SLOVENSKI STANDARD
SIST EN 13726-6:2003

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Neaktivni medicinski pripomoļ ki ï Preskusne metode za sanitetni material za primarno oskrbo rane - 6. del: Kontrola vonja

Non-active medical devices - Test methods for primary wound dressing - Part 6: Odour control

Nichtaktive Medizinprodukte - Prüfverfahren für primäre Verbandstoffe (Wundauflagen) - Teil 6: Geruchsbindung

Dispositifs médicaux non-actifs - Méthodes d'essai pour les pansements primaires en contact avec la plaie - Partie 6: Contrôle de l'odeur

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This European Standard was approved by CEN on 28 February 2003.

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Foreword

This document (EN 13726-6:2003) has been prepared by Technical Committee CEN /TC 205, "Non-active medical devices", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

EN 13726 consists of the following Parts under the general title *Non-active medical devices - Test methods for primary wound dressings:*

Part 1: Aspects of absorbency

Part 2: Moisture vapour transmission rate of permeable film dressings

Part 3: Waterproofness

Part 4: Conformability

Part 5: Bacterial barrier properties

Part 6:Odour control

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

EN 13726 gives test methods and does not contain performance requirements. EN 13726-6 describes a test method for odour control of primary wound dressings.

Test methods for other aspects of primary wound dressings are described in other parts of EN 13726.

1 Scope

This European Standard describes a test method for the evaluation of the resistance of primary wound dressings to penetration by odour.

2 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply:

2.1
primary wound dressing
material or combination of materials, in any shape, form or size that is intended to remain in direct contact with a wound

NOTE Primary wound dressing are used as mechanical barriers, for the absorption or transmission of exudates, to manage the micro-environment of the wound, and can enable the wound to heal by primary or secondary intent. Devices which have a metabolic, pharmacological or immunological interaction as their primary intent are excluded.

3 Test method for odour penetration

3.1 Significance and use

This test is designed to assess the resistance of primary wound dressings to penetration by odours. It only applies to dressings of a design where the odour absorbing material is not penetrated by exudate.

3.2 Equipment

3.2.1 Gas chromatograph (GC), capable of taking a packed column and running under the following conditions:

- Injector temperature : 300 °C;
- Oven temperature : 250 °C;
- Detector temperature : 300 °C;
- N_2 Flow rate : 40 ml/min;
- Detection : Flame Ionization Detector

3.2.2 Packed GC column, 10 % OV-17 (or similar that provides no obstruction to the gaseous sample).

3.2.3 Sealable stainless steel (grade 316) sample vessel, (of known volume) with sealed injection/sampling port (see Figure 1).

3.2.4 Suitable gaskets (material: PTFE).

3.2.5 500 µl gas-tight syringe.

3.2.6 Oven capable of being set at 105 °C.

3.2.7 Oven capable of being set at 37 °C.

3.2.8 1 µl syringe.

3.2.9 Balance readable to 0,001 g.

3.3 Procedure

3.3.1 Control Preparation

3.3.1.1 Condition the sample vessel for approximately 1 h at 105 °C to remove any trace compounds.

3.3.1.2 Place a gasket between the two parts of the vessel.

3.3.1.3 Purge the complete vessel with nitrogen through the injection/sampling port and seal the port with an appropriate septum.

3.3.1.4 Inject 0,5 µl of pure (> 99,7 %) diethylamine into the vessel through the septum, and place into a 37 °C oven for approximately 20 min.

3.3.1.5 Remove a 250 µl sample of gas, taking care to pump the syringe twice before withdrawing the plunger to 500 µl for approximately 10 s and returning to the 250 µl position. Inject this sample slug into the GC. Repeat gaseous sample extraction twice.

3.3.1.6 Use the average of the peak areas as the cut-off limit.

3.3.2 Sample Preparation

3.3.2.1 Condition the sample vessel for approximately 1 h at 105 °C to remove any trace compounds.

3.3.2.2 Make up a 1,3 % w/v solution of diethylamine in water.

3.3.2.3 Place (20,0 ± 0,5) ml of the solution into the lower part of the vessel..

3.3.2.4 Place a gasket and an appropriate size of dressing with the wound contact side facing down over the lower part of the vessel.

3.3.2.5 Purge the top half of the vessel with nitrogen (20 kPa) through the injection/sampling port, for at least 100 s. Seal the top half in place whilst purging, using the second gasket. Remove the purge line and seal the sample port with an appropriate septum.

3.3.2.6 Remove an initial 250 µl sample of gas, taking care to pump the syringe twice before withdrawing the plunger to 500 µl for approximately 10 s and returning to the 250 µl position. Inject this sample of gas into the GC.

3.3.2.7 Place the sample vessel into a 37 °C oven, and repeat 3.3.2.6 at appropriate intervals, adequate to determine the time to achieve 6ppm with an accuracy of 10 %, depending on the sample type. Repeat until the peak area of the control is exceeded.

3.4 Results

All results shall be quoted as time taken for the atmosphere inside the upper half vessel to reach a concentration of 6 ppm of diethylamine.

3.5 Test report

The report shall include at least the following information:

a) type of dressing, including lot number;

b) any deviations from the test method;

c) the result of the test;

d) date of test;

e) identity of the person(s) who carried out the test.