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PURIFIED STERILIZED COTTON

Hydrophilic cotton. Absorbent cotton.

Purified cotton is comprised of fibers from different cultivated seeds of the *Gossypium* (Malvaceae) genus, which are bleached, carded and free from fatty materials, resinous materials and other impurities capable of absorbing water.

Purified cotton, when impregnated with drug substances, must present an evenly distributed concentration. It must not contain substances or concentrations capable of causing toxic or reactional accidents.

CHARACTERISTICS

Aspect. Thin white fibers, soft to the touch and with loose consistency, with no lumps and without any impurities; purified cotton is odorless and tasteless. At the microscopic examination, it presents only fine, hollow, flattened, twisted, ribbed fibers, slightly thickened on the edges.

Length of fiber. Determine the length of the fiber after placing the cotton, free (exempt) from packaging, for four hours in a relative humidity atmosphere (65 ± 2)%, at temperature of (21 ± 1)°C; not less than 60% in weight of the fibers, must measure 12.5 mm or more, with up to 10% in weight of fibers measuring 6 mm or less being permitted.

Absorbent power. Proceed as indicated in the determination of the absorbent power of cotton, after placing the cotton, for four hours, in the atmospheric conditions indicated above; the absorption must be completed in 10 seconds and the cotton must retain water not less than 24 times its weight.

Solubility. It is insoluble in common solvents and soluble in ammonium cupric sulfate RS.

PURITY TESTS

Acidity or alkalinity. Pour approximately 10 g in a precipitation vial containing 100 mL of distilled water recently boiled and cooled down without agitation. Compress the cotton with a glass rod, squeeze and transfer portions with 25 mL to two porcelain capsules. Add one drop of methyl orange SI to one of the capsules and three drops of phenolphthalein SI to the other capsule; no rosy or red coloring should be produced.

Loss by desiccation (5.2.9). Purified cotton, dried at 100°C, must not lose more than 8% of its weight.

Determination of sulfated ashes (5.2.10). Pour about 5 g, accurately weighed, in a tared crucible and moisten with diluted sulfuric acid. Carefully heat until it turns black and, then, increase the heat until full incineration; the residue must not exceed 0.2%.

Coloring agents. Pour 10 g in a percolator with narrow diameter and proceed to its slow extraction with ethylic alcohol, until the percolate achieves 50 mL; observing over a white background, in a column with 20 cm of height, the liquid may present slightly yellowish color, but never green or blue.

Fatty substances. Pour approximately 10 g, accurately weighed, in a Soxhlet extractor and proceed to its extraction with ethyl ether, regulating the heating to obtain, not less than four siphonage

operations per hour. Continue the extraction for five hours. The ether extract must not present vestiges of blue, green or brownish color. Evaporate the extract until it dries, heat at 105°C for one hour, cool down in a drier and weigh; the residue must not exceed 0.7%.

Water-soluble substances. Pour approximately 10 g, accurately weighed, into a precipitation flask with 1000 mL of distilled water and boil in low heat for 30 minutes, adding distilled water, when necessary, to maintain the volume constant. Transfer the content to another vial, removing the excess water retained by the cotton, compressing with a glass rod. Wash the cotton twice, with portions of 250 mL of boiling distilled water, squeezing after each washing. Filter the liquids from extraction and washing, wash the filter with hot water, and evaporate the filtrate until about 50 mL. Transfer the concentrate to a porcelain crucible, tared in advance, wash the container storing it with distilled water, and collect the washing liquids in this crucible. Evaporate until dry; the residue dried at 105°C, until constant weight, must not exceed 0.25%.

Other foreign substances. Portions of hydrophilic cotton, removed from the original packaging, must not present oil stains, metallic particles, or any other foreign substances.

BIOLOGICAL SAFETY TESTS

Sterility (5.5.3.2.1). Hydrophilic cotton must be sterilized in the packages presented for consumption. When expressly declared as sterile or sterilized, it must meet the requirements specified in sterility tests for solids.

PACKAGING AND STORAGE

In rolls with weight not exceeding 500 g, on continuous layers, on adequate paper, with width and length that enable folding not less than 25 mm over the margins of the cotton layer. The rolls must receive a second wrapping that offers full protection against dust. Purified cotton, when declared sterile or sterilized, must be stored in such a way that its sterility is protected from future contamination.

It may also be stored in different manners and in other types of packaging, provided that the sterility conditions required for the product are met.

LABELLING

Comply with current legislation. The label must include the manufacturer’s name, net weight and, in case of cotton impregnated with drug substances, the formula used.

CATEGORY

Adjuvant for use in general healthcare units

GAUZE BANDAGE

The gauze bandage is comprised of a continuous strip of purified gauze, type I, firmly rolled, with varied widths and lengths, free from lints and from folding.

The gauze bandage, previously unrolled, must meet all requirements established for the purified hydrophilic gauze fabrics, determined according to the respective techniques and to the following specifications.

CHARACTERISTICS

Length. Determine by measuring along the medial bandage line, unrolled and straightened without traction; the length must be not less than 98% of the one indicated on the labelling.

Width. Measure the width in three points evenly spread along the open bandage. The average of the three measures must present a maximum dimensional variation of 2% in relation to the one declared on the labelling.

Number of threads. Determine the number of threads of the warp and the weave in five areas with 1 cm × 1 cm, on the central line of the bandage, in regular interval points, not less than 30 cm away from the end, and calculate the number of threads in an area of 5 cm × 5 cm.

Weight. Determine the weight of the entire bandage roll and, using the results from previous measurements, calculate the weight per square meter.

Absorbent power. Hold the bandage, duly unrolled horizontally and almost in contact with a surface of distilled water, and gently allow it to fall over the liquid; the bandage must submerge completely within 30 seconds.

Drug or adhesive substances. The gauze bandage, when impregnated with drug substances or adhesive mixtures, must present an evenly distributed concentration. It must not contain substances in concentrations capable of causing toxic or reactional accidents.

BIOLOGICAL SAFETY TESTS

Sterility (5.5.3.2.1). Applicable when the bandage is declared sterile. Complies with the test.

LABELLING

Comply with current legislation.

MEDICAL TAPE

It consists on fabric from different origins evenly coated in one of the sides with an adhesive layer sensitive to pressure.

The medical tape has a flat, even, lump-free adhesive surface; it presents neutral reaction and is free from toxic or irritating substances. The side that is opposite to the adhesive mixture can be coated with a thin layer of waterproof substances. In general, it is presented as a roll in continued bands with different dimensions. The medical tape must be free from impurities and contamination.

CHARACTERISTICS

Dimension. Determine the length of the medical tape. The result obtained must not be less than 98% of the length declared on the labelling. Determine the width of the medical tape on five different points along its length. The average from results must not present a difference greater than 1.6 of the width declared on the labelling.

Tensile strength (5.7.1). Determine the tape tensile strength after unrolling and storing for a minimum period of four hours in standard atmosphere with (65 ± 2)% of relative humidity, at (21 ± 1.1)°C, using a pendulum device. Proceed as described in *Tensile strength.* The average with three determinations on strips with 2.5 cm of width must not be less than 20 kg.

Adhesion to surface. From the sample manufactured in fabric, cut a band with 2.54 cm of width and approximately 15 cm of length. Apply pressure equivalent to 850 g to one of the tape ends, with surface equal to 12.90 cm^2, 2.54 cm of width by 5.08 cm of length, against a clean glass, plastic or stainless steel surface. Apply pressure with the help of a rubber roll for two consecutive times at a speed of 30 cm per minute. Adjust the surface and tape temperature to 37°C and run the test immediately as described on *Tensile strength* **(5.7.1)**. Use a pendulum, with the rupture conducted in parallel to the warp and to the surface. The average value from not less than 10 tests must be not less than 18 kg.

BIOLOGICAL SAFETY TESTS

Sterility (5.5.3.2.1). Applicable when the medical tape is declared as sterile. Complies with the test.

PACKAGING AND STORAGE

In properly closed packages, protected from light and excessive heat.

The medical tape, when declared sterile or sterilized, must be stored in such a way that its sterility is protected from future contamination.

LABELLING

Comply with current legislation.

ADHESIVE TAPE

It consists of fabric and/or film evenly coated in one of the sides with an adhesive layer sensitive to pressure.

CHARACTERISTICS

Dimensions. Determine the length of the medical tape. Not less than 98.0% of the value declared. Determine the width on five points evenly spaced along the tape central line and calculate the average. Not less than 95.0% of the value declared.

Tensile strength (5.7.1). Determine the tape tensile strength after unrolling and storing for a minimum period of four hours in standard atmosphere with (65 ± 2)% of relative humidity, at (21 ± 1.1)°C, using a pendulum device. Proceed as described in *Tensile strength* **(5.7.1)**. The tape manufactured from fabric must present tensile strength of not less than 20.41 kg by 2.54 cm of width. The tape manufactured from polymeric film must present tensile strength of not less than 3 kg by 2.54 cm of width.

Adhesion to surface. From the sample manufactured in fabric, cut a band with 2.54 cm of width and approximately 15 cm of length. Apply pressure equivalent to 850 g to one of the tape ends, with surface equal to 12.90 cm^2, 2.54 cm of width by 5.08 cm of length, against a clean glass, plastic or stainless steel surface. Apply pressure with the help of a rubber roll for two consecutive times at a speed of 30 cm per minute. Adjust the surface and tape temperature to 37°C and run the test immediately as described on *Tensile strength* **(5.7.1)**. Use a pendulum device, with the rupture conducted in parallel to the warp and to the surface. The average value from not less than10 tests must be not less than 18 kg.

BIOLOGICAL SAFETY TESTS

Sterility (5.5.3.2.1). Complies with the test. Applicable when the tape is declared sterile.

PACKAGING AND STORAGE

In properly closed packages, protected from light and from excessive heat.

The adhesive tape, when declared sterile or sterilized, must be stored in such a way that its sterility is protected from future contamination.

LABELLING

Comply with current legislation.

PETROLATUM GAUZE

Petrolatum gauze is purified hydrophilic gauze saturated with white petrolatum. It is sterile and can be prepared, under aseptic conditions, in the ratio of 60 g of petrolatum for each 20 g of gauze, by adding melted white petrolatum to the purified dried hydrophilic gauze previously cut into the final size. The weight of petrolatum on the gauze is not less than 70% and not more than 80% in relation to the total weight of the petrolatum gauze.

Petrolatum recovered by draining on *Assay* presents the same characteristics and complies with the *Description tests* and *Purity tests* described in the monograph on *White petrolatum.*

CHARACTERISTICS

The conditioned gauze obtained on *Assay* complies with the tests of *Thread count*, *Length*, *Width* and *Basis Weight* described in the monograph for *Purified hydrophilic gauze fabric.*

BIOLOGICAL SAFETY TESTS

Sterility (5.5.3.2.1). Complies with the test.

ASSAY

Weigh not less than 20 units of the sample and transfer them separately to a heated glass funnel, maintaining the temperature at approximately 75°C. Allow the petrolatum to melt and drain through the funnel. The drainage can be facilitated by pressing the gauze with a glass rod or a porcelain spatula. Wash the gauze over the funnel or a porcelain spatula. Wash the gauze over the funnel with successive portions of hot 1,1,1-trichloroethane, until it is petrolatum-free. Allow the residual solvent to evaporate spontaneously. Maintain the gauze at standard atmosphere of (65 ± 2)% relative humidity and (21 ± 1.1)°C for not less than four hours and weigh. The difference between the two weights represents the petrolatum weight.

PACKAGING AND STORAGE

Each petrolatum gauze unit is packaged individually to maintain the sterility until the package is opened for use.

LABELLING

Comply with current legislation.

ABSORBABLE SURGICAL SUTURES (CATGUT)

DESCRIPTION

The catgut is comprised of strips of collagen coming from the intestine of healthy herbivore animals and which are selected, purified, twisted, dried, polished and sterilized. The catgut can be submitted to chemical treatments such as chromium salts to prolong its strength to absorption, and for this reason it is classified as simple, or not treated, and chrome, or treated.

The length, diameter and tensile strength of catgut must comply with the limits described in this monograph.

CHARACTERISTICS

Note: *the following four tests must be run immediately after removing the surgical catgut from the preservative liquid, without submitting it to prior drying.*

Length. It must be determined without submitting the catgut to stretching. The length of each suture must be not less than 90% of the length described on the label.

Diameter (5.7.2). Determine the diameter of ten sutures as described on *Diameter of sutures*. The average and not less than twenty of thirty determinations in the sampling of ten sutures must be within the diameter limits described on **Table 1**, for the respective surgical number. None of the measures must be lower than the average value of the surgical number range that is immediately lower or higher than the average value of the range for the immediately superior surgical number.

Tensile strength (5.7.1). Determine the tensile strength of ten sutures as described in *Tensile strength*. The minimum tensile strength corresponding to each surgical number is represented by the average of the results achieved on the ten sutures analyzed, described on **Table 1**. If more than one thread is out of the individual specification, repeat the test with not less than 20 additional threads. The test requirements are met if none of the additional threads is below the individual limit and if the average strength of all threads tested is not below the value found on the respective table.

Table 1 – Sterile surgical catgut: diameter and tensile strength over knot.

Number		***Diameter***		***Tensile strength***			
				Average (Minimum)		***Individual value (Minimum)***	
Surgical	***Metric***	***Minimum mm***	***Maximum mm***	***kgf***	***N***	***kgf***	***N***
9-0	0.4	0.040	0.049	-	-	-	-
8-0	0.5	0.050	0.069	0.045	0.44	0.025	0.24
7-0	0.7	0.070	0.099	0.07	0.69	0.055	0.54
6-0	1	0.10	0.149	0.18	1.77	0.10	0.98
5-0	1.5	0.15	0.199	0.38	3.73	0.20	1.96
4-0	2	0.20	0.249	0.77	7.55	0.40	3.92
3-0	3	0.30	0.339	1.25	12.26	0.68	6.67
2-0	3.5	0.35	0.399	2.00	19.62	1.04	10.2
0	4	0.40	0.499	2.77	27.17	1.45	14.2

1	5	0.50	0.599	3.80	37.28	1.95	19.1
2	6	0.60	0.699	4.51	44.24	2.40	23.5
3	7	0.70	0.799	5.90	57.88	2.99	29.3
4	8	0.80	0.899	7.00	68.67	3.49	34.2

Needle attachment (5.7.3). Sutures where needles are fixed on must meet the requirements described in *Needle attachment.*

Sterility (5.5.3.2.1). The surgical catgut must meet the requirements described in the *Sterility test*.

Soluble chromium compounds. Weigh an amount of suture equivalent to not less than 250 mg and transfer to an Erlenmeyer flask with 1 mL of water for each 10 mg of sample. Close the Erlenmeyer flask and allow to stand at (37 ± 0.5)°C for 24 hours. After this time, cool down and decant or filter the liquid and pipette 5 mL to a test tube. In a similar tube, pipette 5 mL of a standard potassium dichromate solution with concentration equal to 2.83 µg per mL. Add to both tubes 2 mL of a diphenylcarbazide solution at 1% (w/v) in ethylic alcohol and 2 mL of sulfuric acid 2 *M*. Any color that develops in the test solution must not be more intense than the color of the standard solution (0.0001% Cr).

PACKAGING AND STORAGE

Surgical catgut must be stored in adequate packaging to maintain its sterility condition until it is opened.

SYNTHETIC ABSORBABLE SURGICAL SUTURES

DESCRIPTION

Synthetic absorbable surgical sutures are comprised of a sterilized thread, monofilament or multifilament, prepared from synthetic polymers. The length, diameter and tensile strength of synthetic absorbable surgical sutures must comply with the limits described in this monograph.

CHARACTERISTICS

Note: *the following four tests must be run immediately after removing the suture from its package*.

Length. It must be determined without submitting the suture to stretching. The length of each suture must be not less than 95% of the length described on the label.

Diameter (5.7.2). Determine the diameter of ten sutures as instructed on *Diameter of sutures*. The average must be within the diameter limits described on **Table 1** for the respective surgical number. None of the measures must be lower than the average value of the surgical number range that is immediately lower, or higher than the average value of the range for the immediately superior surgical number.

Tensile strength (5.7.1). Determine the tensile strength of ten sutures as described in *Tensile strength*. The minimum tensile strength corresponding to each surgical number is represented by the average of the results achieved on the ten sutures analyzed and must meet the requirements described on **Table 1**.

Table 1 – Sterilized synthetic absorbable surgical sutures: diameter and tensile strength over knot.

Number		***Diameter***		***Tensile strength***	
				Average (Minimum)	
Surgical	***Metric***	***Minimum mm***	***Maximum mm***	***kgf***	***N***
12-0	0.01	0.001	0.009	-	-
11-0	0.1	0.010	0.019	-	-
10-0	0.2	0.020	0.029	0.025 (1)	0.24 (1)
9-0	0.3	0.030	0.039	0.050 (1)	0.49 (1)
8-0	0.4	0.040	0.049	0.07	0.69
7-0	0.5	0.050	0.069	0.14	1.37
6-0	0.7	0.070	0.099	0.25	2.45
5-0	1	0.10	0.149	0.68	6.67
4-0	1.5	0.15	0.199	0.95	9.32
3-0	2	0.20	0.249	1.77	17.4
2-0	3	0.30	0.339	2.68	26.3
0	3.5	0.35	0.399	3.90	38.2
1	4	0.40	0.499	5.08	49.8
2	5	0.50	0.599	6.35	62.3
3 and 4	6	0.60	0.699	7.29	71.5
5	7	0.70	0.799	-	-

(1) Values of direct tension strength (exceptions).

Needle attachment (5.7.3). Sutures where needles are fixed on must meet the requirements described in *Needle attachment.*

Sterility (5.5.3.2.1). Synthetic absorbable surgical sutures must meet the requirements described in the *Sterility test*.

PACKAGING AND STORAGE

Synthetic absorbable surgical sutures must be stored in adequate packaging to maintain its sterility condition until it is opened.

NON-ABSORBABLE SURGICAL SUTURES

DESCRIPTION

Non-absorbable surgical sutures are sterilized threads that, when used in a living organism, are not absorbed by it. They vary in their origin, which can be animal, vegetal or synthetic. They can be cylindric monofilaments or multifilaments. which consist of elementary fibers gathered by twisting or braiding.

They can be treated to become non-capillary.

Non-absorbable surgical sutures are classified into:

- Class I – comprised of silk or synthetic monofilament fibers, with twisted or braided construction.

- Class II – comprised of cotton, linen or synthetic fibers that have a coating forming a film with significant thickness.

- Class III – comprised of monofilament or multifilament metallic threads.

The length, diameter and tensile strength of non-absorbable surgical threads must comply with the limits described in this monograph.

CHARACTERISTICS

Note: *if the suture is in a package with preservative liquid, the following four tests must be run immediately after removing the suture from its package*.

Length. It must be determined without submitting the suture to stretching. The length of each thread must be not less than 95% of the length described on the label.

Diameter (5.7.2). Determine the diameter of ten threads as described on *Diameter of sutures*. The average must be within the diameter limits described on **Table 1** for the respective surgical number. In braided or twisted sutures, none of the measures must be lower than the average value of the surgical number range that is immediately lower, or higher than the average value of the range for the immediately superior surgical number.

Tensile strength (5.7.1). Determine the tensile strength of ten threads are described in *Tensile strength*. The minimum tensile strength corresponding to each surgical number is represented by the average of the results achieved on the ten threads analyzed, and must be the one described on **Table 1**.

Table 1 – Sterilized non-absorbable surgical sutures: diameter and tensile strength over knot.

Number		***Diameter mm***		***Tensile strength (average - minimum)***					
				Class I[(1)]		***Class II[(2)]***		***Class III[(3)]***	
Surgical	***Metric***	***Minimum***	***Maximum***	***kgf***	***N***	***kgf***	***N***	***kgf***	***N***
12-0	0.01	0.001	0.009	0.001[(4)]	0.01	-	-	0.002[(4)]	0.02[(4)]
11-0	0.1	0.010	0.019	0.006[(4)]	0.06[(4)]	0.005[(4)]	0.05[(4)]	0.02[(4)]	0.20[(4)]
10-0	0.2	0.020	0.029	0.019[(4)]	0.194[(4)]	0.014[(4)]	0.14[(4)]	0.06[(4)]	0.59[(4)]

9-0	0.3	0.030	0.039	0.043(4)	0.424(4)	0.029(4)	0.28(4)	0.07(4)	0.69(4)
8-0	0.4	0.040	0.049	0.06	0.59	0.040	0.39	0.11	1.08
7-0	0.5	0.050	0.069	0.11	1.08	0.06	0.59	0.16	1.57
6-0	0.7	0.070	0.099	0.20	1.96	0.11	1.08	0.27	2.65
5-0	1	0.100	0.149	0.40	3.92	0.23	2.26	0.54	5.30
4-0	1.5	0.150	0.199	0.60	5.88	0.46	4.51	0.82	8.04
3-0	2	0.200	0.249	0.96	9.41	0.66	6.47	1.36	13.3
2-0	3	0.300	0.339	1.44	14.1	1.02	10.0	1.80	17.6
0	3.5	0.350	0.399	2.16	21.2	1.45	14.2	3.40	33.3
1	4	0.400	0.499	2.72	26.67	1.81	17.8	4.76	46.7
2	5	0.500	0.599	3.52	34.5	2.54	24.9	5.90(4)	57.8(4)
3 and 4	6	0.600	0.699	4.88	47.8	3.68	36.1	9.11(4)	89.3(4)
5	7	0.700	0.799	6.16	60.4	-	-	11.4(4)	112(4)
6	8	0.800	0.899	7.28	71.4	-	-	13.6(4)	133(4)
7	9	0.900	0.999	9.04	88.6	-	-	15.9(4)	156(4)
8	10	1.000	1.099	-	-	-	-	18.2(4)	178(4)
9	11	1.100	1.199	-	-	-	-	20.5(4)	201(4)
10	12	1.200	1.299	-	-	-	-	22.8(4)	224(4)

(1) Class I is comprised of silk or monofilaments of synthetic fibers (twisted or braided), where the possible coating does not affect the diameter significantly. For example, braided silk, polyester, polypropylene, polyamide, monofilament of polyamide or polypropylene.

(2) Class II is comprised of cotton, mixed cotton, linen threads (with or without coating), with synthetic fibers where the coating significantly affects the diameter, but does not contribute significantly to the tensile strength.

(3) Class III is comprised of metallic threads.

(4) Exceptions: values of tensile strength by direct tension.

Needle attachment (5.7.3). Sutures where needles are fixed on must meet the requirements described in *Needle attachment.*

Sterility (5.5.3.2.1). Non-absorbable surgical sutures must meet the requirements described in the *Sterility test.*

PACKAGING AND STORAGE

Non-absorbable surgical sutures must be stored in adequate packaging to maintain its sterility condition until it is opened.

PURIFIED HYDROPHILIC GAUZE FABRIC

100% cotton fabric, simple, with low density of threads per centimeters, of mesh type, bleached (free from starch, dextrin, corrective coloring agents, optical brighteners, alkalis and acids), odorless and tasteless.

Purified hydrophile gauze is a white fabric with different thread counts and weights, in different lengths and widths. On **Table 1** there is the designation for each commercial type, number of threads, and the respective basis weight.

Table 1 – Commercial types of gauzes with the respective numbers of threads and basis weight.

Type of gauze	*Minimum number of warp threads per 10 cm*	*Minimum number of weave threads per 10 cm*	*Minimum number of threads per 100 cm^2 of area*	*Basis Weight (g/m^2)*	*Variation in percentage*
I	158	138	296	73.0	± 6
II	138	138	276	66.5	± 6
III	118	79	197	38.5	± 6
IV	89	69	158	31.0	± 6
V	79	59	138	26.8	± 6
VI	74	54	128	25.2	± 6
VII	74	34	108	21.3	± 6
VIII	69	29	98	19.3	± 6
IX	59	29	88	16.6	± 6

CHARACTERISTICS

Keep the sample for a minimum of four hours in standard atmosphere with relative humidity of (65 ± 2)%, at (20 ± 2)°C, before running the tests of *Thread count*, *Basis weight* and *Absorbing power*. Remove the sample from its packaging before submitting it to conditioning atmosphere. If the sample is in the form of rolls, cut the necessary amount to run the tests, excluding the first and the last two meters, when the total amount of sample available permits so.

Thread count. Collect a sample with at least 50 cm of length and width equal to the fabric width. Put the sample, with no wrinkles and no tension, over a flat surface. Start counting on the space between two threads. Do not count on the selvedge area. Put the scale over the sample and count the number of threads that exist in 5 cm. Cut in the warp direction, along the sample width. The counting must be made in five different parts of the sample. Cut in the warp direction, along the sample length. The counting must be made in five different parts of the sample. Divide the number of threads from each measure by 5 cm, to determine the number of threads per centimeter.

Calculate the arithmetic average of the five counts done in each direction. The average, multiplied by 10, must be within the rage of variation from **Table 1**.

Length. Unfold or unroll the sample, spread without stretching and measure the length along the central line, using a graded ruler. It must present not less than 98% of the length stated.

Width. Remove a sample with not less than 50 cm of length, on the total width of the fabric and one meter away from the roll ends. Measure the width with the help of a graduated ruler, on not less than three points, at equal intervals not superior to 10 cm, distributed along the sample. The average of the three dimensions must not present a difference superior to 1.6 mm of the width written on the label.

Basis Weight. Cut three test bodies from the sample with area equal to 100 cm^2. Weigh each test body on a scale with precision of 0.001 g. Calculate the average of the masses obtained and multiply by 100, to express the result in grams per square meter. The basis weight meets the specification indicated on **Table 1**.

Absorbent power. Fill with water at approximate temperature of 20°C a container with 11 to 12 cm of diameter. Fold with a tweezer a square of the sample with about 1 g and smoothen the surface. Carefully place the square of the sample on water surface. Determine with a timer the necessary time for full submersion of the sample. The immersion time, expressed by the average of times registered throughout three tests, must not exceed 10 seconds.

PURITY TESTS

Water-soluble substances. Transfer, quantitatively, about 20 g of the sample to a 1000 mL beaker with 500 mL of purified water. Heat to ebullition, for 15 minutes, adding boiling water to maintain the initial volume. Carry out hot filtration through a funnel, pressing the sample retained with a pestle, to completely remove the water. Wash with two portions of 200 mL of boiling water, pressing the gauze after each washing. Collect the filtrate in a 1000 mL volumetric flask and complete the volume with water. Transfer 400 mL of the extract to a previously tared porcelain crucible and evaporate until residue on water bath.

Residue after desiccation: dry the residue obtained in *Water-soluble substances* in an oven at 105°C until constant weight. Calculate the percentage of residue in relation to the mass from the initial sample. It must be not more than 0.25% of the initial weight.

Residue after incineration: incinerate the residue obtained in *Residue after desiccation,* in a muffle furnace at 600°C until constant weight. Calculate the percentage of residue in relation to the mass from the initial sample. It must be not more than 0.075% of the initial weight.

Acidity or alkalinity. Cut the sample of 10 g of fabric with tolerance of ± 0.1 g. Moderately boil 250 mL of purified water in a beaker. Immerse the sample, cover the beaker with a Petri dish or watch glass and boil for another five minutes. Keeping the beaker and the content covered, cool down to room temperature. Remove the sample with tweezer or tong and press all excess liquid in the beaker Determine the pH of the aqueous extract potentiometrically **(5.2.19)**. The pH value must be between 5.0 and 8.0.

Dextrin or starch. Drip over the sample two to three drops of iodine RS. The color of the solution on the fabric after 30 seconds remains yellowish. A change to greenish hues indicates residues of dextrin; blue or violet coloring indicates the presence of starch.

Determination of sulfated ashes (5.2.10). Accurately weigh about 5 g of the sample and transfer to a previously tared crucible. Moisten with 0.5 mL of sulfuric acid *M* and carefully burn over direct flame, until the sample turns black. Cool down, add to the residue three to five drops of sulfuric acid *M* and slowly heat until no more white fumes are released. Incinerate at 800°C until constant weight. The residue must be not more than 0.2% of the initial weight.

Fatty substances. Accurately weigh about 10 g of the sample and adapt it to the Soxhlet extractor. Weigh a 250 mL flat bottom flask with glass beads or pieces of porcelain and add 180 mL of ethyl ether. Adapt the flask to the Soxhlet extractor and to the heating mantle with temperature adjustment

and heat the set for five hours, keeping not less than four refluxes per hour (the ether extract must not present vestiges of blue, green or brown coloring) Remove the heating mantle after the extraction period and allow the set to cool, so that a few milliliters of ethyl ether stay in the flask. Disconnect the extractor from the flask and evaporate the ether, carefully using a light flow of nitrogen inside the flask, always inside the fume hood. Dry the flask in an oven at 105°C until constant weight. It must be not more than 0.7%.

Corrective coloring agents. Transfer 10 g of the sample to a percolator. Slowly proceed to the extraction with ethylic alcohol until obtaining 50 mL of alcoholic extract. The percolate, observed over a white background, on a column with 20 cm of height, may present a slight yellow color, but not a blue or green color.

BIOLOGICAL SAFETY TESTS

Sterility (5.5.3.2.1). Gauze declared sterile complies with the test.

PACKAGING AND STORAGE

In properly closed packages. Gauze declared sterile is packaged to maintain sterility, until it is opened for use.

LABELLING.

Comply with current legislation.