SLOVENSKI STANDARD
oSIST prEN 14348:2026

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Kemična razkužila in antiseptiki - Kvantitativni suspenzijski preskus za ocenjevanje mikobaktericidnega ali tuberkulocidnega delovanja kemičnih razkužil in antiseptikov v humani medicini - Preskusne metode in zahteve (faza 2, stopnja 1)

Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of tuberculocidal or mycobactericidal activity in the medical area - Test methods and requirements (phase 2, step 1)

Sample Document

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der tuberkuloziden oder mykobakteriziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

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Antiseptiques et désinfectants chimiques - Essai quantitatif de suspension pour l'evaluation de l'activité tuberculocide et mycobactéricide des désinfectants chimiques utilisés en médecine humaine - Méthode d'essai et prescriptions (phase 2, étape 1)

Ta slovenski standard je istoveten z: **prEN 14348**

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11.080.20	Dezinfektanti in antiseptiki	Disinfectants and antiseptics

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EUROPEAN STANDARD

NORME EUROPÉENNE

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prEN 14348

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Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of tuberculocidal or mycobactericidal activity in the medical area - Test methods and requirements (phase 2, step 1)

Antiseptiques et désinfectants chimiques - Essai quantitatif en suspension pour l'evaluation de l'activité tuberculocide ou mycobactéricide en médecine - Méthode d'essai et exigences (phase 2, étape 1)

Chemische Desinfektionsmittel und Antiseptika - Quantitativer Suspensionsversuch zur Bestimmung der tuberkuloziden oder mykobakteriziden Wirkung im humanmedizinischen Bereich - Prüfverfahren und Anforderungen (Phase 2, Stufe 1)

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European foreword

This document (prEN 14348:2026) has been prepared by Technical Committee CEN/TC 216 “Chemical disinfectants and antiseptics”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN-Enquiry.

This document will supersede EN 14348:2005.

A collaborative trial has been undertaken and will be evaluated to provide a precision annex to this document.

Other methods to evaluate the efficacy of chemical disinfectants and antiseptics for different applications in the medical area are in preparation.

The document was revised to adapt it to the latest state of science, to correct errors and ambiguities, to harmonize the structure and wording with other tests of CEN/TC 216 existing or in preparation and to improve the readability of the standard and thereby make it more understandable. The following is a list of significant technical changes since the last edition:

— Annex ZA was included for harmonization;

— membrane filtration method was added;

— test method for ready-to-use products added;

— test methods for hygienic handwash and textile disinfection added;

— clarification of the neutralization time of 10 s [5.5.2.2. c) and 5.5.2.5 b)];

— further options for neutralization were included;

— an additional pre-diluted method validation *C* was added;

— validation suspension for the neutralizer control (N_{VB}) was added;

— the figures in Annex C have been revised, in particular figures for the membrane filtration and the modified methods have been included.

The changes of this revision have no impact on the test results obtained with reference to the version EN 14348:2005. Those results are still valid.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

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Introduction

This document describes a suspension test for establishing whether a chemical disinfectant or an antiseptic has or does not have a tuberculocidal or mycobactericidal activity in the area defined in the scope.

This laboratory test takes into account practical conditions of application of the product including contact time, temperature, test organisms and interfering substances, i.e. conditions which may influence its action in practical situations.

The conditions are intended to cover the general uses described in this document, demonstrating that each utilization concentration of the chemical disinfectant or antiseptic determined by this test corresponds to the defined experimental conditions

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1 Scope

This document specifies a test method and the minimum requirements for tuberculocidal or mycobactericidal activity of chemical disinfectant and antiseptic products that form a homogeneous, physically stable preparation when diluted with hard water, or - in the case of ready-to-use products - with water. Products can only be tested at a concentration of 80 % or less (97 % with a modified method for special cases) as some dilution is always produced by adding the test organisms and interfering substance.

This document applies to products that are used in the medical area in the fields of hygienic handrub, hygienic handwash, instrument disinfection by immersion, surface disinfection by wiping, spraying, flooding or other means, and textile disinfection.

This document applies to areas and situations where disinfection or antisepsis is medically indicated. Such indications occur in patient care, for example:

— in hospitals, in community medical facilities and in dental institutions;

— in clinics of schools, of kindergartens and of nursing homes;

and can occur in the workplace and in the home. It can also include services such as laundries and kitchens supplying products directly for the patients.

NOTE 1 The method described is intended to determine the activity of commercial formulations or active substances under the conditions in which they are used.

NOTE 2 This method corresponds to a phase 2, step 1 test.

EN 14885 specifies in detail the relationship of the various tests to one another and to “use recommendations”.

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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.

NOTE EN 12353 and EN 14885 are updated on an ongoing basis as the standards to which they refer are developed and evolve. As the revision of both standards is much more frequent than the updating of this standard, the standards are not dated. Users will refer to the latest version of the referenced standards.

EN 12353, *Chemical disinfectants and antiseptics - Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 14885, *Chemical disinfectants and antiseptics - Application of European Standards for chemical disinfectants and antiseptics*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 14885 apply.

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

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

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4 Requirements

Regardless of whether a product manufacturer wishes to claim its products as medical devices or not, the entire content of the standard shall be applied. The product shall demonstrate at least a 4 decimal logarithms (lg) reduction (for hygienic handwash at least a 2 lg reduction) when tested in accordance with Table 1 and Clause 5.

Table 1 — Minimum and additional test conditions

Test Conditions	Hygienic handrub and handwash	Instrument disinfection	Surface disinfection	Textile disinfection
Minimum spectrum of test organisms	**Tuberculocidal activity** *Mycobacterium terrae* **Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**Tuberculocidal activity** *Mycobacterium terrae* **Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**Tuberculocidal activity** *Mycobacterium terrae* **Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*	**Tuberculocidal activity** *Mycobacterium terrae* **Mycobactericidal activity** *Mycobacterium terrae* *Mycobacterium avium*
additional	Any relevant test organisms			
Test temperature	according to the manufacturer's recommendation, but at / between			
	20 °C	20 °C ≤ 60°C[e]	4 °C and 30 °C	20 °C and < 60°C[e] or any higher temp.
Contact time	according to the manufacturer's recommendation			
	but between	but no longer than		
	30 s and 60 s	60 min	60 min [a]	
Interfering substance				
clean conditions	0,3 g/l bovine albumin solution (hygienic handrub)[b]	0,3 g/l bovine albumin solution and/or	0,3 g/l bovine albumin solution and/or	0,3 g/l bovine albumin solution (for pre-washed process)
dirty conditions	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes (hygienic handwash)[c]	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes	3,0 g/l bovine albumin solution plus 3,0 ml/l erythrocytes (for non-pre-washed process)
Additional conditions [d]	clean or dirty [b, c]; any relevant substance	any relevant substance	any relevant substance	any relevant substance

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a	The contact times for surface disinfectants stated in this table are chosen on the basis of the practical conditions of the product. For further information see EN 14885.
b	Hygienic handrub shall be tested as a minimum under clean conditions.
c	Hygienic handwash shall be tested as a minimum under dirty conditions.
d	For the additional conditions, the concentration defined as a result can be lower than the one obtained under the minimum test conditions.
e	For further information regarding validity at relevant temperatures see EN 14885.

5 Test methods

5.1 Principle

5.1.1 A test suspension of mycobacteria in a solution of an interfering substance is added to a sample of the product as delivered and/or diluted with hard water (for ready to use products: water). The mixture is maintained at the temperature and the contact time specified in Clause 4 and 5.5.1.1. At the end of this contact time, an aliquot is taken; the tuberculocidal or mycobactericidal and/or the mycobacteriostatic action in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used. The numbers of mycobacteria surviving in each sample are determined and the reduction is calculated.

The numbers of surviving mycobacteria in each sample are determined and the reduction is calculated.

NOTE Handwash products are always prediluted with hard water (5.2.2.8). The resulting solution is regarded as a ready-to-use product (5.4.2).

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5.1.2 The test is performed using *Mycobacterium avium* and *Mycobacterium terrae* or only *Mycobacterium terrae* as test organisms (Clause 4, Table 1).

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5.1.3 Additional and optional contact times and temperatures are specified (Clause 4, Table 1). Additional interfering substances may be used.

5.2 Materials and reagents

5.2.1 Test organisms

The mycobactericidal activity shall be evaluated using the following two test-organisms[1)]selected according to Clause 4, (Table 1):

Mycobacterium avium ATCC 15769

Mycobacterium terrae ATCC 15755

The tuberculocidal activity shall be evaluated using only *Mycobacterium terrae*.

Refer to Annex A for strain reference in some other culture collections.

If additional test organisms are used, they shall be incubated under optimum growth conditions (temperature, time, atmosphere, media) noted in the test report. If the additional test organisms selected do not correspond to the specified strains, their suitability for supplying the required inocula shall be verified. If these additional test organisms are not classified at a reference centre, their identification characteristics shall be stated. In addition documentation ensuring the traceability of the test organism

1) The ATCC numbers are the collection numbers of strains supplied by the American Type Culture Collections (ATCC). This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.

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shall be retained by its owner—either the testing laboratory or the national culture collection—for a minimum of five years.

5.2.2 Culture media and reagents

5.2.2.1 General

All weights of chemical substances given in this standard refer to the anhydrous salts. Hydrated forms may be used as an alternative, but the weights required shall be adjusted to allow for consequent molecular weight differences.

The reagents shall be of analytical grade and/or appropriate for microbiological purposes. They shall be free from substances that are toxic or inhibitory to the test organisms.

To improve reproducibility, it is recommended that commercially available dehydrated material is used for the preparation of culture media. The manufacturer's instructions relating to the preparation of these products should be rigorously followed.

For each culture medium and reagent a limitation for use should be fixed.

5.2.2.2 Water

The water shall be freshly glass-distilled water or demineralized water, which meets the requirements of max. 0,1µS/cm conductivity or use water for injections (see bibliographic reference [1]).

Sterilize in the autoclave [5.3.1.1 a)]. Sterilization is not necessary if the water is used e.g. for preparation of culture media and subsequently sterilized. Alternatively, cell culture grade water is suitable for preparation of cell culture media and other solutions used in cell culture.

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See 5.2.2.7 for the procedure to prepare hard water.

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5.2.2.3 Middlebrook and Cohn 7 H 10 medium with 10 % OADC enrichment (MCO)

Middlebrook 7 H 10 agar-powder	19,0 g
Glycerol ($C_3H_8O_3$) (see [1])	5,0 ml
Water (5.2.2.2)	to 900,0 ml

Heat to boiling to dissolve completely. Sterilize in the autoclave [5.3.2.1 a)] and cool to 50 °C to 55 °C. Add 100 ml Middlebrook OADC enrichment under aseptic conditions. Fill 18 ml to 20 ml per plate (5.3.2.10). The pH of the medium shall be equivalent to 6,6 ± 0,2 when measured at 25 °C (5.3.2.4).

NOTE In special circumstances (problems with neutralization see 5.5.1.2 and 5.5.1.3) it may be necessary to add neutralizer to MCO (see Annex B.3). Do not use neutralizer that causes opalescence in the agar.

5.2.2.4 Diluent

Tryptone Sodium Chloride Solution:

Tryptone, pancreatic digest of casein	1,0 g
Sodium chloride (NaCl)	8,5 g
Water (5.2.2.2)	to 1 000,0 ml

Sterilize in the autoclave [see 5.3.2.1 a)]. After sterilization the pH (5.3.2.1) of the diluent shall be equivalent to 7,0 ± 0,2 when measured at 20 °C.

NOTE There is scientific experience that sodium chloride (NaCl) may inhibit the growth of mycobacteria. But the presence of NaCl in products and in the interfering substance (5.2.2.9) is unavoidable and therefore diluent might be used for the preparation of neutralizer (5.5.1.2).

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5.2.2.5 Neutralizer

The neutralizer shall be validated for the product being tested in accordance with 5.5.1 and 5.5.2. The neutralizer shall be sterile.

Information on neutralizers that have been found to be suitable for some categories of products is given in Annex B

5.2.2.6 Rinsing liquids (for membrane filtration)

The rinsing liquids shall be validated for the product being tested in accordance with 5.5.1.2, 5.5.1.3 and 5.5.3. It shall be sterile, compatible with the filter membrane and capable of filtration through the filter membrane under the test conditions described in 5.5.3.

Recommendations for rinsing liquids 1 and 2:

— rinsing liquid 1: 1,0 g/l polysorbate 80; 0,5 g/l sodium oleate

— rinsing liquid 2: 0,5 g/l polysorbate 80; 0,5 g/l lecithin

NOTE Information on rinsing liquids that have been found to be suitable for some categories of products and also the combined membrane filtration and chemical neutralization procedure is given in Annex B.

5.2.2.7 Middlebrook 7 H 9 broth with 10 % ADC enrichment (MADC-broth)

MADC-broth will be used for deep freeze storage.

Middlebrook 7H9 broth-powder	4,7 g
Glycerol ($C_3H_8O_3$) (see [1])	100,0 ml
Water (5.2.2.2)	750,0 ml

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Sterilize in the autoclave [5.3.2.1 a)] and cool to 45 °C. Add under aseptic conditions 100 ml Middlebrook ADC enrichment and sterilized water (5.2.2.2) to 1 000,0 ml. The pH of the medium shall be equivalent to 6,6 ± 0,2 when measured at 25 °C (5.3.2.4).

5.2.2.8 Hard water for dilution of products

Prepare:

— prepare solution A: dissolve 19,84 g magnesium chloride (MgCl2) and 46,24 g calcium chloride (CaCl2) in water (5.2.2.2) and dilute to 1 000 ml. Sterilize by membrane filtration (5.3.2.7) or in the autoclave [5.3.2.1 a)]. Autoclaving – if used – may cause a loss of liquid. In this case make up to 1 000 ml with water (5.2.2.2) under aseptic conditions. Store the solution in the refrigerator (5.3.2.7) for no longer than one month;

— prepare solution B: dissolve 35,02 g sodium bicarbonate (NaHCO3) in water (5.2.2.2) and dilute to 1 000 ml. Sterilize by membrane filtration (5.3.2.6). Store the solution in the refrigerator (5.3.2.7) for no longer than one week;

— place 600 ml to 700 ml of water (5.2.2.2) in a 1 000 ml volumetric flask (5.3.2.12) and add 6,0 ml (5.3.2.9) of solution A, then 8,0 ml of solution B. Mix and dilute to 1 000 ml with water (5.2.2.2). The pH (5.3.2.4) of the hard water shall be 7,0 ± 0,2. If necessary, adjust the pH by using a solution of approximately 40 g/l (about 1 mol/l) of sodium hydroxide (NaOH) or approximately 36,5 g/l (about 1 mol/l) of hydrochloric acid (HCl).

The hard water shall be freshly prepared under aseptic conditions and used within 12 h.

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NOTE When preparing the product test solutions (5.4.2) the addition of the product to this hard water produces a different final water hardness in each test tube. In any case the final hardness is lower than 300 mg/l of calcium carbonate ($CaCO_3$) in the test tube.

5.2.2.9 Interfering substance

5.2.2.9.1 General

The interfering substance shall be chosen according to the conditions of use laid down for the product.

The interfering substance shall be sterile and prepared at 10 times its final concentration in the test (50 times in the case of the modified method, see 5.2.2.9.4).

The ionic composition e.g. pH, calcium and/or magnesium hardness and chemical composition e.g. mineral substances, protein, carbohydrates, lipids, detergents shall be defined.

NOTE In the following the term “interfering substance” is used even if it contains more than one substance.

5.2.2.9.2 Clean conditions (bovine albumin solution – low concentration)

Dissolve 0,30 g of bovine albumin fraction V (suitable for microbiological purposes) in 100 ml of diluent (5.2.2.4).

Sterilize by membrane filtration (5.3.2.7), keep in a refrigerator (5.3.2.8) and use within 1 month.

The final concentration of the bovine albumin in the test procedure (see 5.5) is 0,3 g/l.

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5.2.2.9.3 Dirty conditions (Mixture of bovine albumin solutions – high concentration with sheep erythrocytes)

Dissolve 3,00 g of bovine albumin fraction V (suitable for microbiological purposes) in 97 ml of diluent (5.2.2.4).

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Sterilize by membrane filtration (5.3.2.7).

Prepare at least 8,0 ml fresh sterile defibrinated sheep blood (5.2.2.10) or purchase such blood from a commercial supplier (5.2.2.10). Centrifuge the erythrocytes at 800 g for 10 min. After discarding the supernatant, resuspend erythrocytes in diluent (5.2.2.4). Repeat this procedure at least 3 times, until the supernatant is colourless. Resuspend 3 ml of the packed sheep erythrocytes in the 97 ml of sterilized bovine albumin solution (see above). To avoid later contamination this mixture should be split in portions probably needed per day and kept in separate containers for a maximum of 7 days in a refrigerator (5.3.2.7).

The final concentration of bovine albumin and sheep erythrocytes in the test procedure (5.5) shall be 3 g/l and 3 ml/l respectively.

5.2.2.9.4 Clean and dirty conditions for the modified method for ready-to-use products (5.5.4)

Follow the procedures for preparation according to 5.2.2.9.2 and 5.2.2.9.3, but prepare the interfering substance in fivefold higher concentrations, for the dirty conditions maximum 50 ml to avoid problems with the filtration.

a) Clean conditions (5.2.2.9.2) – dissolve 1,50 g bovine albumin (instead of 0,3 g) in 100 ml of diluent;

b) Dirty conditions (5.2.2.9.3) – dissolve 7,5 g bovine albumin (instead of 1,5 g) in 42,5 ml of diluent (instead of 48,5 ml). Prepare at least 20 ml (instead of 4,0 ml) sheep blood. Resuspend 7,5 ml (instead of 1,5 ml) of the packed sheep erythrocytes in 42,5 ml of sterilized bovine albumin solution to obtain 50 ml.

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5.2.2.10 Sterile defibrinated sheep blood

The defibrinated sheep blood should be sterile (aseptic blood-letting and preparation), pooled from more than one sheep and can be acquired from a commercial supplier.

5.3 Apparatus and glassware

5.3.1 General

Sterilize all glassware and parts of the apparatus that will come into contact with the culture media and reagents or the sample, except those which are supplied sterile, by one of the following methods:

a) by moist heat, in the autoclave [5.3.2.1 a)];

b) by dry heat, in the hot air oven [5.3.2.1 b)].

5.3.2 Usual microbiological laboratory equipment [2] and in particular, the following

5.3.2.1 Apparatus for sterilization:

a) for moist heat sterilization, an autoclave capable of being maintained at $(121\ ^{+3}_{0})$ °C for a minimum holding time of 15 min;

b) for dry heat sterilization, a hot air oven capable of being maintained at $(180\ ^{+5}_{0})$ °C for a minimum holding time of 30 min, at $(170\ ^{+5}_{0})$ °C for a minimum holding time of 1 h or at $(160\ ^{+5}_{0})$ °C for a minimum holding time of 2 h.

Sample Document

5.3.2.2 Water baths, capable of being controlled at 20° C ± 1 °C until 60 °C ± 1 °C and at additional test temperatures ± 1 °C (5.5.1).

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5.3.2.3 Incubator, capable of being controlled at either 36 °C ± 1 °C or at 37 °C ± 1°C.

NOTE 1 The same temperature is to be used for all incubations performed during a test and its controls and validation.

NOTE 2 A CO_2 – incubator and a temperature of 36 °C ± 1 °C are better suited for the test organisms. If a CO_2 – incubator is not used, the inoculated plates is to be protected from drying by sealing with insulating tape or packing them into polyethylene bags.

5.3.2.4 pH-meter, having an inaccuracy of calibration of no more than ± 0,1 pH units at 20 °C. The additional inaccuracy of the electrodes shall not be more than ± 0,1 pH units.

NOTE A puncture electrode or a flat membrane electrode is to be used for measuring the PH of the agar media (5.2.2.3).

5.3.2.5 Stopwatch

5.3.2.6 Electromechanical agitator e.g. Vortex® mixer [3].

[2] Disposable equipment is an acceptable alternative to reusable glassware.

[3] Vortex® in an example of a suitable product available commercially. This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of this product.

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5.3.2.7 Membrane filtration apparatus, constructed of a material compatible with the substances to be filtered, with a filter holder of at least 50 ml volume, and suitable for use of filters of diameter 47 mm to 50 mm and with a maximum pore size of 0,45 µm for sterilization of hard water (5.2.2.7), bovine albumin (5.2.2.9.2, 5.2.2.9.3 and 5.2.2.9.4), and if the membrane filtration method is used (5.5.3).

The vacuum source used shall give an even filtration flow rate. In order to prevent overlong filtration, the device shall be set so as to obtain the filtration of 100 ml in 20 s to 40 s.

5.3.2.8 Refrigerator, capable of being controlled at 2 °C to 8 °C.

5.3.2.9 Graduated pipettes of nominal capacities 10 ml and 1 ml and 0,1 ml or suitable volume, **or calibrated automatic pipettes.**

5.3.2.10 Petri dishes (plates) of size 90 mm to 100 mm.

5.3.2.11 Glass or ceramic beads (Diameter: 3 mm to 4 mm).

5.3.2.12 Volumetric flasks

5.3.2.13 Centrifuge (800 g*N*).

5.3.2.14 Plastic disposable 10µl loops

5.3.2.15 Coned bottom screw cap tubes, contents of 50 ml (diameter about 28 mm).

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5.4 Preparation of test organism suspensions and product test solutions

5.4.1 Test organism suspensions (test and validation suspension)

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5.4.1.1 General

For each test organism, two different test organism suspensions have to be prepared: the “test suspension” to perform the test and the “validation suspension” to perform the controls and method validation.

5.4.1.2 Preservation of test organisms

Test organisms shall be prepared and kept in accordance with the requirements of EN 12353, after having been supplemented by specific procedures for mycobacteria.

Cultures are prepared by subcultivating lyophilized test organisms (5.2.1) dissolved according to the culture collection’s instructions on plates containing MCO (5.2.2.3). Incubate *Mycobacterium terrae* and *Mycobacterium avium* for 21 days (5.3.2.3). The test organisms are recovered from the plates using 10 ml MADC broth (5.2.2.7) and diluted up to 100 ml with MADC broth. Pipette from this solution, 0,5 ml portions (minimum amount) in cryovials and store them at minimum – 70 °C or less for prolonged storage.

An alternative way of storage is by coating of beads: Pipette 1 ml of suspension into a cryovial containing beads (5.3.2.10). Shake the vial to distribute the suspension onto the beads. Allow to stand for 30 min at 20 °C. Remove the excess cryoprotectant solution with a pipette and store them at minimum – 70 °C or less for prolonged storage.

Calculating the number of cryovials needed for testing is advised, taking into account that two subcultures can be obtained from one cryovial.

NOTE It is possible to prepare the test organisms for prolonged storage directly from the dissolved lyophilized test organisms by diluting the dissolution broth with 100 ml to 120 ml of MADC broth (5.2.2.7). Immediately afterwards the cryovials are filled (up to 2,0 ml) according to the amount of working cultures to be prepared.

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