UKAS TESTING 1492

S . M . T . L .

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

date: **16th December 2009**

from: **Dr Gavin Hughes**
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Report No: 09/3201/7

Test Report

09/3201/7

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2. Introduction

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

This testing was originally reported in SMTL Test Report 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 AG Gentle 10 x 10cm	66800465	0926	39	18/8/2009	09/3104/1

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

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

3.1 Departures/Abnormalities of Sample Condition

None

4. Date of Testing

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 Fluid Handling Properties

The fluid handling properties of the dressings were examined using SMTL test method TM-390,[2] 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).*[3]

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

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

and the weight of fluid retained by the dressing calculated by difference.
This test can be repeated over a period of 48 hours.

5.3 Conformability

The conformability of the dressing was determined using SMTL test method TM-16.[4]

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 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.

5.4 Waterproofness

The waterproofness of the outer layer of the dressing was determined using SMTL test method TM-395,[5] which is written in accordance with the European Standard *BS EN 13726:3:2003 - Section 3.2.*[6]

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

† 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.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

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.

5.5 List of SMTL Test Methods Used.

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

— TM-390 - Fluid Handling Capacity BS EN 13726-1:2002[2]

— TM-16 - Conformability of Hydrocolloid and Film Dressings[4]

— TM-395 - Waterproofness to BS EN 13726-3:2003[5]

5.6 Standards relevant to the test method.

— The test method TM-390 Fluid Handling Capacity BS EN 13726-1:2002[2] 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)*[3]

— The SMTL test method TM-395[5] 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*

5.7 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.

5.8 Sampling Details

All samples were selected and supplied by the client.

5.9 Sample Preparation

As per the relevant SMTL Test Method.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

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 AG Gentle - Moisture Vapour Transmission over 24 Hours

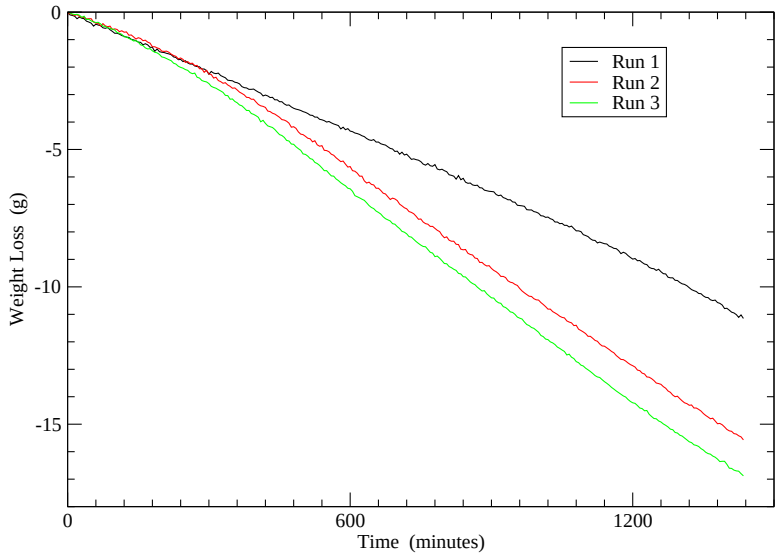

TABLE 2. Allevyn AG Gentle - MVTR over 24 hours

	MVTR (g/m^2/24Hrs)	
	4hrs	**24hrs**
Run 1	10,149	10,920
Run 2	10,056	16,441
Run 3	12,226	17,908
Mean	10,810	15,090

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

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

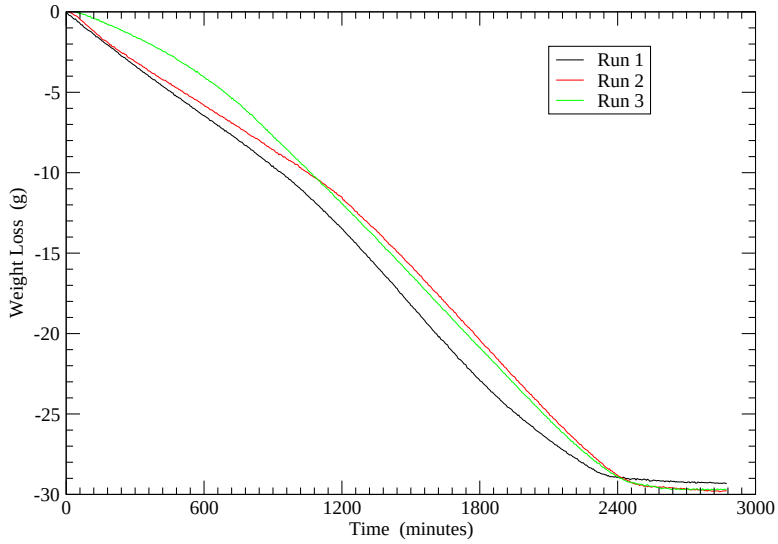

TABLE 3. Allevyn AG Gentle - MVTR over 48 hours

	MVTR (g/m^2/24Hrs)	
	4hrs	**Max Time †**
Run 1	16,019	18,670
Run 2	16,443	17,058
Run 3	7,725	18,676
Mean	13,396	18,135

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

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

6.2 Fluid Handling Testing

The results of the fluid handling tests are presented in Tables 4 and 5.

TABLE 4. Allevyn AG 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 AG Gentle	16.35 (0.659)	6.57 (0.334)	22.92 (0.498)

TABLE 5. Allevyn AG 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 AG Gentle ‡	28.02 (1.258)	1.82 (1.228)	29.84 (0.070)

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

‡ The absorbency of the dressing following 48 hours incubation is less than that of the 24 hour results. This is indicative that the Allevyn AG Gentle has handled the maximum capacity of test fluid the Paddington cups can hold, and that the dressing has started to dry out. These results are an indication of the amount of fluid applied and not necessarily the fluid handling capacity of the dressing.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

6.3 Conformability

The results of the conformability tests are presented in Table 6.

TABLE 6. Conformability Properties - Allevyn AG Gentle

Dressing No.	Inflation Pressure (mm Hg)
Allevyn AG Gentle	126
	129
	128
	121
	126
Mean	126.00 (3.082)

Note:
- Figure in brackets denote standard deviations.

6.4 Waterproofness

The results of the waterproofness testing are presented in Table 7.

TABLE 7. Waterproofness - Allevyn AG Gentle

Dressing	Water Penetration/ Time Period		BS EN 13726-3 Compliance
	5 Minutes	15 Minutes	
Allevyn AG 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.

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

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

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

References

1. Surgical Materials Testing Lab., "Moisture Vapour Transmission Rate from Dressings by Electronic Data Capture Method.," TM-8 ().
2. Surgical Materials Testing Lab., "Fluid Handling Capacity BS EN 13726-1:2002," TM-390 ().
3. "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).
4. Surgical Materials Testing Lab., , "Conformability of Hydrocolloid and Film Dressings," TM-16 ().
5. Surgical Materials Testing Lab., "Waterproofness to BS EN 13726-3:2003," TM-395 ().
6. "Test methods for primary wound dressings. Part 3; Waterproofness," *BS EN 13726-3*, British Standards Institution, (2003).

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

CONTENTS

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

LIST OF FIGURES

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

LIST OF TABLES

RCS Version Info: $Header: /projects/3201/Reports/report-Allevyn-AG-Gentle,v 1.2 2010/02/24 11:14:10 gavin Exp $

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