

**AFRICAN
STANDARD**

DARS 2214:2026

First Edition

Textiles — Disposable wet wipes — Specification

PUBLIC REVIEW DRAFT



Reference No. WDARS
ICS

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Contents

Page

Foreword.....	Error! Bookmark not defined.
Introduction.....	Error! Bookmark not defined.
1 Scope.....	4
2 Normative references	4
3 Terms and definitions	5
4 Requirements	5
4.1 General requirements	5
4.2 Specific requirements	6
4.2.1 Fibre composition	6
4.2.2 Dimensions	6
4.2.3 Performance requirements	6
4.2.4 Chemical requirements	7
4.2.5 Microbiological requirements	7
4.2.6 Biocompatibility	7
5 Packaging	8
6 Labelling	8
6.1 Labelling on the primary package.....	8
6.2 Labelling on the bulk package.....	8
7 Sampling.....	9
Annex A (normative) Determination of moisture content.....	10
A.1 Principle	10
A.2 Apparatus	10
A.3 Sample preparation	10
A.4 Procedure	10
A.5 Calculation	10
Annex B (normative) Determination of flushability	12
B.1 Apparatus	12
B.2 Test method	12
B.3 Test report	12
Annex C (normative) Determination of disinfecting efficacy.....	13
C.1 Outline of the method	13
C.2 Apparatus	13
C.3 Media	13
C.3.1 Growth media for test organisms.....	13
C.3.2 Recovery medium.....	14
C.3.3 Hard water	14
C.3.4 Yeast suspension	14
C.3.5 Ringers solution, 25 % (v/v).....	14
C.4 Selection of the most resistant organism by the minimum inhibitory concentration test.....	15
C.5 Preparation of inoculum.....	15
C.6 Preparation of the sanitizer dilutions	15
C.7 Test procedure.....	16
C.8 Interpretation of results	16
Bibliography	17

Foreword

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Textiles — Disposable wet wipes — Specification

1 Scope

This Draft African Standard specifies requirements, sampling, and test methods for non-woven disposable wet wipes applicable for general personal hygiene and sanitizing purposes.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ARS 1524-1 Cosmetics — Safety of cosmetic products ingredients — Part 1: List of prohibited substances

ARS 1524-2 Cosmetics — Safety of cosmetic products ingredients — Part 2: List of substances which cosmetic products must not contain, except subject to the restrictions laid down

ARS 1524-3 Cosmetics — Safety of cosmetic products ingredients — Part 3: List of allowed colorants, preservatives and UV filters

ISO 23674 Cosmetics — Analytical methods — Direct determination of traces of mercury in cosmetics by thermal decomposition and atomic absorption spectrometry

ISO 21392 Cosmetics — Analytical methods — Measurement of traces of heavy metals in cosmetic finished products using ICP/MS technique

ISO 22716 Cosmetics — Good Manufacturing Practices (GMP) — Guidelines on Good Manufacturing Practices

ISO 1833-11, *Textiles — Quantitative chemical analysis — Part 11: Mixtures of certain cellulose fibres with certain other fibres (method using sulfuric acid)*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

ISO 3071, *Textiles — Determination of pH of aqueous extract*

ISO 9073-1, *Textiles — Test methods for nonwovens — Part 1: Determination of mass per unit area*

ISO 9073-18, *Textiles — Test methods for nonwovens — Part 18: Determination of breaking strength and elongation of nonwoven materials using the grab tensile test*

ISO 10993-10, Biological evaluation of medical devices Part 10: Tests for skin sensitization

ISO 11480, *Pulp, paper and board — Determination of total chlorine and organically bound chlorine*

ISO 18416, *Cosmetics — Microbiology — Detection of Candida albicans*

ISO 20743, *Textiles — Determination of antibacterial activity of textile products*

ISO 21149, *Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria*

ISO 21150, *Cosmetics — Microbiology — Detection of Escherichia coli*

ISO 22198, *Textiles — Fabrics — Determination of width and length*

ISO 22717, *Cosmetics — Microbiology — Detection of Pseudomonas aeruginosa*

ISO 22718, *Cosmetics — Microbiology — Detection of Staphylococcus aureus*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

non-woven

structure that is formed into web of fibres (either natural or man-made) that are bonded together by mechanical, chemical, thermal, or solvent means, without being woven or knitted

3.2

disposable wet wipe

single use non-woven material treated with a cleansing or sanitizing agent used for cleaning, hygiene, or personal care purposes and safely disposed after use

3.3

active ingredient

chemical and/or bioactive component that is included in the formulation of cleaning/sanitizing agents used to treat wipes to achieve their intended purposes

3.4

personal hygiene wet wipes

pre-moistened disposable cloths designed to clean and refresh the skin without the need for water, soap, or a towel

3.5

sanitizing wet wipes

pre-moistened, disposable cloths treated with chemicals designed to reduce or eliminate bacteria, viruses, and other microorganisms from surfaces and skin

4 Requirements

4.1 General requirements

Disposable wet wipes shall:

- a) be made in accordance with ISO 22716 and be of a non-woven construction.
- b) Be evenly pre-moistened with a non-toxic, hypoallergenic, and alcohol-free cleansing solution.
- c) if any, be pre-moistened with a non-toxic perfume ingredient;

- d) be pre-soaked with a non-toxic and hypoallergenic concentrated sanitizing solution, in case of sanitizing wipes.
- e) be made from ingredients complying with ARS 1524-1, ARS 152-2, and ARS 1524-3.
- f) leave no lint on the wiped surface; and
- g) be free from any foreign matter or any other defect that might impair their appearance or performance.

4.2 Specific requirements

4.2.1 Fibre composition

When tested in accordance with ISO 1833-11, disposable wet wipes shall consist of at least 20 % cellulose fibres.

4.2.2 Dimensions

When tested in accordance with ISO 22198, the nominal dimensions of disposable wet wipes shall be as declared subject to a tolerance of ± 2 % of the declared dimensions.

4.2.3 Performance requirements

Disposable wet wipes shall comply with the performance requirements given in Table 1 when tested in accordance with the test methods specified therein.

Table 1 — Performance requirements for disposable wet wipes

S/N	Parameter			Requirement	Test method
i	Mass per unit area, g/m ² , min.			36	ISO 9073-1
ii	Breaking strength, N, min.	Machine direction (wet)	100% Cellulose	5	ISO 9073-18
			Man-made & Blends of Cellulose and Manmade fibres	30	
		Cross direction (wet)	100% Cellulose	4	
			Man-made & Blends of Cellulose and Manmade fibres	7	
iii	pH of extract			4.0 – 8.5	ISO 3071
iv	Moisture content, %, min.			50	Annex A
v	Flushability ^a			Pass the test	Annex B

^a Flushability is applicable to only wipes that are claimed to be flushable

Commented [JW1]: Research to be done on the requirement of breaking strength during public review period

4.2.4 Chemical requirements

Disposable wet wipes shall comply with the chemical requirements given in Table 2 when tested in accordance with the test methods specified therein.

Table 2 — Chemical requirements for disposable wet wipes

S/N	Parameter	Requirement mg/kg, max.	Test method
i.	Lead	10	ISO 21392
ii.	Arsenic	2	
iii.	Cadmium	2	
iv.	Mercury	5	ISO 23674
v.	Chlorinated organic compounds	150	ISO 11480

4.2.5 Microbiological requirements

Disposable wet wipes shall comply with the microbiological requirements given in Table 3 when tested in accordance with the test methods specified therein.

Table 3 — Microbiological requirements for disposable wet wipes

S/N	Parameter	Requirement		Test method
		Personal hygiene wipes	Sanitizing wipes	
i.	Anti-bacterial activity (A) (if declared), min.	2		ISO 20743
ii.	Bacterial efficacy	N/A	To pass test	Annex C
iii.	Total viable count, cfu/1 g or 1 ml, max.	100	Not detected	ISO 21149
iv.	<i>Pseudomonas aeruginosa</i> , cfu/g	Not detected		ISO 22717
v.	<i>Staphylococcus aureus</i> , cfu/g	Not detected		ISO 22718
vi.	<i>Candida albicans</i> , cfu/g	Not detected		ISO 18416
vii.	<i>Escherichia coli</i> , cfu/g	Not detected		ISO 21150

4.2.6 Biocompatibility

Wet wipes shall not cause any harmful effect to the skin when tested in accordance with the relevant parts of ISO 10993-10.

5 Packaging

5.1 Disposable wet wipes shall be packaged in a suitable resealable material, that allows a single towelette to be easily dispensed at a time.

5.2 The primary packaging shall be designed to prevent loss of moisture or other active ingredients.

5.3 Only disposable wet wipes of the same size shall be packaged together in both primary and bulk packages.

5.4 The bulk package shall be such that it prevents any damage during transport and storage.

6 Labelling

6.1 Labelling on the primary package

The primary package shall be legibly and indelibly labelled in the official language(s) of the country of use, and shall include the following information:

- a) manufacturer's name, address and/or trademark;
- b) for imported wipes, importer and /or distributors name, address;
- c) product name and intended use such as "Baby wet wipes", "Adult wet wipes" or "Sanitizing/disinfection wipes";
- d) list of ingredients used (for sanitizing wipes, the active ingredient used and its percentage composition);
- e) declaration, "Anti-bacterial" if claimed anti-bacterial;
- f) number of wipes in the package;
- g) size of wipes in the package;
- h) fibre composition;
- i) instruction for use, storage and disposal;
- j) date of manufacture and expiry; or "Best before";
- k) batch number;
- l) country of origin and manufacture; and
- m) Declare "flushable" or "non-flushable"

WARNING STATEMENT "Discontinue the use of the product if any skin irritations or rashes are experienced"

6.2 Labelling on the bulk package

The bulk package shall be legibly and indelibly labelled in the official language(s) of the country of use, and shall include the following information:

- a) manufacturer's name, address and/or registered trademark;

- b) product name and intended use such as “Baby wet wipes”, “Adult wet wipes” or “Sanitizing/disinfection wipes”;
- c) number of packages;
- d) date of manufacture and expiry;
- e) batch or lot number; and
- f) country of origin and manufacture.

7 Sampling

Sampling shall be done in accordance with ISO 2859-1.

Annex A (normative)

Determination of moisture content

A.1 Principle

A specimen of specified mass of filler material of the disposable wet wipe is dried in an oven at specified temperature and the moisture content is determined.

A.2 Apparatus

A.2.1 Balance, with an accuracy of 0.05 % of the weighed mass.

A.2.3 Sample container, waterproof when sealed, is used for transferring analyzed material and during weighing.

A.2.4 Oven, well ventilated with a temperature of 102 °C to 105 °C.

A.3 Sample preparation

A.3.1 Take a sufficient number of dry sample containers, number them and take their masses after they are held open for a short period of time so that they will have the same air pressure as the surrounding atmosphere. Then leave them open until you take the test piece.

A.3.2 Take five random pieces of the wet wipe. The test pieces shall weigh 5 g.

A.3.3 If the surrounding atmosphere is hot and humid, prevent water condensation on the internal and external surfaces of the container.

A.3.4 Handle the test pieces gently to prevent dirt or changes in water content. Do not touch the test pieces with your bare hands. Put the test pieces in a container just after taking them and close the container immediately.

A.4 Procedure

A.4.1 Dry the test pieces in an oven with a temperature of 102 °C to 105 °C. Open the container's lid and dry the specimen inside the container. Open the container for a moment, to balance the air pressure inside the container with the surrounding pressure, weigh the container that holds the specimen again and calculate the weight of the specimen.

A.4.2 First cycle of drying will last at least 30 min. Return the container with the test pieces to the oven, for at least half the first cycle's drying time. Take the container out and take the mass with the test pieces inside. Repeat the drying and weighing cycles. When the drying time on every cycle is at least half of the total previous drying cycle times, continue the process until the difference between two consecutive masses does not exceed 0.1 % of the original mass of the specimen.

A.5 Calculation

Calculate the moisture content using the following formula and round up the results to the nearest 0.1 %.

$$V = 100 \frac{(a-b)}{a}$$

where

V is the moisture content, in percentage weight.

a is the weight of the container with the specimen, in grams, before drying;

b is the weight of the container with the specimen, in grams, after drying.

PUBLIC REVIEW DRAFT

Annex B (normative)

Determination of flushability

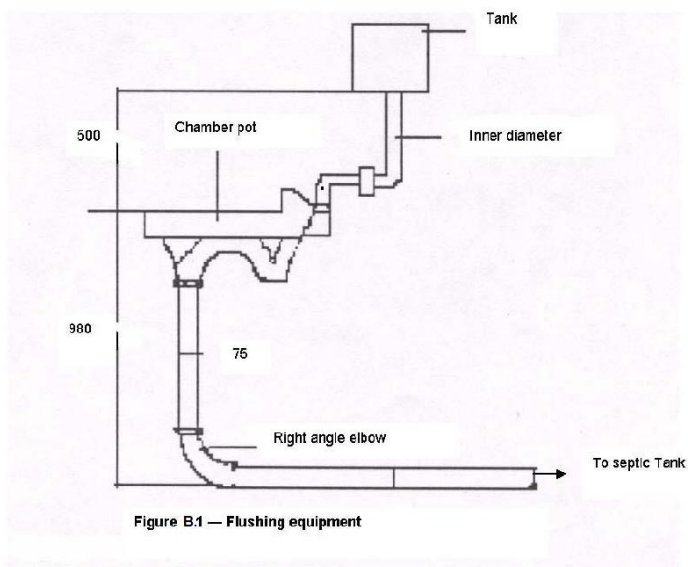
B.1 Apparatus

Use the flushing toilet equipment as described in Figure B.1. The pipes to the septic tank should be transparent acrylic tubes to allow the sanitary end of the tube to connect to an open tank, thereby collecting the products.

B.2 Test method

Throw three wipes into the chamber pot, and flush water (8 L to 12 L per time) from the flush tank.

Dimensions in millimetres



B.3 Test report

Report whether the wipes are completely flushed down or not.

Annex C

(normative)

Determination of disinfecting efficacy

C.1 Outline of the method

C.1.1 A sanitizing wipe is pressed to obtain the sanitizing solution. The sanitizing solution is tested at the recommended 'use-dilution' and concurrently at 0.5 and 1.5 times that dilution. The test consists of challenging the diluted sanitizer with bacterial inoculum, withdrawing a sample after a given time and culturing the sample in a suitable recovery medium. After this sampling, the mixture is again challenged by a second inoculum, and after a second interval, is again sampled for culturing. This process is then repeated to provide a third challenge.

C.1.2 The sample is considered to have passed or failed the test according to the extent of growth shown in the first two cultured samples.

C.2 Apparatus

C.2.1 Facility, for incubation at $37\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

C.2.2 Facility, for incubation at $2\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

C.2.3 Stop clock, indicating in seconds.

C.2.4 Facility, for refrigeration at $4\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

C.2.5 Universal containers, made of glass and having metal tops with rubber liners. Plastic containers or glass containers with plastic tops shall not be used.

C.2.6 Test tubes, 19 mm X 150 mm.

C.2.7 Filter paper, No. 4 Whatman (sterile) or equivalent.

C.2.8 Facility, for autoclaving at $121\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

C.2.9 Pipette, capable of dispensing $0.02\text{ ml} \pm 0.005\text{ ml}$.

C.2.10 pH meter.

C.2.11 Facility, to sterilize by filtration.

C.2.12 150- μm test sieve.

C.2.13 Oven, capable of maintaining temperature at $100\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

C.3 Media

C.3.1 Growth media for test organisms

C.3.1.1 The growth media for test organisms shall be Wright and Mundy Broth with Dextrose (WMBD).

C.3.1.2 Dispense 10 ml and 6 ml quantities of the Wright and Mundy Broth into universal bottles, and autoclave at $121\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for 12 min.

C.3.1.3 Add to this medium, 10 % (m/v) dextrose solution sterilized by filtration, to give a final dextrose concentration of 0.1 % (m/v), (that is, to 10 ml broth add 0.1 ml dextrose solution and to 6.0 ml broth, add 0.06 ml dextrose solution).

C.3.2 Recovery medium

C.3.2.1 Composition

A nutrient broth prepared as follows:

- a) beef extract, 10 g;
- b) peptone, 10 g;
- c) sodium chloride, 5 g; and
- d) polyoxyethylene sorbitan mono-oleate, 30 g.

C.3.2.2 Preparation

Add the ingredients to 1 000 ml of water. Mix well. Dispense 10-ml quantities into test tubes and autoclave at $121\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for 15 min.

C.3.3 Hard water

Standard hard water with 342 mg/l (ppm) hardness prepared as follows: dissolve 0.304 g of anhydrous calcium chloride hexahydrate ($\text{MgCl}_2 \cdot 6\text{H}_2\text{O}$) in distilled water and make up the volume to one litre. Sterilize the standard hard water by autoclaving at $121\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for 15 min. Allow this to reach room temperature before use.

C.3.4 Yeast suspension

C.3.4.1 Weigh to the nearest gram about 65 g of active dry yeast. Cream by the gradual addition of sterile hard water (see C.3.3) using a heavy glass rod for stirring. Decant the creamed portion into a flask, add more hard water to any lumpy residue remaining and repeat the creaming and decantation until no residue remains, and 500 ml of hard water has been used.

C.3.4.2 Shake the contents of the flask vigorously and strain-through a 150- μm sieve (see C.2.12) breaking down any remaining lumps.

C.3.4.3 Add 500 ml sterile hard water, shake vigorously.

C.3.4.4 Transfer 50-ml or 100-ml portions into screw-capped bottles, screw the caps tightly and autoclave at $121\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for 15 min. Allow the autoclave to cool without releasing the pressure. Store cold but not freezing.

C.3.4.5 Dry two glass petri-dishes to constant mass. Into each of these dishes, pipette 25 ml of sterilized yeast suspension and dry to constant mass at $100\text{ }^{\circ}\text{C}$. Calculate the average solids content of the suspension.

C.3.4.6 Before use, pipette 25 ml of the sterilized yeast suspension into a beaker. Determine the pH using a glass electrode, and determine the volume of 40 g/l sodium hydroxide solution needed to adjust the pH to 7.0 ± 0.1 .

C.3.4.7 Immediately before use, add to each bottle of sterilized yeast suspension a volume of sterile hard water and a volume of 40 g/l sodium hydroxide calculated to adjust the concentration of dry yeast to 5 % (m/v) and the pH to 7.0 ± 0.1 . Discard prepared yeast, two weeks after preparation.

C.3.5 Ringers solution, 25 % (v/v)

Dissolve 9.00 g of sodium chloride, 0.42 g of potassium chloride, 0.24 g of anhydrous calcium chloride and 0.20 g of sodium bicarbonate in water and dilute to 1 000 ml. Add one volume of this solution to three volumes of

water to give a 25 % solution. Dispense into test tubes fitted with suitable closures and sterilized by auto-claving at $121^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 15 min.

C.4 Selection of the most resistant organism by the minimum inhibitory concentration test

C.4.1 The following organisms shall be used for the test:

- a) *Pseudomonas aeruginosa* (NCTC 6749 or equivalent);
- b) *Proteus vulgaris* (NCTC 4635 or equivalent); and
- c) *Staphylococcus aureus* (NCTC 4163 or equivalent).

These organisms may be obtained as freeze dried cultures. Once sub-cultured, the organisms shall be maintained on agar slopes of suitable nutrient medium at $4^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

C.4.2 Subculture each organism daily into a universal bottle containing 6 ml of growth medium (see C.3.1) and incubate for $24\text{ h} \pm 2\text{ h}$ at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.

C.4.3 Dilute one part of freshly grown sub-culture of each organism, which is at least a fifth sub-culture and not more than a fourteenth, with ten parts of the growth medium (see C.3.1) before dilution, the *P. aeruginosa*, culture shall be filtered using a Whatman No.4 filter paper.

C.4.4 Prepare three sets of ten, doubling dilutions of the sanitizer in universal containers (see C.2.5). For this purpose, dilute the neat sanitizer in the growth medium (see C.3.1) or the recovery medium (see C.3.2) to give a final volume of 5 ml of the diluted sanitizer for each dilution.

C.4.5 Inoculate each dilution in one set with 0.02 ml of a diluted culture of one organism (see C.4.3).

C.4.6 Incubate all the three sets of inoculate dilutions at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for 72 h, and examine to determine the organism most resistant to the sanitizer, that is the organism for which the minimum inhibitory concentration is highest.

C.5 Preparation of inoculum

C.5.1 Daily sub-cultures of the test organism selected as in C.4.6 shall be grown in 6-ml quantities of the growth medium (see C.3.1) and incubated at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for $24\text{ h} \pm 2\text{ h}$.

C.5.2 The day before the test, inoculate 10 ml of the growth medium (see C.3.1) with the test organism from a daily sub-culture and not more than a fourteenth. Incubate the inoculated, broth at $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for $24\text{ h} \pm 2\text{ h}$.

C.5.3 Add 6 ml of the test organism culture (see C.5.1 and C.5.2) to 4 ml of the yeast suspension (see C.3.4) thus making a final concentration of 2 % (m/v) of yeast in the yeast/organism suspension. If a culture of *P. aeruginosa* is used, it shall be filtered using a Whatman No.4 filter paper before addition.

C.5.4 Shake the yeast/organism suspension for one minute with a few sterile glass beads. Immediately before the test, count the number of viable organisms in the inoculum by decimal dilutions in 25 % Ringers solution (see C.3.5) and by the Drop plate method. The viable count shall not be less than 10^8 organisms/ml or more than 10^{10} organisms/ml, otherwise, the test results are considered invalid.

C.6 Preparation of the sanitizer dilutions

C.6.1 Prepare three dilutions of the sanitizer in hard water (see C.3.3) based on the recommended 'use dilution' of the sanitizer, as follows:

- a) A = 0.5 times the recommended 'use-dilution';
- b) B = 1.0 times the recommended 'use-dilution'; and
- c) C = 1.5 times the recommended 'use-dilution'.

C.6.2 The sanitizer dilutions shall be prepared and tested on the same day.

C.7 Test procedure

C.7.1 The test shall be carried out at $27\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

C.7.2 Dispense 3 ml of each dilution of sanitizer (see C.6) into separate universal bottles labelled A, B, and C, then allow to equilibrate to $27\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

C.7.3 Add 1 ml of the inoculum to A, B and C at 0 min, 1 min and 5 min respectively and mix by swirling gently.

C.7.4 Eight minutes after the addition of the inoculum, remove a sample of the inoculum/sanitizer mixture and put 0.02 ml into each of the first group of five tubes of recovery broths. Return the remainder of the mixture in the pipette to the universal container.

C.7.5 Ten minutes after the first addition of the inoculum, add another 1 ml of the inoculum to each of the sanitizer dilutions and mix by swirling gently.

C.7.6 After 8 min, remove a sample of the mixture as put before (see C.7.4) and put 0.02 ml into each of the second group of five tubes of recovery broths.

C.7.7 Twenty minutes after the first addition of the inoculum, add a further 1 ml of inoculum to each of the sanitizer dilutions and mix by swirling gently.

C.7.8 After 8 min, remove a sample of the mixture as before and place 0.02 ml into each of the third group of five tubes of recovery broths.

C.7.9 Swirl the recovery broths and incubate at $37\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ for $48\text{ h} \pm 2\text{ h}$. Examine the growth and record the results.

C.8 Interpretation of results

C.8.1 The sanitizing wipe, shall be regarded as having passed the test at the recommended use dilution if there is no growth in at least two of the five recovery broths for the first and second additions of the inoculum.

C.8.2 To be acceptable, the sanitizing wipe shall pass the test on three separate occasions using freshly prepared sanitizing solution and freshly prepared inoculum on each occasion.

Bibliography

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