UKAS TESTING 1492

S . M . T . L .

subject: **Testing of Allevyn Gentle Wound Dressing**

date: **16th December 2009**

from: **Dr Gavin Hughes**
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Report No: 09/3201/5

Test Report

09/3201/5

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2. Introduction

The SMTL were requested by the client to perform various tests on Allevyn Gentle Foam Wound Dressings.

This testing was originally reported in SMTL Test Reports 09/3045/1 and 09/3104/1.

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

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

Manufacturer	Item	Cat No	Batch/Lot No	Quantity	Date Received	SMTL Original Report Number
Smith & Nephew	Allevyn Gentle 10 x 10cm	66800248	0924	58	17/07/2009	09/3045/1
	Allevyn Gentle 15 x 15cm	66800250	0913	7	17/07/2009	09/3045/1
	Allevyn Gentle 10 x 10cm	66800248	0907	10	18/08/2009	09/3104/1

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

3.1 Departures/Abnormalities of Sample Condition

None

4. Date of Testing

SMTL Project 3045 July-August 2009
SMTL Project 3104 August-November 2009

5. Testing Details

5.1 Moisture Vapour Transmission Rate

The moisture vapour permeability of the dressings was determined using SMTL test method TM-8.(1)

In this test, a sample of dressing is applied to a Paddington 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 sample) upon the pan of a top loading balance located within an incubator set at 37±2°C . 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.

5.2 Moisture Vapour Transmission Rate - BS EN 13726-2:2002

The moisture vapour transmission rate of the dressings *in contact with vapour* were examined using the SMTL test method TM-394(2) which is written in accordance with the method specified in BS EN 13726-2:2002 section 3.2.(3)

In this, the flange of the Paddington cup was used as a template and 5 samples of the test dressing were cut. The base of five Paddington cups were clamped together and 30 ml of solution added to each cup (30ml was sufficient to leave an air gap of 5 ±1mm between the liquid surface and the dressing sample). The dressing samples were then clamped onto the top of the Paddington cups to ensure a watertight seal.

The moisture vapour transmission rate of the dressings *in contact with liquid* were examined using the method specified in BS EN 13726-2:2002 section 3.3.(3)

In this, the flange of the Paddington cup was used as a template and 5 samples of the test dressing were cut. The dressing samples were then clamped onto the top of the Paddington cups to ensure a watertight seal. 30 ml of solution was then added to each cup so that the fluid is in contact with the dressing, the metal base plates of the five Paddington cups were then clamped.

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5.3 Fluid Handling Properties

The fluid handling properties of the dressings were examined using SMTL test method TM-390,[4] which is written in accordance with the European Standard *BS EN 13726:1:2002 - Test methods for primary wound dressings. Part 1; Aspects of absorbency. Section 3.3 - Fluid Handling Capacity (absorbency plus moisture vapour transmission rate, liquid in contact).*[5]

In this test, five samples of each dressing are applied to Paddington 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 using a calibrated analytical balance and placed in a temperature and humidity controlled incubator used to maintain an environment of 37±2°C and a relative humidity level below 20% for a period of 24 hours.

At the end of the test the cups are removed from the incubator, and are allowed to equilibrate at room temperature for a period of 30 minutes prior to reweighing on the analytical balance.

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.† After a period of 15±2min the cup is then reweighed once again and the weight of fluid retained by the dressing calculated by difference.
This test can be repeated over a period of 48 hours.

5.4 Conformability

The conformability of the dressing was determined using SMTL test method TM-16.[6]

The testing apparatus is a modification of the *Apparatus for the Measurement of Waterproofness* as originally described in the *British Pharmacopoeia 1988, Appendix XX K* and recently adopted as a European Standard *BS EN 13726-3: 2003 - Test methods for primary wound dressings; Waterproofness.* It consists of a chamber, open at one end, bearing a flange with an internal diameter of 50 mm. A retaining ring with the same internal diameter as the hole in the flange is mounted over the open end of the cylinder and this can be lowered down and clamped onto the flange, by means of a screw thread.

In use, a sample of the dressing under examination is placed on the flange and held firmly in place by means of the retaining ring.

During the course of this test, air is slowly forced into the chamber by means of a large syringe. The resultant rise in the pressure within the chamber causes the dressing to expand and form a hemisphere which gradually increases in size.

The pressure in the chamber, measured by means of a transducer and digital display unit, is increased until the upper surface of the dressing comes into contact with a marker placed 20 mm above the surface of the dressing at the start of the test. This pressure

† 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.

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value is then recorded.

In this test, the conformability of a dressing is considered to be inversely proportional to the pressure required to distort it by a predetermined amount.

5.5 Bacterial Barrier Testing

The bacterial barrier properties of the dressing samples was investigated using TM-43.[7]

5.6 Waterproofness

The waterproofness of the outer layer of the dressing was determined using SMTL test method TM-395,[8] which is written in accordance with the European Standard *BS EN 13726:3:2003 - Section 3.2.*[9]

In this test, a specimen is cut from the dressing under test that is sufficient to completely cover the opening of the test cell (the test cell is a modified Paddington Cup as illustrated in Figure 1 of *BS EN 13726:3:2003*). The test cell is then filled completely with water at 21±2°C. The specimen is then slid horizontally over the cell with its outer facing layer in contact with the water in such a way as to avoid the inclusion of air between the surface of the water and the lower surface of the specimen.

The upper surface is then covered with a dry filter paper and the upper ring of the apparatus tightened. A hydrostatic head of 500mm is then generated and maintained for 300±10sec, after which time the filter paper is examined for penetration of water and the results recorded.

The test is performed on three individual specimens, and if water penetration has occurred on any of the three specimens then the sample is deemed to have failed the test.

5.7 List of SMTL Test Methods Used.

— TM-8 - Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method[1]

— TM-394 - Moisture Vapour Transmission Rate (MVTR) of Permeable Film Dressings to BS EN 13726-2:2002[2]

— TM-390 - Fluid Handling Capacity BS EN 13726-1:2002[4]

— TM-16 - Conformability of Hydrocolloid and Film Dressings[6]

— TM-43 - Bacterial Barrier Testing[7]

— TM-395 - Waterproofness to BS EN 13726-3:2003[8]

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5.8 Standards relevant to the test method.

— The test method TM-394[2] is written in accordance with the method described in the *BS EN 13726-2: 2002 - Test methods for primary wound dressings. Part 2; Moisture vapour transmission rate of permeable film dressings. Section 3.2 MVTR of a wound dressing when in contact with water vapour and Section 3.3 MVTR of a wound dressing when in contact with liquid.*[3]

— The test method TM-390 Fluid Handling Capacity BS EN 13726-1:2002[4] is performed in accordance with the method described in the European Standard *BS EN 13726-1:2002: Test methods for primary wound dressings. Aspects of absorbency. Section 3.3 Fluid handling capacity (absorbency plus moisture vapour transmission rate, liquid in contact)*[5]

— The SMTL test method TM-395[8] is written in accordance with the method described in the *BS EN 13726-3: 2003: Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness*

5.9 Deviations/exclusions from, and additions to standard methods.

— Due to the high fluid handling capacity expected with at least one of the dressings, the fluid amount introduced into the Paddington cups at the start of the testing was increased from 20ml to 30ml for all testing.

— BS EN 13726-3:2003 waterproofness has a stated non-penetration time of 5 minutes for compliance, the dressings were tested over 5 minutes as per the standard and also over an extended period of 15 minutes at the clients request.

5.10 Sampling Details

All samples were selected and supplied by the client.

5.11 Sample Preparation

As per the relevant SMTL Test Method.

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6. Results

6.1 Moisture Vapour Transmission Rate (MVTR) - SMTL TM-8 Method

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

Figure 1. Allevyn Gentle - Moisture Vapour Transmission over 24 Hours

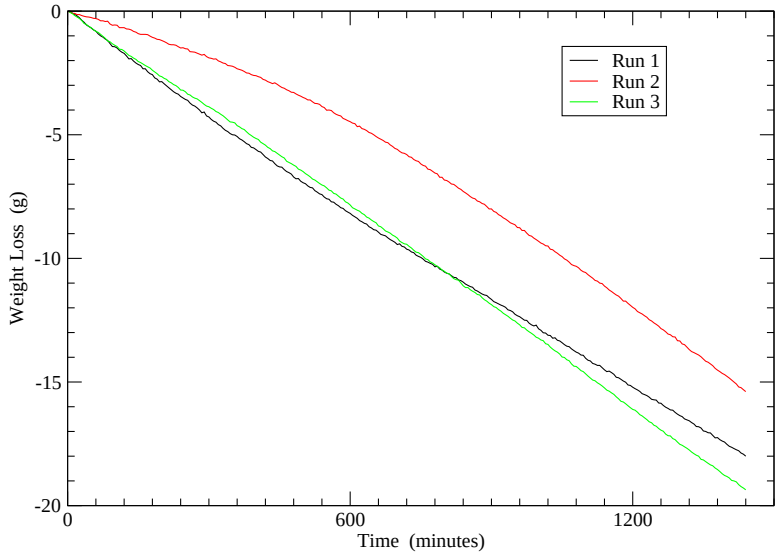

TABLE 2. Allevyn Gentle - MVTR over 24 hours

	MVTR (g/m^2/24Hrs)	
	4hrs	**24hrs**
Run 1	21146	17716
Run 2	8798	15693
Run 3	19059	19392
Mean	16334.3	17600.3

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Figure 2. Allevyn Gentle - Moisture Vapour Transmission over 48 Hours

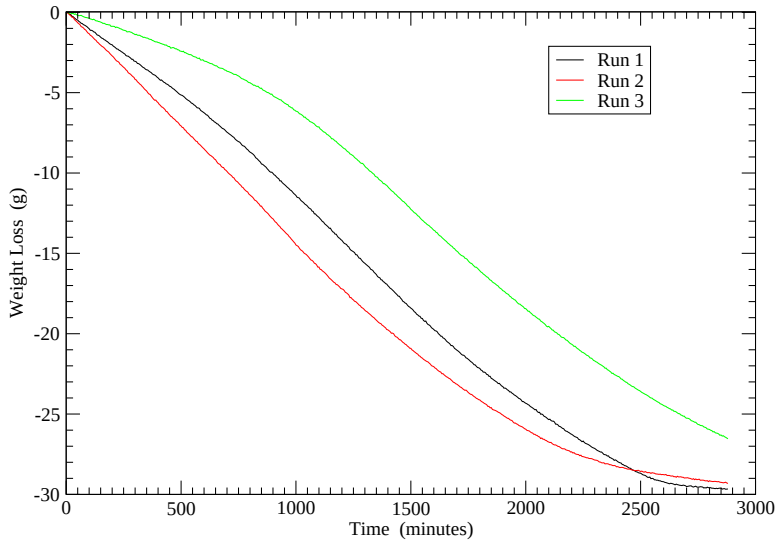

TABLE 3. Allevyn Gentle - MVTR over 48 hours

	MVTR ($g/m^2/24Hrs$)	
	4Hrs	**Max time †**
Run 1	14935	18292
Run 2	19937	20243
Run 3	6483	14801
Mean	13785	17778.7

Note:
† Values taken from slope of the testing prior to Paddington cups running dry.

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6.2 MVTR - BS EN 13726-2:2002 Method

The results of the MVTR testing over 24 hours when the dressings were in contact with the vapour and liquid are presented in Table 4 and Table 5 respectively.

TABLE 4. MVTR in contact with vapour

Dressing	Sample Number	Moisture Vapour Loss ($g/m^2/24hrs$)	Mean Moisture Vapour Loss ($g/m^2/24hrs$)
Allevyn Gentle	1	1798.3	**1953.1 (92.45)**
	2	2044.8	
	3	1989.3	
	4	1957.9	
	5	1975.1	

Note:
- Figures in brackets denote standard deviation

TABLE 5. MVTR in contact with liquid

Dressing	Sample Number	Moisture Vapour Loss ($g/m^2/24hrs$)	Mean Moisture Vapour Loss ($g/m^2/24hrs$)
Allevyn Gentle	1	20753.0	**20019.2 (1439.40)**
	2	20302.0	
	3	21335.0	
	4	20121.5	
	5	17584.6	

Note:
- Figures in brackets denote standard deviation

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6.3 Fluid Handling Testing

Following incubation, the Paddington cups were weighed and remaining exudate allowed to drain out of the cups in accordance with the test method. The cups were then re-weighed, to calculate the intact dressing absorbency.

The results of the fluid handling tests are presented in Tables 6 to 8

TABLE 6. Allevyn Gentle Fluid Handling Properties over 24 hours

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Allevyn Gentle	15.383 (0.8862)	6.734 (0.0733)	22.117 (0.8939)

TABLE 7. Allevyn Gentle Fluid Handling Properties over 48 hours

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Allevyn Gentle ‡	28.636 (1.4753)	1.388 (1.4774)	30.02 (0.0830)

TABLE 8. Allevyn Gentle Fluid Handling Properties over 72 hours

Dressing	Moisture Vapour Loss ($g/10cm^2$)	Absorbency ($g/10cm^2$)	Fluid Handling Capacity ($g/10cm^2$)
Allevyn Gentle ‡	29.801 (0.0739)	0.264 (0.01040	30.065 (0.0733)

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

‡ As presented in the 48 hour test data (Table 7) and 72 hour test data (Table 8), the Allevyn Gentle dressings handle the maximum capacity of test fluid the Paddington cups can hold. These results therefore are an indication of the amount of fluid applied and not necessarily the fluid handling capacity of the dressing.

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6.4 Conformability

The results of the conformability tests are presented in Table 9.

TABLE 9. Conformability Properties - Allevyn Gentle

Dressing	Inflation Pressure (mm Hg)
Allevyn Gentle	123
	120
	134
	143
	127
Mean	129.40 (9.236)

Note:
- Figures in brackets denote standard deviations.

6.5 Bacterial Penetration Test Results

The results of the bacterial barrier tests are presented in Table 10.

TABLE 10. Bacterial Barrier Test Results - Allevyn Gentle

Dressing	Sample No	Contamination of Sterile Broth +/-
Allevyn Gentle	1	-
	2	-
	3	-

Note:
- From the results all test samples were impermeable to *Serratia marcescens* for the duration of the test (seven days)

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6.6 Waterproofness

The results of the waterproofness testing are presented in Table 11.

TABLE 11. Waterproofness - Allevyn Gentle

Dressing	**Water Penetration/ Time Period**		**BS EN 13726-3 Compliance**
	5 Minutes	15 Minutes	
Allevyn Gentle	None	None	**Complies**

Note:
- 3 replicates tested.
- No water penetration was observed during the testing on any of the samples tested, therefore exhibiting compliance with the BS EN 13726-3:2003.

Peter Phillips, Director, SMTL. Date: 8th March 2010

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References

1. Surgical Materials Testing Lab., "Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method.," TM-8 ().
2. Surgical Materials Testing Lab., "Moisture Vapour Transmission Rate (MVTR) of Permeable Film Dressings to BS EN 13726-2:2002," TM-394 ().
3. "Test methods for primary wound dressings. Part 2; Moisture vapour transmission rate of permeable film dressings.," *BS EN 13726-2*, British Standards Institution, (2002).
4. Surgical Materials Testing Lab., , "Fluid Handling Capacity BS EN 13726-1:2002," TM-390 ().
5. "Test methods for primary wound dressings. Part 1; Aspects of absorbency. Section 3.3 - Fluid Handling Capacity (absorbency plus moisture vapour transmission rate, liquid in contact).," *BS EN 13726-1 Section 3.3*, British Standards Institution, (2002).
6. Surgical Materials Testing Lab., , "Conformability of Hydrocolloid and Film Dressings," TM-16 ().
7. Surgical Materials Testing Lab., "Bacterial Penetration Of Film Dressings," TM-43 ().
8. Surgical Materials Testing Lab., "Waterproofness to BS EN 13726-3:2003," TM-395 ().
9. "Test methods for primary wound dressings. Part 3; Waterproofness," *BS EN 13726-3*, British Standards Institution, (2003).

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S. M. T. L. Cover Sheet for Test Report

Title: **Testing of Allevyn Gentle Wound Dressing**

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