Title: Wound Dressing Testing - New Allevyn

Date: 25th April 2007

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subject: Wound Dressing Testing - New Allevyn

date: 25th April 2007

from: Alex Hallett
Princess of Wales
Tel: +44-1656-752820

Report No: 07/2402/1

Test Report

07/2402/1

1. Name & Address of Client/Requesting Authority.

   Ed Walton
   Clinical Project Manager
   Healthcare Ltd
   Healthcare House
   Goulton Street
   Hull
   HU3 4DJ

   Email: ed.walton@smith-nephew.com

2. Introduction

   The SMTL were requested by the client to perform moisture vapour transmission rate and fluid handling testing over 24 hours on the new Allevyn Adhesive and Competitor A Island Dressings. The fluid handling testing was performed in accordance with BS EN 13726-1:2002(1)

3. Test Product(s)/Sample(s)

   TABLE 1. Test Product(s)/Sample(s) tested by SMTL.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Item</th>
<th>Cat No</th>
<th>Batch/Lot No</th>
<th>Quantity</th>
<th>Date Received</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith &amp; Nephew</td>
<td>Allevyn Adhesive</td>
<td>66000599</td>
<td>0637</td>
<td>10</td>
<td>4/10/2006</td>
</tr>
<tr>
<td>Competitor A</td>
<td>Product A Foam</td>
<td>xxxxxxxx</td>
<td>xxxx</td>
<td>10</td>
<td>4/10/2006</td>
</tr>
<tr>
<td></td>
<td>Island Dressing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

   NOTE: The test results in this report relate only to the test sample(s) analysed.

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3.1 Departures/Abnormalities of Sample Condition
None.

4. Date of Testing
March 2007.

5. Testing Details
5.1 Test Method

5.2 Moisture vapour permeability
The moisture vapour permeability of the dressings was determined using SMTL test method TM-8.\textsuperscript{(2)}

In this test, a sample of dressing is applied to a Paddington cup (a modified Payne cup) to which is added 20 ml of a solution of sodium and calcium chloride containing 142 mmoles/litre of sodium ions and 2.5 mmoles/litre of calcium ions.

The cup is placed in an inverted position (with the test solution in contact with the film) in an incubator set at 37±2°C upon the pan of a top loading balance. The balance is connected to an electronic data logging device which records changes in the weight of the cup resulting from the loss of moisture vapour through the dressing. A tray containing 1 kg of freshly dried silica gel is placed in the bottom of the incubator to maintain a low relative humidity within the chamber.

At the end of the test the recorded data is down-loaded for examination.

5.3 Fluid handling properties
The fluid handling properties of the dressings were examined using SMTL test method TM-65\textsuperscript{(3)} which is based on the method originally described in the \textit{British Pharmacopoeia} 1993 (Addendum 1996) \textit{Semipermeable hydrocolloid dressings} and recently adopted as a European Standard BS EN 13726-1:2 2002 - \textit{Test methods for primary wound dressings: Aspects of absorbency}.

In this test five samples of each dressing of known weight are applied to Paddington cups (modified Payne cups) to which are added 20 ml of a solution of sodium/calcium chloride containing 142 mmol/litre of sodium ions and 2.5 mmol/litre of calcium ions. The cups are weighed and placed in an incubator at 37±0.5°C together with a tray containing 1 kg of freshly regenerated self indicating silica gel for a period of 24 hours. At the end of the test the cups are removed from the incubator, allowed to equilibrate to room temperature and reweighed. From these weighings the loss in weight due to the passage of moisture vapour through the dressing is determined. The base of each cup is then removed and any remaining fluid allowed to drain.\textsuperscript{†} The cup is then reweighed

\textsuperscript{†} If there is an accumulation of test fluid between two components of the dressing, the inner component must be slit with a scalpel blade to allow free drainage of the entrapped fluid.
once again and the weight of fluid retained by the dressing calculated by difference.

5.4 List of SMTL Test Methods Used.
— TM-8 - Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method.\(^{(2)}\)
— TM-65 - Fluid Handling Properties of Wound Management Dressings.\(^{(3)}\)

5.5 Standards relevant to the test method.
— BS EN 13726-1:2002: Test methods for primary wound dressings. Aspects of absorbency: Section 3.3 Fluid handling capacity (plus moisture vapour transmission rate, liquid in contact).\(^{(1)}\)

5.6 Deviations/exclusions from, and additions to standard methods.
The following deviation from the SMTL test method TM-8\(^{(2)}\) was employed.
— The dressing was tested for a period of 6 hours with it not being in contact with the fluid and then for a period of 18 hours with the dressing in contact.

The following deviations from the SMTL test method TM-65\(^{(3)}\) were employed to ensure the dressings were tested to the requirements of BS EN 13726-1:2002\(^{(1)}\)
— The testing was performed in a temperature/humidity controlled incubator to maintain an environment of 37°C (±1°C) and relative humidity below 20%. Therefore, the use of 1kg of silica gel was not required for this testing.
— Weighing was performed on a calibrated analytical balance.
— Following incubation, Paddington cups were allowed to acclimatise at room temperature for 30 minutes prior to weighing.

5.7 Sampling Details
All samples were selected and supplied by the client.

5.8 Sample Preparation
As stated in the SMTL test method.
6. Results

6.1 Moisture Vapour Transmission Rate

Results from MVTR experiments are presented in Tables 2 and 3. Data is also expressed graphically in Figures 1, 2, 3, 4, 5 and 6.

**TABLE 2.** Allevyn Moisture Vapour Transmission Rate over 24 hours

<table>
<thead>
<tr>
<th>Run</th>
<th>Maximum MVTR (g/m²/24Hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not in contact</td>
</tr>
<tr>
<td>Run 1</td>
<td>1915</td>
</tr>
<tr>
<td>Run 2</td>
<td>1568</td>
</tr>
<tr>
<td>Run 3</td>
<td>2247</td>
</tr>
<tr>
<td>Mean</td>
<td>1910</td>
</tr>
</tbody>
</table>

**Figure 1.** Allevyn Moisture Vapour Transmission - Run 1
Figure 2. Allevyn Moisture Vapour Transmission - Run 2

Figure 3. Allevyn Moisture Vapour Transmission - Run 3
**TABLE 3.** Product A Moisture Vapour Transmission Rate over 24 hours

<table>
<thead>
<tr>
<th></th>
<th>Maximum MVTR (g/m²/24Hrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Not in contact</td>
</tr>
<tr>
<td>Run 1</td>
<td>1177</td>
</tr>
<tr>
<td>Run 2</td>
<td>1270</td>
</tr>
<tr>
<td>Run 3</td>
<td>1206</td>
</tr>
<tr>
<td>Mean</td>
<td>1218</td>
</tr>
</tbody>
</table>

**Figure 4.** Product A Moisture Vapour Transmission - Run 1

![Graph showing the moisture vapour transmission rate over time for Product A, with separate lines for 'Not in contact' and 'In contact' conditions.](image-url)
Figure 5. Product A Moisture Vapour Transmission - Run 2

Figure 6. Product A Moisture Vapour Transmission - Run 3

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6.2 Fluid Handling Properties

The results of the fluid handling tests are presented in Table 4.

TABLE 4. Fluid Handling Properties of Allevyn Adhesive and Product A - 24 hours incubation

<table>
<thead>
<tr>
<th>Dressing</th>
<th>Moisture Vapour Loss (g/10cm²)</th>
<th>Absorbency (g/10cm²)</th>
<th>Fluid Handling Capacity (g/10cm²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allevyn Adhesive</td>
<td>1.5590 (0.0328)</td>
<td>0.3206 (0.0952)</td>
<td>1.8796 (0.1041)</td>
</tr>
<tr>
<td>Product A</td>
<td>1.1967 (0.1747)</td>
<td>2.2037 (0.5099)</td>
<td>3.4004 (0.5985)</td>
</tr>
</tbody>
</table>

Note:
- The results are the mean of 5 determinations
- Figures in brackets denote standard deviations

Authorised by: Peter Phillips
Acting Director, SMTL
April 2007
References


2. Surgical Materials Testing Lab., “Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method,” TM-8 ().