of water, combine the washings with the residue in the weighing bottle, and dry at 105°C to constant mass: the mass of the residue is not more than 20.0 mg. Perform a blank determination, and make any necessary correction.

(2) Acid or alkali—To 200 mL of the extract obtained in (1), add 5 drops of phenolphthalein TS: no red color develops. To 200 mL of the sample solution add 2 drops of methyl orange TS: no red color develops.

(3) Dextrin or starch—To 200 mL of the extract obtained in (1) add 2 drops of iodine TS: no red-purple to blue color develops.

(4) Dyes—Digest 10 g of Absorbent Gauze with 80 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.

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

(6) Submersion rate—Prepare a test basket from copper wire 0.4 mm in diameter (No. 26 wire) 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, the basket weighing 3.0 g. Place 10 g of Absorbent Gauze evenly 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.

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

Texture The texture requirements of Absorbent Gauze are given in the following table.

Type	Threads per 1 cm (number)				Tolerance in average counts of threads per 1 cm × 1 cm	Standard width (cm)	Standard mass (g)
	Warp		Filling				
	Average	Tolerance	Average	Tolerance			
I	12	±1	12	±1	24^{+2}_{-1}	$30^{+0.5}_{-1.0}$	width 30 cm length 100 cm 10.3 + 8%
II	12	±1	12	±1	24^{+2}_{-1}	91.4 + 1.5	width 91.4 cm length 30 cm 8.7 + 8%
III	11	±1	9	±1	20^{+2}_{-1}	91.4 + 1.5	width 91.4 cm length 30 cm 7.6 + 8%
IV	9	±1	8	±1	17^{+2}_{-1}	91.4 + 1.5	width 91.4 cm length 30 cm 6.1 + 8%

Length: Place Absorbent Gauze on a flat plate, eliminate the unnatural creases or tensions, and measure the full length at the center line: the length is not less than 95% of the labeled length. When it has closely woven parts at both edges in the direction of the length, measure the full length. When it has no closely woven parts, measure only the net.

Width: Place Absorbent Gauze on a flat plate, smooth out the unnatural creases or tensions, and measure the full width at more than 3 different locations: the average of these measurements is not less than 80% and not more than 120% of the labeled width which is not more than 5 cm, not more than −1.0 cm and not less than +0.5 cm of the labeled width which is between 5 cm and 30 cm, and within ±1.5 cm of the labeled width which is above 30 cm. When it has closely woven parts at both edges in the direction of the width, measure the full width. When it has no closely woven parts, measure only the net.

Number of threads: Prepare a frame of 1 cm × 1 cm, and set the thread to the edge of the frame. Count the integral number of the threads in the frame and average the results of more than 3 counts. Except the closely woven parts.

Mass: Fold Absorbent Gauze into about a 10-cm square, allow to stand at ordinary temperature for 4 hours in a desiccator, previously saturated with the vapor above a saturated solution of sodium nitrite, and weigh. For pieces in various

dimensions not conforming to the standard width and length as specified for each type, use about 900 cm^2 of sample, and calculate by making the necessary correction based on the mass of the standard area. In this case, the tolerance is ±12%. When it has closely woven parts at both edges in the length and width directions, measure full length and full width. When it has no closely woven parts in the length and width directions, prepare only the net, measure the length and the width, and calculate by making the necessary correction based on the mass of the standard area.

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 Gauze

滅菌ガーゼ

Sterile Absorbent Gauze is sterilized Absorbent Gauze.

Description Sterile Absorbent Gauze occurs as white cotton cloth. It is odorless and tasteless.

Purity **(1)** Water-soluble substances—Place 20 g of Sterile Absorbent Gauze in 500 mL of water, and boil gently for 15 minutes, while adding water to maintain the original volume. Pour the extract through a funnel into a 1000-mL flask, transfer the absorbent gauze to the funnel, press out the water absorbed therein with a glass rod, and wash the absorbent gauze with two 250-mL portions of boiling water, pressing after each washing. Combine the extract and the washings, filter, and add water to make 1000 mL. Transfer 400 mL of the filtrate to a beaker, evaporate to concentrate, and place the residue in a weighing bottle. Wash the beaker with a small amount of water, combine the washings with the residue in the weighing bottle, and dry at 105°C to constant mass: the mass of the residue is not more than 20.0 mg. Perform a blank determination, and make any necessary correction.

(2) Acid or alkali—To 200 mL of the extract obtained in (1), add 5 drops of phenolphthalein TS: no red color develops. Too 200 mL of the extract solution add 2 drops of methyl orange TS: no red color develops.

(3) Dextrin or starch—To 200 mL of the extract obtained in (1) add 2 drops of iodine TS: no red-purple to blue color develops.

(4) Dyes—Digest 10 g of Sterile Absorbent Gauze with 80 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.

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

(6) Submersion rate—Prepare a test basket from copper wire 0.4 mm in diameter (No. 26 wire) in the form of cylinder 50.0 mm in diameter and 80.0 mm in depth, with spaces of 200 mm between the wires, the basket weighing 3.0 g. Place 10 g of Sterile Absorbent Gauze evenly 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.

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

Texture The texture requirements of Sterile Absorbent Gauze are given in the following table.

Type	Threads per 1 cm (number)				Tolerance in average counts of threads per 1 cm × 1 cm	Standard width (cm)	Standard mass (g)
	Warp		Filling				
	Average	Tolerance	Average	Tolerance			
I	12	±1	12	±1	24^{+2}_{-1}	$30^{+0.5}_{-1.0}$	width 30 cm length 100 cm 10.3 + 8%
II	12	±1	12	±1	24^{+2}_{-1}	91.4 + 1.5	width 91.4 cm length 30 cm 8.7 + 8%
III	11	±1	9	±1	20^{+2}_{-1}	91.4 + 1.5	width 91.4 cm length 30 cm 7.6 + 8%
IV	9	±1	8	±1	17^{+2}_{-1}	91.4 + 1.5	width 91.4 cm length 30 cm 6.1 + 8%

Length: Place Sterile Absorbent Gauze on a flat plate, eliminate the unnatural creases or tensions, and measure the full length at the center line: the length is not less than 95% of the labeled length. When it has closely woven parts at both edges in the direction of the length, measure the full length. When it has no closely woven parts, measure only the net.

Width: Place Sterile Absorbent Gauze on a flat plate, smooth out the unnatural creases or tensions, and measure the full width at more than 3 different locations: the average of these measurements is not less than 80% and not more than 120% of the labeled width which is not more than 5 cm, not more than −1.0 cm and not less than +0.5 cm of the labeled width which is between 5 cm and 30 cm, and within ±1.5 cm of the labeled width which is above 30 cm. When it has closely woven parts at both edges in the direction of the width, measure the full width. When it has no closely woven parts, measure only the net.

Number of threads: Prepare a frame of 1 cm × 1 cm, and set the thread to the edge of the frame. Count the integral number of the threads in the frame and average the results of more than 3 counts. Except the closely woven parts.

Mass: Fold Sterile Absorbent Gauze into about a 10-cm square, allow to stand at ordinary temperature for 4 hours in a desiccator, previously saturated with the vapor above a saturated solution of sodium nitrite, and weigh. For pieces in various dimensions not conforming to the standard width and length as specified for each type, use about 900 cm^2 of sample, and calculate by making the necessary correction based on the mass of the standard area. In this case, the tolerance is ±12%. When it has closely woven parts at both edges in the length and width directions, measure full length and full width. When it has no closely woven parts in the