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Antimikrobni sanitetni material - Zahteve in preskusne metode

Antimicrobial wound dressings - Requirements and test method

Antimikrobielle Wundauflagen - Anforderungen und Prüfverfahren

Pansements antimicrobiens - Exigences et méthode d'essai

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Antimicrobial wound dressings - Requirements and test method

Pansements antimicrobiens - Exigences et méthode d'essai

Antimikrobielle Wundauflagen - Anforderungen und Prüfverfahren

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 17854:2022) has been prepared by Technical Committee CEN/TC 205 “Non-active medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

Introduction

This document describes a test method for establishing whether a wound dressing exerts antimicrobial activity.

The laboratory test attempts to simulate conditions of application, through the use of appropriate test fluids, temperature, organisms, and contact times reflecting the parameters found in clinical situations. Conditions which may influence the action of wound dressings having antimicrobial properties have been included.

The conditions are intended to cover general purposes and to allow comparison between laboratories and product types.

This edition of the document is considered to be most suited for dressings that have been tested as part of the inter-laboratory comparisons, i.e. that have an active antimicrobial agent incorporated and with at least a small amount of absorbent capacity. No data has currently been generated on other types of dressing (e.g. film, non-absorbing, multi-layered, adhesive, bacteria-binding dressing, etc.).

1 Scope

This document specifies minimum requirements and a test method for the antimicrobial (microbicidal or microbistatic) activity of wound dressing products. It applies to all wound dressing products that specifically claim antimicrobial activity according to this document.

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.

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*

3 Terms, definitions, symbols and abbreviated terms

3.1 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:

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

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

3.1.1
antimicrobial dressing
wound dressing which can be shown to exert microbicidal or microbistatic properties

3.1.2
antimicrobial activity
A
capability of a wound dressing to either inhibit the growth or produce a reduction in the number of viable cells of relevant test organisms under defined conditions, including viable bacterial cells and/or viable vegetative yeast cells

3.1.3
CFU
colony forming unit(s)

3.1.4
microbicidal
capability of the dressing to produce at least a 3 log reduction in the number of viable cells from the challenge organisms when tested under the conditions in Clause 5

3.1.5
microbistatic
capability of the dressing to at least prevent further growth of the initial inoculum when tested under the conditions in Clause 5

3.1.6
negative control dressing
wound dressing which is the same dressing as the dressing to be tested but without the antimicrobial treatment

Note 1 to entry: If no similar non-medicated dressing is available, then a sterile gauze swab shall be used.

3.1.7
neutralizer
chemical formulation to stop the antimicrobial effect of antimicrobial agents

3.1.8
plate count method
method in which the number of viable microorganisms present after incubation is calculated by counting the number of CFU

3.1.9
plate factor
factor used in CFU calculations which accounts for the volume of suspensions plated out onto agar plates

Note 1 to entry: This factor differs depending on choice of pour plates or spread plates.

3.1.10
saturation volume
SV
maximum volume of fluid absorbed by the dressing when tested according to the method in 5.5 of this document

3.1.11
simulated wound fluid
SWF
test medium intended to simulate wound exudate, for suspension of test organisms prior to exposure to test sample

3.1.12
test dressing
wound dressing which is tested to assess its antimicrobial activity

3.1.13
working volume
WV
volume of SWF added to the test or control dressing during the test, determined as 80 % of the saturation volume (ml)

3.2 Symbols and abbreviated terms

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

A	Antimicrobial activity
C_0	CFU value at T = 0 h for negative control dressing
C_{24}	CFU value at T = 24 h for negative control dressing
C_C	Microbial concentration of *INOC C*
C_s	Microbial concentration per sample (CFU / sample) used to calculate *INOC* C (in Table 5)
C_T	Viable counts per dressing sample
C_V	Viable counts per ml
DF	Dilution factor
h	Hour
INITIAL STOCK	Microbial suspension in MRD harvested from agar sub-culture
INOC C	Inoculum for negative control dressing (prepared from STOCK B and calculated volume of uninoculated SWF equating to WV_C – 0,5 ml)
INOC T	Inoculum for test dressing (prepared from *STOCK B* and calculated volume of uninoculated SWF equating to WV_T – 0,5 ml)
LOD	Limit of detection
Log C_0	is the average Log value for the number of organisms obtained from three negative control dressing samples immediately after inoculation
Log T_{24}	is the average Log value for the number of organisms obtained from three test dressing samples after incubation for 24 h
min	Minutes
N	Average number of CFU on P_1 and P_2
N_0	Undiluted test suspension
NE	Neutralization effectiveness (%)
N_{EFF}	Average Neutralizer efficacy in neutralization validation (CFU/ml)
NT	Neutralization toxicity (%)
N_{TOX}	Average Neutralizer toxicity in neutralization validation (CFU/ml)
N_{VIAB}	Average Test organism viability in neutralization validation (CFU/ml)
P_1	The number of organisms on plate 1 of duplicate agar plates (CFU)
P_2	The number of organisms on plate 2 of duplicate agar plates (CFU)
PF	Plate factor

s	Second
STOCK A	Microbial suspension of *INITIAL STOCK* diluted in MRD to contain 3×10^8 CFU/ml to 1×10^9 CFU/ml, used to prepare *STOCK B* and *STOCK N*
STOCK B	Microbial suspension of *STOCK A* diluted in SWF to contain 3×10^6 CFU/ml to 1×10^7 CFU/ml
STOCK N	Microbial suspension of *STOCK A* diluted in MRD to contain $1{,}5 \times 10^3$ CFU/ml to $5{,}0 \times 10^3$ CFU/ml, used in Neutralization Validation when using 1 ml pour plates
SV	Saturation volume
SV_A	Average saturation volume of five replicates (g)
SV_{HIGH}	Highest percentage saturation volume of five replicates (%)
SV_{LOW}	Lowest percentage saturation volume of five replicates (%)
SV_{MAX}	Highest measured saturation volume of five replicates (g)
SV_{MIN}	Lowest measured saturation volume of five replicates (g)
SV_{SPREAD}	Percentage spread for the five replicates (%)
T_{24}	CFU value at T = 24 h for test dressing
V_N	Neutralizer Volume
V_S	Volume sampled from the paddle blender bag when preparing serial decimal dilutions in 5.8.2.4 (ml)
V_T	Test volume = Neutralizer volume (V_N) + Working Volume (WV_T or WV_c) (ml)
W_0	Average dressing weight at T = 0 h (g)
W_{Te}	The average fully saturated dressing weight (g), as determined by the weight not changing between two time points by more than 5 %
W_{Tv}	Dressing weight following saturation in SWF at each time point as applicable (g)
WV	Working volume (3.1.13) – the volume of SWF added to the test or control dressing during the test, determined as 80 % of the saturation volume (ml)
WV_C	Working volume (*WV*) added to the negative control dressing (ml)
WV_T	Working volume (*WV*) added to the test dressing (ml)

4 Requirements

4.1 Documentation and training

Laboratories performing the test in this document should be operating under an appropriate quality management system (such as EN ISO 13485 [1], EN ISO/IEC 17025 [2] or similar). Therefore, ensuring that suitable records are retained by the test laboratory to allow full traceability of all raw data contributing to the results in the test report (5.9) and that competence in microbiological testing has been established.

4.2 Microbicidal dressings

When tested using the test method described in this document, antimicrobial dressings shall demonstrate an antimicrobial activity of at least a 3 log reduction in activity in a valid test (5.8.5) at the mandatory contact time of 24 h (T = 24 h) and against all three test organisms (5.3.1).

NOTE 1 Log values in this document refer to Log_{10}.

NOTE 2 Rationale for microbicidal requirements is given in Annex D.

4.3 Microbistatic dressings

When tested using the test method described in this document, microbistatic dressings shall demonstrate an antimicrobial activity that prevents further growth of the initial inoculum in a valid test (5.8.5) at the mandatory contact time of 24 h (T = 24 h) and against all three test organisms (5.3.1). This means at least a 0 log reduction is obtained, which represents no increase in test organism numbers at the mandatory contact time of 24 h (T = 24 h) against all three test organisms (5.3.1).

4.4 Performance table

Table 1 shows the performance requirements for antimicrobial dressings to be classified as microbicidal or microbistatic.

Table 1 — Performance requirements for antimicrobial dressings

Microbicidal	Microbistatic
$A \geq 3{,}0$ against all 3 test organisms	$A \geq 0{,}0$ against all 3 test organisms
A = Antimicrobial activity (5.8.3.5)	

If a test dressing does not meet either a microbicidal or microbistatic requirement then it is non-antimicrobial according to this document.

The test report (5.9) shall be supplied where claims of compliance with this document are made.

If a manufacturer makes a claim for antimicrobial activity for contact times in addition to the mandatory contact time of 24 h (T = 24 h) then those additional time points may be tested using this document and the results shall be included in the test report (5.9) and made available on request.

The test method in this document may be used with additional test organisms, including molds, provided that appropriate neutralization validation has been performed. If the results using such additional test organisms are made publicly available, then the neutralization validation shall be made available on request.

NOTE Example tables are given in Annex G.

5 Test method

5.1 Principle

A test suspension of bacteria or yeast in a solution of simulated wound fluid is inoculated into a sample of a wound dressing (test sample). The volume of test suspension added is determined by calculating the saturation volume of the test sample prior to inoculation. The test sample is maintained at a specified temperature for a defined contact time, then transferred to a previously validated neutralization medium so that the action of the antimicrobial agent is neutralized. The number of surviving bacteria or yeast, which can be recovered from the test sample, is then quantitatively determined, and compared to the number of bacteria or yeast in a negative control at start of the test.

The negative control sample dressing shall be treated in the same manner in place of the test sample during the whole test period.

NOTE Rationale for chosen test parameters is given in Annex D.

Any permitted deviations to this test method shall be suitably validated, documented in the report and their use justified.

5.2 General conditions

5.2.1 Volume accuracy

Volumes shall be measured with calibrated pipettes. Unless otherwise specified, all volumes are expected to be accurate to ±5 %.

5.2.2 Agar plates

This document is written with the intention that 1 ml agar pour plates are used for enumeration. However, it is known that some laboratories may be limited to the use of spread plates for enumeration. The change in volume when spread plates are used requires accounting for at various points in the method. Therefore, throughout this document instructions for the adjustments required when using spread plates have been given and users of this document should ensure the required adjustments are carefully followed.

NOTE The use of a very low volume for spread plates will reduce the sensitivity of the test and this may affect the ability to ability to calculate the required 3 log reduction. Therefore, the use of 1 ml pour plates at all times is encouraged.

5.3 Materials and reagents

5.3.1 Test organism strains

5.3.1.1 Storage of organisms

The organisms shall be stored in accordance with the supplier's recommendations or EN 12353.

The identification and origin (culture collection) of the organisms as well as the laboratory storage method shall be recorded.

National collection test organism strains equivalent to those listed in 5.3.1.2 and 5.3.1.3 may be used; some common alternative references in other national collections are given in Annex A.

5.3.1.2 Bacteria

The following two strains of bacteria shall be evaluated:

Pseudomonas aeruginosa ATCC 9027

Staphylococcus aureus ATCC 6538

5.3.1.3 Yeast

The following strain of yeast shall be evaluated:

Candida albicans ATCC 10231

5.3.1.4 Additional test organism strains

Additional test organism strains to those listed in 5.3.1.2 and 5.3.1.3 may be used for evaluation. Their suitability for producing inocula of sufficient concentration shall be verified prior to use.