Study Report

JGKSL150113Dk

To determine the oxygen permeability
of a hydrogel product supplied by the sponsor

Study Sponsor

SwissLens SA
Ch. des Creuses 9
CH-1008 Prilly

Report Author	Report Approval	
Julia Glej-Kaliciak	Richard Young	13th January 2015
Analytical Chemist	Technical Group Manager	

Contamac Ltd

Orchard House Bearwalden Business Park Wendens Ambo Saffron Walden Essex CB11 4JX UK
Tel: +44 (0)1799 542000 Fax: +44 (0)1799 543000 E-mail: connect@contamac.co.uk

www.contamac.com

Company Registration No. 2609319 Incorporated in England and Wales Vat Registration No. 782 4505 20

Objective

The objective of this study is to determine the oxygen permeability of a moulded hydrogel product supplied by the sponsor.

All test services and reports provided by Contamac are provided on the following basis:

The test services provided by Contamac Limited ("Contamac") are not consultation services and no advice, guidance or solution is provided or should be inferred from Contamac's report. The report only provides the readings and results of the tests performed on the products supplied to Contamac by the customer, and it is provided for informational purposes. The customer relies on the contents of the report at its own risk. Contamac warrants to the customer that its services shall be performed using reasonable care and skill. Contamac makes no other warranties, express or implied. All other warranties, conditions and other terms implied by statute or common law (including but not limited to any implied warranties of suitability or fitness for purpose) are, to the fullest extent permitted by law, excluded. The report must only be used by the customer for its own internal business purposes and must not be disclosed to any third party, excluding the customer's professional advisors, without Contamac's prior written consent.

Sample Designation

The sponsor provided the following samples for this testing:

Reference samples

Lot No.	Exp.	BCOR	Diam	PWR	Qty	thickness
1407637	2017.01	8.9	15	-0.48	1	0.18
1407716	2017.01	8.9	15	-0.48	1	0.18
1407721	2017.01	8.9	15	-0.74	1	0.25
1407722	2017.01	8.9	15	-0.74	1	0.25
1407727	2017.01	8.9	15	-0.98	1	0.32
1407728	2017.01	8.9	15	-0.98	1	0.32
1407733	2017.01	8.9	15	-1.28	1	0.4
1407734	2017.01	8.9	15	-1.28	1	0.4

Opaque Colour samples

Lot No.	Exp.	BCOR	Diam	PWR	Qty	Thickness
1408691	2017.01	8.9	15	-0.48	1	0.18
1407718	2017.01	8.9	15	-0.48	1	0.18
1407723	2017.01	8.9	15	-0.74	1	0.25
1409262	2017.01	8.9	15	-0.74	1	0.25
1409263	2017.01	8.9	15	-0.98	1	0.32
1407730	2017.01	8.9	15	-0.98	1	0.32
1407735	2017.01	8.9	15	-1.28	1	0.4
1407736	2017.01	8.9	15	-1.28	1	0.4

Colour samples

Lot No.	Exp.	BCOR	Diam	PWR	Qty	thickness
1407719	2017.01	8.9	15	-0.48	1	0.18
1407720	2017.01	8.9	15	-0.48	1	0.18
1407725	2017.01	8.9	15	-0.74	1	0.25
1407726	2017.01	8.9	15	-0.74	1	0.25
1407731	2017.01	8.9	15	-0.98	1	0.32
1407732	2017.01	8.9	15	-0.98	1	0.32
1407737	2017.01	8.9	15	-1.28	1	0.4
1409264	2017.01	8.9	15	-1.28	1	0.4

Procedure

The testing was performed according to the following procedure.

Oxygen Permeability Measurements

Overview

The oxygen permeability is determined using Contamac Standard Procedure (CSP 128.03) which follows the guidance specified in EN ISO 18369-4:2006. This method uses the polarographic method for Dk determination.

The Polarographic method directly measures the number of oxygen molecules diffusing through a test material by electrochemically removing the molecules from the solution as soon as they pass through the material. As a molecule of oxygen emerges from the sample material, it contacts the centre electrode (cathode) of the oxygen sensor, placed against the back surface of the sample, and is instantaneously converted into hydroxyl ions. This production of ions constitutes the electric current, which is quantified by the apparatus and is proportional to the number of molecules removed. The measured current is used to calculate the uncorrected oxygen transmissibility and then corrected for both the boundary layer and edge effects. This enables the corrected oxygen permeability of a material to be calculated.

For DK to be measured four lens thicknesses are required. When measuring disposable lenses to achieve four separate thicknesses, lenses have to be 'stacked' one above the other. Care must be taken when stacking the lenses that no air bubbles are trapped between the layers. This is a deviation from the standard method since it is recommended that 4 lenses substantially differing with respect to thickness be used. However, any boundary layers formed between the lenses will act as constant barriers to oxygen flow and their effects can be eliminated by the reciprocal slope technique used in this measurement.

A key aspect of oxygen permeability determination is to ensure an accurate value is used for the thickness of the lens. The standard recommends a mean harmonic thickness value be used and if this is not supplied by the customer this can be calculated following the measurement of lens thickness at a series of points at increasing distances from the lens centre. For this measurement an electronic thickness gauge is used which has been specifically designed for this application, which ensures the lens is not squeezed in any way during measurement.

Equipment

Createch Model 201T Permeometer
Spherical Surface Polarographic Cell with
the area of the cathode face = 0.12775cm^2
Dark Current = 0.1Amps

Procedure

Before any measurements can be carried out, the environmental chamber must be stabilised at 35ºC ±0.5ºC with a maximum percentage of humidity. The chamber has been designed to achieve humidity values of approximately 95%. Samples are placed into the chamber to equilibrate prior to measurements.

Once the chamber has reached equilibrium, the measurements can be performed. The lens is placed carefully on the cell ensuring that no air bubbles are trapped between the sample and the surface of the cell. The current is allowed to stabilise on the permeometer and then recorded ensuring that the temperature of the cell is between 34.5ºC and 35.5ºC.

When a result is recorded, the temperature and humidity within the chamber are recorded. The atmospheric pressure is also recorded as this has a significant effect on the calculation of the Dk value. The thickness of the sample is known and is then used in the Dk calculation. This process is repeated until results are obtained for the samples at 4 different thickness values. The oxygen permeability corrected for both the edge and boundary layer effects is then mathematically derived from these values.

Enter the results in the appropriate spreadsheet that calculates the Dk value. The program will express the results in the form of a straight-line graph of the reciprocal of the transmissibility (resistance) versus thickness. A linear trendline is also generated and the R^2 value determines whether the results are valid by the following criteria.

Passing criteria :

If the R^2 value of the linear trendline is superior to 0.95.

Failing criteria :

If R^2 is inferior to 0.95, then measurements of abnormal points have to be carried out again.

Results

The results for this testing are summarised in the following tables and the actual experimental data can be found in the Appendix section found in the final pages of this report.

Test Article

Reference samples

	Mean	Standard deviation	Number of measurements
Oxygen permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x hPa))	18.24	0.67	5
Oxygen permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg))	24.31	0.89	5

Opaque Colour samples

	Mean	Standard deviation	Number of measurements
Oxygen permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x hPa))	18.08	0.53	5
Oxygen permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg))	24.10	0.71	5

Colour samples

	Mean	Standard deviation	Number of measurements
Oxygen permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x hPa))	18.53	0.89	5
Oxygen permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg))	24.71	1.19	5

Discussion

The results show good consistency across the samples measured for the test article.