

***Storage Stability Study for
Cutimed® Sorbact® Hydroactive***

Annex

This is a separate attachment for former(i.e. invalid) issues of storage stability study for Cutmed® Sorbact® Hydroactive.

Appendix 1 Storage Stability Study Issue 02 from 14th April 2011

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STORAGE TRIAL STILL IN PROGRESS

Interim Storage Stability Report:

Product: BSN Cutimed Sorbact Hydroactive Under Real Time,
Accelerated (40°C) and Accelerated (55°C) Storage Conditions

Report Number ST10-005

Issue Number / Status 2nd Issue (shelf-life extended to 29mths)

Issue Date 14th April 2011

		Signature	Date
Reviewed by	Dianne Wicks Laboratory Supervisor		
Issued by	Dr Nick Boote R&D Manager		

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Summary

This is an interim storage stability report (based on a 25C maximum storage temperature). The dressings have been validated as stable for 29 months by accelerated ageing at 55C, one year at 40C (test on-going) and one year at ambient conditions (test on-going). All test averages fall within the 95% confidence interval derived from the benchmark tests, which means there is no statistical difference between the aged dressings and their properties at the start of the study. There are no obvious trends in the test results either. Based on this interim assessment, it is extremely likely that the product will achieve a three year shelf-life at 25C.

Conclusion: Pass/Fail and Recommended Shelf Life

PASS (interim report: shelf-life not finalised, but currently accepted up to 29 mths with an anticipated minimum three years)

Anticipated Restrictions

None - anticipated to achieve three years minimum

Applicability to Substantially Equivalent Products

Equivalent to Hydroform (3 years achieved already) and applicable to all other sizes of CSH dressing

Issue Date 14th April 2011

Issued By Dr Nick Boote

Print Date 19 March 2014

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Purpose of Study

The purpose of the study is to evaluate properties of the dressing that are reflective of product performance, to ensure they do not change significantly over the course of the shelf-life in AMCOR PFL-302 packaging material. Water activity shows the relative humidity of the dressing is not changing in the storage conditions; saline uptake pertains to the fluid handling capability but more importantly the integrity of the crosslinked polymer network. The study is applicable to all other sizes of dressing.

Product Identification

Product Name

Cutimed Sorbact Hydroactive: 14 x 14 DC2LS/641/C1/1

Gamma Treatment and Date

27.0 - 34.5 kGy, 9th - 15th Feb 2010

General Description of Product

Gel Type

RDEV010: 40% crosslinked polymer, 30% water, 30% glycerol

Substrate Type

30 micron polyurethane with medium tack adhesive (Inspire 2331)

Top Liner Type

Sorbact

Packaging Type

AMCOR PFL-302 (generic name), AMCOR 5124 (specific name)

Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Identification and Control of Key Factors

Related Studies which Inform Assessment

Hydroform

Parameter	Required in This Study?	Justification or Method of Assessment
Pouch Properties		
Pouch Integrity	N	Weight Change, Burst Pressure
Pouch Printing	N	Qualitative Inspection
Dressing Release from Pouch	Y	Qualitative Inspection
Liner Function		
Gel Bonding & Release from Top Liner	N	Qualitative Inspection
Gel Bonding & Release from Substrate Liner	N	Qualitative Inspection
Gel Adhesion to Mesh	Y	Qualitative Inspection
Dressing Adhesion to substrate	N	Instron Peel Test
Liner & substrate appearance	Y	Qualitative Inspection
Gel Properties		
Qualitative - feel, residue, colour, odour, general appearance, tack	Y	Qualitative Inspection
Gel Physical Integrity	Y	24 hour Calcium/Sodium Saline uptake, Rheology
Adhesion to substrate	N	Instron Peel Test
Dressing Fluid Handling	Y	24 hour Calcium/Sodium Saline uptake, Dynamic Wound Model, Wicking Speed
Gel Chemical stability	Y	Surface pH, Water activity, Ion exchange or release
Product-Specific Properties and Function		

Specification Requirements

Property	Limits	Method or Notes
See specific tests for details		

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Protocols

Basis of Assessment

Products are characterised shortly after manufacture, and periodically thereafter while being stored at either ambient or elevated temperature and relative humidity. The required inspections are selected in order to ensure that key properties of the products are maintained, which ensure that the product remain fit for purpose throughout its planned shelf-life. The purpose of a storage stability study is to assess changes in properties rather than variation in manufacturing. Therefore, limits for storage stability studies will not generally coincide with sales specifications. Acceptance limits are established based on the initial characterisation, knowledge of the measurement reproducibility, characteristics of related products, and the impact of any variation. Minor variation in product characteristics may be acceptable provided that it is evaluated as not adversely impacting product function or perceived quality.

Ultimate acceptance and recommendations concerning shelf life are made on the basis of expert technical judgement. However, where appropriate, statistical analysis is used as a factor to support such assessments and a significance level ("p") of 0.05 is used, along with any other available information relating to measurement reproducibility. Information from related products may be used to assist technical assessments. Initially, it may be necessary to recommend relatively short shelf life, pending completion of further studies.

Real Time Storage

Samples are monitored as received from the initiator, in this case the First Water R&D Manager. Samples are stored in the First Water Archive, in the storage packaging as received. The archive is a dedicated area in the Ramsbury Production Facility, and is not temperature or humidity controlled, but is subject to normal variation according to building air conditioning effects. Typically, this is a temperature variation of approximately 18-24°C, with humidity of 25-40%.

Accelerated Ageing Storage (40°C, 55%RH, and 55°C, 55%RH)

Samples are monitored as received from the initiator, in this case the First Water R&D Manager. Samples are stored in a calibrated incubator (Mercia Scientific Model MER-700-SCN/RH/Alm), in the storage packaging as received. The incubator is set to a nominal 40°C, 55% humidity. In the case of the 55°C, 55%RH study the storage cabinet is a Fisons HC (No. 5741). A log of the incubator conditions is made on each working day.

Note that as an operational device, the storage cabinet is subject to transient variation in conditions when it is opened for samples. A log of the recorded conditions is attached.

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Report Reference: BSN CSH DC2LS/641/C1/1(A B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Condition

Inspection Date	30 Mar 10	Tester	DW
Parameter	Observation		
Pouch Printing			
Pouch Visual Integrity	pouches appear well sealed		
Gel Release fr. Top Liner	N/A		
Gel Release fr. Substrate Liner	N/A		
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)		
Border Release fr. liners	Mesh is well stuck to the borders (x3)		
Liner & substrate appearance	Back liners remove easily		
Gel Visual and Colour	Gel is starting to yellow slightly, but is entirely covered in green mesh		
Dressing Odour	Slight smell - slightly stale		
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)		
Gel Residue	No residue (x3)		
PHOTO / NOTES			

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Report Reference: BSN CSH DC2LS/641/C1/1(A B&C) Storage trial ST10-005
Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Condition

Inspection Date	4-May-2010	11wks	Tester	DW
Parameter	Observation			
Pouch Printing				
Dressing Release from Pouch	14 x 14cm dressing	All 3 dressings remove easily - no sticking.		
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is slightly yellow, with skin, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slightly stale smell.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES	No change			

Inspection Date	8-Jun-2010	11wks	Tester	DW
Parameter	Observation			
Pouch Printing				
Pouch Visual Integrity	pouches appear well sealed			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is light yellow/brown, with skin, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slightly sharp/stale smell.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES				

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Report Reference: BSN CSH DC2LS/641/C1/1(A B&C) Storage trial ST10-005
Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Condition

Inspection Date	14-Jul-2010	16wks	Tester	DV
Parameter	Observation			
Pouch Printing				
Dressing Release from Pouch	14 x 14cm dressing. All 3 dressings remove easily - no sticking.			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is light yellow/brown, with skim, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slightly sharp/stale smell. If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Feel and tack				
Gel Residue	No residue (x3)			
PHOTO / NOTES				

Inspection Date		Tester	
Parameter	Observation		
Pouch Printing			
Pouch Visual Integrity			
Dressing Release from Pouch			
Gel Release fr. Top Liner			
Gel Release fr. Substrate Liner			
Gel Adhesion to Mesh			
Border Release fr. liners			
Liner & substrate appearance			
Gel Visual and Colour			
Dressing Odour			
Gel Feel and tack			
Gel Residue			
PHOTO / NOTES			

Conclusions: Assessment of Qualitative Inspections

There are no deleterious changes to the attributes of the product that were qualitatively assessed during this study. Test results PASS.

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Fast (55°C) Accelerated Storage Conditions

Test Method **Ramsbury Laboratory SDP: "Water Activity of a Gel or Solution"**
(Method used is revision applicable at time of test, following method for each individual sample;

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	Water Activity
Mean	0.652
Standard Deviation	0.003
Number of samples	6.000
± 85% Confidence	0.008
Expected Min	0.644
Expected Max	0.659
± 95% Confidence	0.003

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	Water Activity
Min Limit	0	0.64
	16	0.64
Max Limit	0	0.66
	16	0.66

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Water Activity Properties

There is no change in the water activity throughout the entire duration of the storage trial at 55°C. The results at each time point are all within the 95% confidence intervals derived from the benchmark data. TEST RESULT: PASS

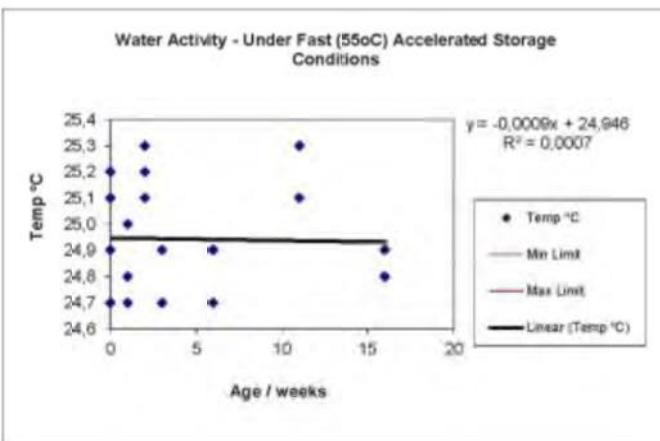
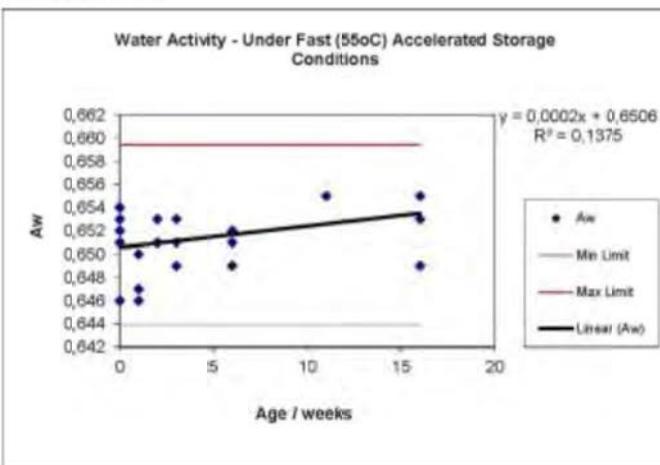
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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Fast (55°C) Accelerated Storage Conditions

Water Activity Graphs



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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Fast (55°C) Accelerated Storage Conditions

Test Method Ramsbury Laboratory SOP: "% Ca/NaCl Saline Uptake of a Gel"
(Method used is revision applicable at time of test, following method for each individual sample.)

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	% Ca/NaCl Uptake	Initial Wt: .g
Mean	1394.696	0.216
Standard Deviation	59.674	0.010
Number of samples	6.000	6.000
± 95% Confidence	153.397	0.026
Expected Min	1241.299	0.191
Expected Max	1548.093	0.242
± 99% Confidence	62.624	0.010

Acceptance Limits*(These limits are not sales specifications)*

Limit Type	Weeks	% Ca/NaCl Uptake	Initial Wt: .g
Min Limit	0	1241	0.095
	16	1241	0.095
Max Limit	0	1548	0.363
	16	1548	0.363

Justification for Acceptance Limits

For saline uptake, use 95% confidence. For weight, show no trends of change.

Conclusions: Assessment of Calcium/Sodium Chloride Saline Uptake Properties

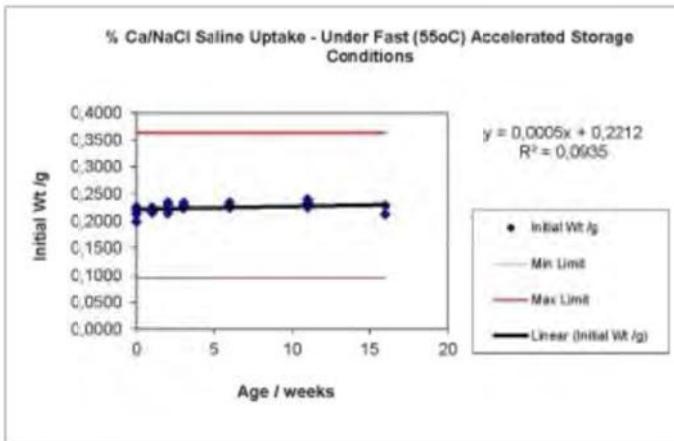
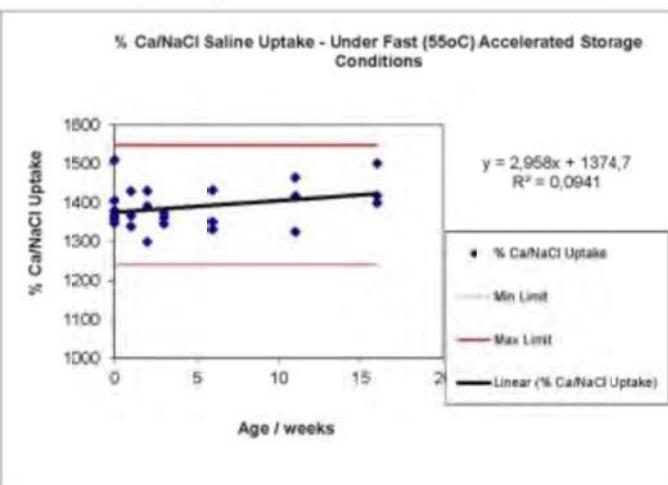
The saline uptake test is a simple but powerful test for evaluating the integrity of the crosslinked polymer network in the hydrogel. The averages at each time point are within ± 95% of the benchmark values. The weight of the samples show no changes during the course of the study. The polymer network is maintaining its integrity over the duration of the study. TEST RESULT: PASS

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
% Ca/NaCl Saline Uptake - Under Fast (55°C) Accelerated Storage Conditions

% Ca/NaCl Saline Uptake Graphs



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Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Accelerated (40°C) Storage Conditions

Inspection Date	21 April 10	4 wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	Slight smell, but not unpleasant			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

Inspection Date	12 May 2010	7 wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	Slightly stale smell, but not too unpleasant			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

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Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Accelerated (40°C) Storage Conditions

Inspection Date	Due 20th Sept 2011	Tester	Observation
Parameter			
Pouch Visual Integrity			
Dressing Release from Pouch			
Gel Release fr. Top Liner			
Gel Release fr. Substrate Liner			
Gel Adhesion to Mesh			
Border Release fr. liners			
Liner & substrate appearance			
Gel Visual and Colour			
Dressing Odour			
Gel Feel and tack			
Gel Residue			
PHOTO / NOTES			

Conclusions: Assessment of Qualitative Inspections

This trial is still in-progress. The findings after 26 weeks show that there are no deleterious changes in the qualitative attributes of the dressing. RESULT: TEST currently PASSED

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Accelerated (40°C) Storage Conditions

Test Method **Ramsbury Laboratory SOP: "Water Activity of a Gel or Solution"**
(Method used is revision applicable at time of test, following method for each individual sample)

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	Water Activity
Mean	0.652
Standard Deviation	0.003
Number of samples	6,000
± 95% Confidence	0.008
Expected Min	0.644
Expected Max	0.659
± 95% Confidence	0.003

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	Water Activity
Min Limit	0	0.644
	52	0.644
Max Limit	0	0.659
	52	0.659

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Water Activity Properties

Trial still in progress: there is no change in the water activity throughout the current duration of the storage trial at 40C. The average at each time point are all within the 95% confidence intervals derived from the benchmark data. Current RESULT: PASS

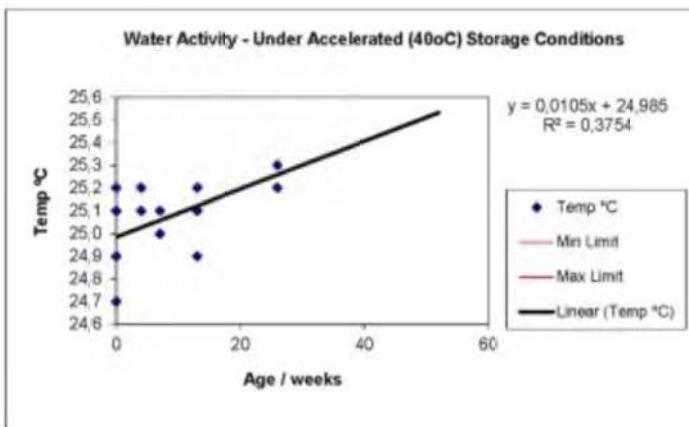
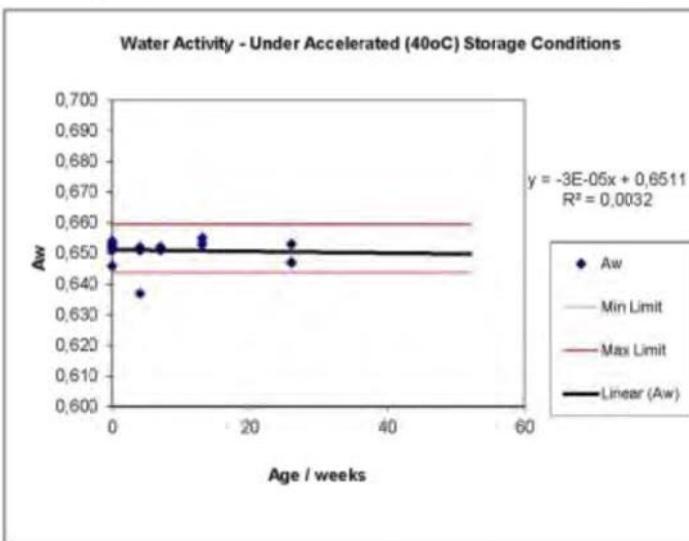
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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Accelerated (40°C) Storage Conditions

Water Activity Graphs



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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Accelerated (40°C) Storage Conditions**Base Data**

Accelerated Ageing	Weeks	Aw	Temp °C		Test date	Tested by
Sample 1	0	0.654	25.2		23 Mrz 10	DW
Sample 2	0	0.646	25.1		23 Mrz 10	DW
Sample 3	0	0.654	24.7		23 Mrz 10	DW
Sample 4	0	0.651	24.9		25 Mrz 10	AM
Sample 5	0	0.652	24.9		25 Mrz 10	AM
Sample 6	0	0.653	24.9	0.652	25 Mrz 10	AM
Sample 1	4	0.651	25.1		20 Apr 10	DW
Sample 2	4	0.637	25.1		20 Apr 10	DW
Sample 3	4	0.652	25.2	0.647	20 Apr 10	DW
Sample 1	7	0.652	25.1		11 Mai 10	DW
Sample 2	7	0.651	25.1		11 Mai 10	DW
Sample 3	7	0.652	25.0	0.652	11 Mai 10	DW
Sample 1	13	0.653	24.9		22 Jun 10	DW
Sample 2	13	0.655	25.2		22 Jun 10	DW
Sample 3	13	0.655	25.1	0.654	22 Jun 10	DW
Sample 1	26	0.653	25.3		22 Sep 10	DW
Sample 2	26	0.647	25.3		22 Sep 10	DW
Sample 3	26	0.647	25.2	0.649	22 Sep 10	DW
Sample 1	39					
Sample 2	39					
Sample 3	39					
Sample 1	52					
Sample 2	52					
Sample 3	52					

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Accelerated (40°C)Storage Conditions

Test Method **Ramsbury Laboratory SOP: "% Ca/NaCl Saline Uptake of a Gel"**
(Method used is revision applicable at time of test, following method for each individual sample)

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	% Ca/NaCl Uptake	Initial Wt. /g
Mean	1394.696	0.216
Standard Deviation	59.674	0.010
Number of samples	6,000	6,000
± 95% Confidence	153.397	0.026
Expected Min	1241.299	0.191
Expected Max	1548.093	0.242
± 95% Confidence	62.624	0.010

Acceptance Limits*(These limits are not sales specifications)*

Limit Type	Weeks	% Ca/NaCl Uptake	Initial Wt. /g
Min Limit	0	1241	0.095
	78	1241	0.095
Max Limit	0	1548	0.363
	78	1548	0.363

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Calcium/Sodium Chloride Saline Uptake Properties

This trial is still in progress: the saline uptake test is a simple but powerful test for evaluating the integrity of the crosslinked polymer network in the hydrogel. The averages at each time point are within ± 95% of the benchmark values. The weight of the samples show no changes during the course of the study. The polymer network is maintaining its integrity over the duration of the study. Current RESULT: PASS

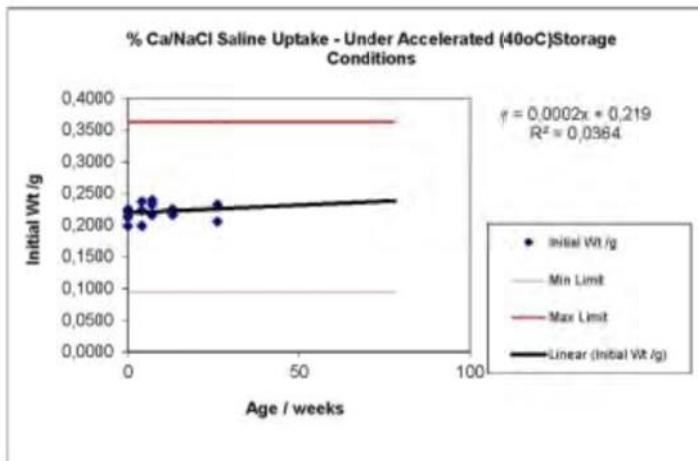
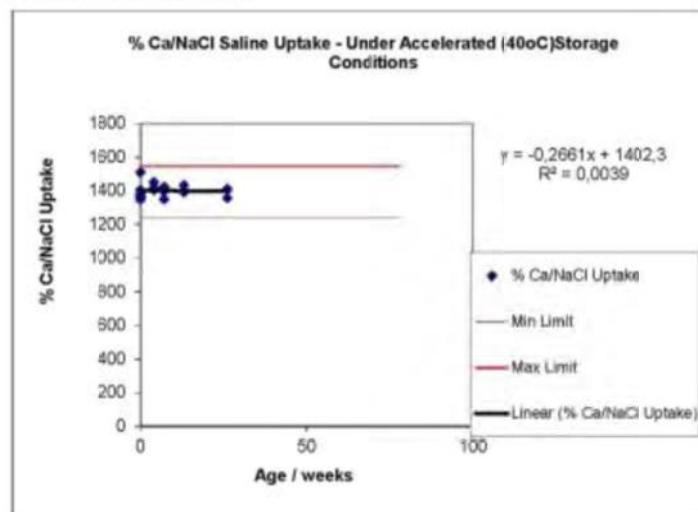
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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Accelerated (40°C)Storage Conditions

% Ca/NaCl Saline Uptake Graphs



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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Accelerated (40°C)Storage Conditions**Base Data**

Accelerated Ageing	Weeks	% Ca/NaCl Uptake	Initial Wt /g	Final Wt /g	Test date	Tested by
Sample 1	0	1359	0.2193	3.20	24 Mrz 10	DW
Sample 2	0	1380	0.2195	3.25	24 Mrz 10	DW
Sample 3	0	1405	0.2239	3.37	24 Mrz 10	DW
Sample 4	0	1347	0.1983	2.87	25 Mrz 10	AM
Sample 5	0	1510	0.2249	3.62	25 Mrz 10	AM
Sample 6	0	1367	0.2120	3.11	25 Mrz 10	AM
Sample 1	4	1450	0.2368	3.67	21 Apr 10	DW
Sample 2	4	1404	0.1988	2.99	21 Apr 10	DW
Sample 3	4	1416	0.2229	3.38	21 Apr 10	DW
Sample 1	7	1423	0.2390	3.64	12 Mai 10	DW
Sample 2	7	1396	0.2153	3.22	12 Mai 10	DW
Sample 3	7	1349	0.2325	3.37	12 Mai 10	DW
Sample 1	13	1389	0.2250	3.35	23 Jun 10	DW
Sample 2	13	1433	0.2159	3.31	23 Jun 10	DW
Sample 3	13	1401	0.2245	3.37	23 Jun 10	DW
Sample 1	26	1356	0.2054	2.99	23 Sep 10	DW
Sample 2	26	1405	0.2326	3.50	23 Sep 10	DW
Sample 3	26	1411	0.2323	3.51	23 Sep 10	DW
Sample 1	78	#DIV/0!				
Sample 2	78	#DIV/0!				
Sample 3	78	#DIV/0!				

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Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005
Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	24 Mar 10	Benchmark	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	One pouch from each lot (A,B&C). 20cm x 18.5cm pouch. All 3 pouches appear well sealed.			
Dressing Release from Pouch	14 x 14cm dressing	All 3 dressings remove easily - no sticking		
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is clear, with skim, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slight smell, but not unpleasant - slight almonds			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES				

Inspection Date	23 Mar 10	Benchmark	Tester	AM
Parameter	Observation			
Pouch Visual Integrity	20 x 21cm pouch. All 3 pouches sealed well			
Dressing Release from Pouch	14 x 14cm dressing	All removed easily from pouch -no sticking		
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel stuck to mesh but feels dry. Mesh stuck to borders			
Border Release fr. liners				
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is clear with skim			
Dressing Odour	Slight almond odour - not unpleasant			
Gel Feel and tack	If fingers are run over the dressing it appears dry. When pressure applied in single place, then feels slightly sticky			
Gel Residue	No residue			
PHOTO / NOTES				

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Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005
Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	21 April 10	4 wks	Tester	D/W
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	As for benchmark			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

Inspection Date	13 July 10	16 wks	Tester	D/W
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	As for benchmark			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	23 Mar 11	52wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	As for benchmark			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

Inspection Date		Tester	
Parameter	Observation		
Pouch Visual Integrity			
Dressing Release from Pouch			
Gel Release fr. Top Liner			
Gel Release fr. Substrate Liner			
Gel Adhesion to Mesh			
Border Release fr. liners			
Liner & substrate appearance			
Gel Visual and Colour			
Dressing Odour			
Gel Feel and tack			
Gel Residue			
PHOTO / NOTES			

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Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	Tester	Observation
Parameter		
Pouch Visual Integrity		
Dressing Release from Pouch		
Gel Release fr. Top Liner		
Gel Release fr. Substrate Liner		
Gel Adhesion to Mesh		
Border Release fr. liners		
Liner & substrate appearance		
Gel Visual and Colour		
Dressing Odour		
Gel Feel and tack		
Gel Residue		
PHOTO / NOTES		

Inspection Date	Tester	Observation
Parameter		
Pouch Visual Integrity		
Dressing Release from Pouch		
Gel Release fr. Top Liner		
Gel Release fr. Substrate Liner		
Gel Adhesion to Mesh		
Border Release fr. liners		
Liner & substrate appearance		
Gel Visual and Colour		
Dressing Odour		
Gel Feel and tack		
Gel Residue		
PHOTO / NOTES		

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Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage under Real Time Conditions

Conclusions: Assessment of Qualitative Inspections

This trial is still in-progress. The findings after 1 year show that there are no deleterious changes in the qualitative attributes of the dressing. RESULT: TEST currently PASSED

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Water Activity - Under Real Time Storage Conditions

Test Method **Ramsbury Laboratory SOP: "Water Activity of a Gel or Solution"**
(Method used is revision applicable at time of test, following method for each individual sample,

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	Water Activity
Mean	0.652
Standard Deviation	0.003
Number of samples	6.000
± 95% Confidence	0.008
Expected Min	0.644
Expected Max	0.659
± 95% Confidence	0.003

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	Water Activity
Min Limit	0	0.644
	156	0.644
Max Limit	0	0.659
	156	0.659

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Water Activity Properties

Trial still in progress: there is no change in the water activity throughout the current duration of the storage trial at ambient conditions. The average at each time point are all within the 95% confidence intervals derived from the benchmark data.
Current RESULT: PASS.

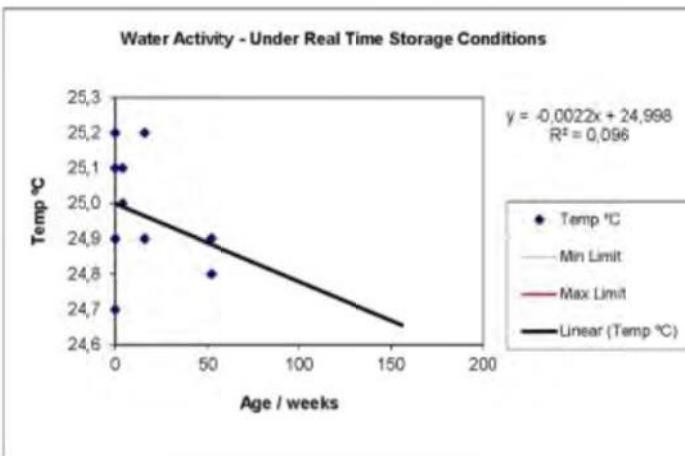
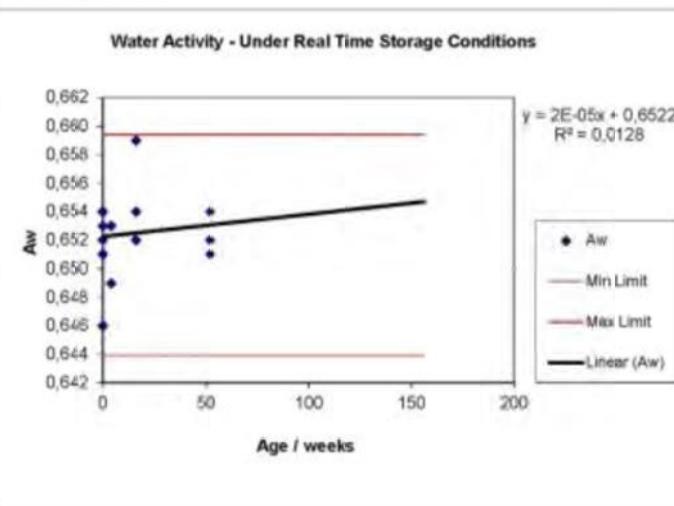
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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Real Time Storage Conditions

Water Activity Graphs



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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Water Activity - Under Real Time Storage Conditions

Base Data

Real Time Ageing	Weeks	Aw	Temp °C		Test date	Tested by
Sample 1	0	0.654	25.2		23.Mrz.10	DW
Sample 2	0	0.646	25.1		23.Mrz.10	DW
Sample 3	0	0.654	24.7		23.Mrz.10	DW
Sample 4	0	0.651	24.9		25.Mrz.10	AM
Sample 5	0	0.652	24.9		25.Mrz.10	AM
Sample 6	0	0.653	24.9		25.Mrz.10	AM
Sample 1	4	0.653	25.1		20.Apr.10	DW
Sample 2	4	0.649	25.0		20.Apr.10	DW
Sample 3	4	0.653	25.1		20.Apr.10	DW
Sample 1	16	0.659	25.2		14.Jul.10	DW
Sample 2	16	0.654	24.9		14.Jul.10	DW
Sample 3	16	0.652	24.9		14.Jul.10	DW
Sample 1	52	0.652	24.9		22.Mrz.11	DW
Sample 2	52	0.651	24.9		22.Mrz.11	DW
Sample 3	52	0.654	24.8		22.Mrz.11	DW
Sample 1	104					
Sample 2	104					
Sample 3	104					
Sample 1	156					
Sample 2	156					
Sample 3	156					

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Report Reference: BSN CSH DC2LSI641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Real Time Storage Conditions

Test Method **Ramsbury Laboratory SOP: "% Ca/NaCl Saline Uptake of a Gel"**
(Method used is revision applicable at time of test, following method for each individual sample)

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	% Ca/NaCl Uptake	Initial Wt /g
Mean	1394.696	0.216
Standard Deviation	59.674	0.010
Number of samples	6.000	6.000
± 95% Confidence	153.397	0.026
Expected Min	1241.299	0.191
Expected Max	1548.093	0.242
± 95% Confidence	62.624	0.010

Acceptance Limits*(These limits are not sales specifications)*

Limit Type	Weeks	% Ca/NaCl Uptake	Initial Wt /g
Min Limit	0	1241.299	0.095
	156	1241.299	0.095
Max Limit	0	1548.093	0.363
	156	1548.093	0.363

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Calcium/Sodium Chloride Saline Uptake Properties

This trial is still in progress: the saline uptake test is a simple but powerful test for evaluating the integrity of the crosslinked polymer network in the hydrogel. The averages at each time point are within ± 95% of the benchmark values. The weight of the samples show no changes during the course of the study. The polymer network is maintaining its integrity over the duration of the study. Current RESULT: PASS

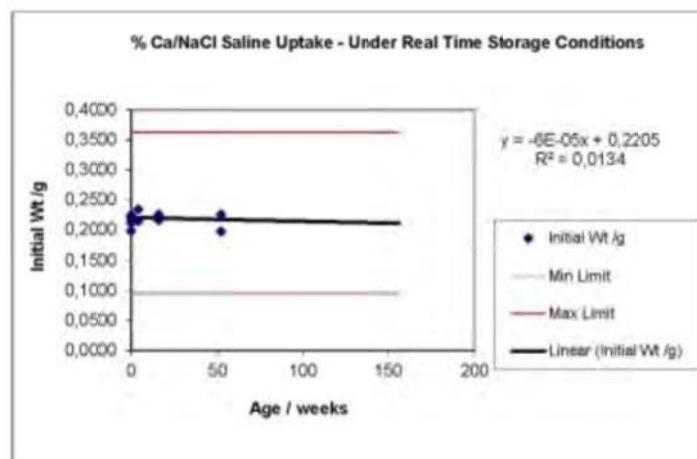
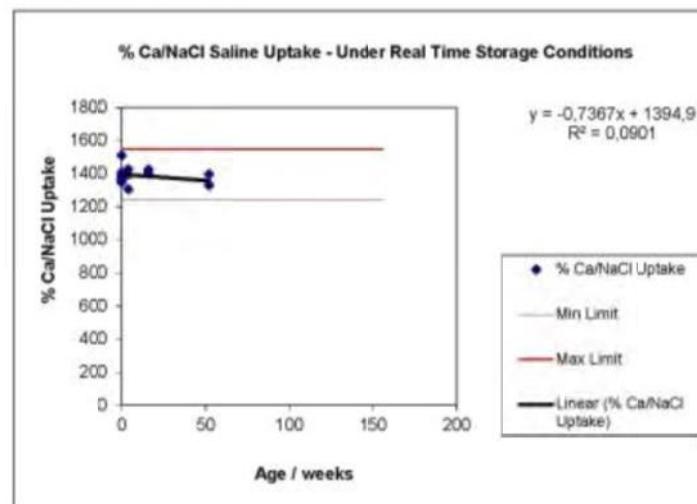
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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Real Time Storage Conditions

% Ca/NaCl Saline Uptake Graphs



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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Real Time Storage Conditions**Base Data**

Real Time Ageing	Weeks	% Ca/NaCl Uptake	Initial Wt /g	Final Wt /g	Test date	Tested by
Sample 1	0	1359	0.2193	3.20	24 Mrz.10	DW
Sample 2	0	1380	0.2196	3.25	24 Mrz.10	DW
Sample 3	0	1405	0.2239	3.37	24 Mrz.10	DW
Sample 4	0	1347	0.1983	2.87	25 Mrz.10	AM
Sample 5	0	1510	0.2249	3.62	25 Mrz.10	AM
Sample 6	0	1367	0.2120	3.11	25 Mrz.10	AM
Sample 1	4	1393	0.2344	3.50	21 Apr.10	DW
Sample 2	4	1426	0.2143	3.27	21 Apr.10	DW
Sample 3	4	1304	0.2343	3.29	21 Apr.10	DW
Sample 1	16	1401	0.2225	3.34	14 Jul.10	DW
Sample 2	16	1397	0.2165	3.24	14 Jul.10	DW
Sample 3	16	1423	0.2258	3.44	14 Jul.10	DW
Sample 1	52	1330	0.2252	3.22	24 Mrz.11	DW
Sample 2	52	1395	0.1973	2.95	24 Mrz.11	DW
Sample 3	52	1327	0.2257	3.22	24 Mrz.11	DW
Sample 1	104	#DIV/0!				
Sample 2	104	#DIV/0!				
Sample 3	104	#DIV/0!				
Sample 1	156	#DIV/0!				
Sample 2	156	#DIV/0!				
Sample 3	156	#DIV/0!				

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END OF DOCUMENT

Appendix 2 Storage Stability Study Issue 01 from 11th April 2011

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STORAGE TRIAL STILL IN PROGRESS

Interim Storage Stability Report:

Product: BSN Cutimed Sorbact Hydroactive Under Real Time, Accelerated
(40°C) and Accelerated (55°C) Storage Conditions

Report Number ST10-005
Issue Number / Status First Issue
Issue Date 11th April 2011

		Signature	Date
Reviewed by	Dianne Wicks Laboratory Supervisor		13 APR 11
Issued by	Dr Nick Boote R&D Manager		13-APR-11

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Summary

This is an interim storage stability report (assuming a 30C maximum storage temperature). The dressings have been validated as stable for 19 months by accelerated ageing at 55C, one year at 40C (test on-going) and one year at ambient conditions (test on-going). All test averages fall within the 95% confidence interval derived from the benchmark tests, which means there is no statistical difference between the aged dressings and their properties at the start of the study. There are no obvious trends in the test results either. Based on this interim assessment, it is extremely likely that the product will achieve a three year shelf-life at 30C.

Conclusion: Pass/Fail and Recommended Shelf Life

PASS (interim report: shelf-life not finalised, but currently accepted up to 19 mths with an anticipated minimum three years)

Anticipated Restrictions

None - anticipated to achieve three years minimum

Applicability to Substantially Equivalent Products

Equivalent to Hydroform (3 years achieved already) and applicable to all other sizes of CSH dressing

Issue Date 12th April 2011

Issued By Dr Nick Boote

Print Date 10 June 2011

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Purpose of Study

The purpose of the study is to evaluate properties of the dressing that are reflective of product performance, to ensure they do not change significantly over the course of the shelf-life in AMCOR PFL-302 packaging material. Water activity shows the relative humidity of the dressing is not changing in the storage conditions; saline uptake pertains to the fluid handling capability but more importantly the integrity of the crosslinked polymer network. The study is applicable to all other sizes of dressing.

Product Identification

Product Name

Cutimed Sorbact Hydroactive 14 x 14 DC2LS/641/C1/1

Gamma Treatment and Date

27.0 - 34.5 kGy, 9th - 15th Feb 2010

General Description of Product

Gel Type

RDEV010: 40% crosslinked polymer, 30% water, 30% glycerol

Substrate Type

30 micron polyurethane with medium tack adhesive (Inspire 2331)

Top Liner Type

Sorbact

Packaging Type

AMCOR PFL-302 (generic name), AMCOR 5124 (specific name)

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Identification and Control of Key Factors

Related Studies which Inform Assessment

Hydroform

Parameter	Required in This Study?	Justification or Method of Assessment
Pouch Properties		
Pouch Integrity	N	Weight Change, Burst Pressure
Pouch Printing	N	Qualitative Inspection
Dressing Release from Pouch	Y	Qualitative Inspection
Liner Function		
Gel Bonding & Release from Top Liner	N	Qualitative Inspection
Gel Bonding & Release from Substrate Liner	N	Qualitative Inspection
Gel Adhesion to Mesh	Y	Qualitative Inspection
Dressing Adhesion to substrate	N	Instron Peel Test
Liner & substrate appearance	Y	Qualitative Inspection
Gel Properties		
Qualitative - feel, residue, colour, odour, general appearance, tack	Y	Qualitative Inspection
Gel Physical Integrity	Y	24 hour Calcium/Sodium Saline uptake, Rheology
Adhesion to substrate	N	Instron Peel Test
Dressing Fluid Handling	Y	24 hour Calcium/Sodium Saline uptake, Dynamic Wound Model, Wicking Speed
Gel Chemical stability	Y	Surface pH, Water activity, Ion exchange or release
Product-Specific Properties and Function		

Specification Requirements

Property	Limits	Method or Notes
See specific tests for details		

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Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005

Protocols

Basis of Assessment

Products are characterised shortly after manufacture, and periodically thereafter while being stored at either ambient or elevated temperature and relative humidity. The required inspections are selected in order to ensure that key properties of the products are maintained, which ensure that the product remain fit for purpose throughout its planned shelf-life. The purpose of a storage stability study is to assess changes in properties rather than variation in manufacturing. Therefore, limits for storage stability studies will not generally coincide with sales specifications. Acceptance limits are established based on the initial characterisation, knowledge of the measurement reproducibility, characteristics of related products, and the impact of any variation. Minor variation in product characteristics may be acceptable provided that it is evaluated as not adversely impacting product function or perceived quality.

Ultimate acceptance and recommendations concerning shelf life are made on the basis of expert technical judgement. However, where appropriate, statistical analysis is used as a factor to support such assessments and a significance level (" α ") of 0.05 is used, along with any other available information relating to measurement reproducibility. Information from related products may be used to assist technical assessments. Initially, it may be necessary to recommend relatively short shelf life, pending completion of further studies.

Real Time Storage

Samples are monitored as received from the initiator, in this case the First Water R&D Manager. Samples are stored in the First Water Archive, in the storage packaging as received. The archive is a dedicated area in the Ramsbury Production Facility, and is not temperature or humidity controlled, but is subject to normal variation according to building air conditioning effects. Typically, this is a temperature variation of approximately 18-24°C, with humidity of 25-40%.

Accelerated Ageing Storage (40C, 55%RH, and 55C, 55%RH)

Samples are monitored as received from the initiator, in this case the First Water R&D Manager. Samples are stored in a calibrated incubator (Mercia Scientific Model MER-700-SCN/RH/Alm), in the storage packaging as received. The incubator is set to a nominal 40°C, 55% humidity. In the case of the 55C, 55%RH study the storage cabinet is a Fisons HC (No. 5741). A log of the incubator conditions is made on each working day.

Note that as an operational device, the storage cabinet is subject to transient variation in conditions when it is opened for samples. A log of the recorded conditions is attached.

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Report Reference: BSN CSH DC2LS.641/C 1/1(A,B&C) Storage trial ST10-005
Schedule of Testing

Planned tests

Test	Accel'd. Storage	Real Time Storage
Qualitative Inspections (General visual inspection, smell, colour, texture, filter release)	Y	Y
Rheology	n	n
Surface pH	n	n
Water Activity	Y	Y
Water Uptake (NaCl/CaCl ₂ electrolytic solution)	Y	Y
Fluid Handling By DWM	n	n
Fluid Retention	n	n
Non Contact MVTR	n	n
Pouch Integrity by weight loss	n	n

Target Test Dates

Fast Accelerated Tests (55°C)

Weeks	Date	Day	Notes and Specific Planned Requirements
Benchmarking			
0	23. Mrz 10	dddd	
Repeat Tests at			
1	30. Mrz 10	dddd	
2	06. Apr 10	dddd	
3	13. Apr 10	dddd	
6	04. Mai 10	dddd	
11	08. Jun 10	dddd	
16	13. Jul 10	dddd	

Accelerated Tests (40°C)

Weeks	Date	Day	Notes and Specific Planned Requirements
Benchmarking			
0	23. Mrz 10	dddd	
Repeat Tests at			
4	20. Apr 10	dddd	
7	11. Mai 10	dddd	
13	22. Jun 10	dddd	
26	21. Sep 10	dddd	
78	20. Sep 11	dddd	

Real Time Tests

Weeks	Date	Day	Notes and Specific Planned Requirements
Benchmarking			
0	23. Mrz 10	dddd	
Repeat Tests at			
4	20. Apr 10	dddd	
16	13. Jul 10	dddd	
52	22. Mrz 11	dddd	
104	20. Mrz 12	dddd	
156	19. Mrz 13	dddd	

Variations to this planned series of tests are permitted, provided that sufficient observations be generated to ensure an adequate assessment of storage stability can be made. Changes to test plans may be desirable in order to investigate any possible changes or accommodate other priorities near the time of the planned test.

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Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Condition

Inspection Date	24 Mar 10	Benchmark	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	20 x 21cm pouch. All 3 pouches sealed well			
Dressing Release from Pouch	14 x 14cm dressing. All removed easily from pouch - no sticking			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel stuck to mesh but feels dry. Mesh stuck to borders			
Border Release fr. liners	Mesh is well stuck to the borders (>3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is clear with skim			
Dressing Odour	Slight almond odour - not unpleasant			
Gel Feel and tack	If fingers are run over the dressing it appears dry. When pressure applied in single place, then feels slightly sticky			
Gel Residue	No residue			
PHOTO / NOTES				

Inspection Date	23 Mar 10	Benchmark	Tester	AM
Parameter	Observation			
Pouch Visual Integrity	20 x 21cm pouch. All 3 pouches sealed well			
Dressing Release from Pouch	14 x 14cm dressing. All removed easily from pouch - no sticking			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel stuck to mesh but feels dry. Mesh stuck to borders			
Border Release fr. liners				
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is clear with skim			
Dressing Odour	Slight almond odour - not unpleasant			
Gel Feel and tack	If fingers are run over the dressing it appears dry. When pressure applied in single place, then feels slightly sticky			
Gel Residue	No residue			
PHOTO / NOTES				

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Report Reference: BSN CSH DC2LS/641/C1M(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Condition

Inspection Date	30. Mrz 10	Tester	DW
Parameter	Observation		
Pouch Printing			
Pouch Visual Integrity	pouches appear well sealed		
Gel Release fr. Top Liner	N/A		
Gel Release fr. Substrate Liner	N/A		
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)		
Border Release fr. liners	Mesh is well stuck to the borders (x3)		
Liner & substrate appearance	Back liners remove easily		
Gel Visual and Colour	Gel is starting to yellow slightly, but is entirely covered in green mesh		
Dressing Odour	Slight smell - slightly stale		
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)		
Gel Residue	No residue (x3)		
PHOTO / NOTES			

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Condition

Inspection Date	06-Apr-2010	2wks	Tester	DW
Parameter	Observation			
Pouch Printing				
Dressing Release from Pouch	14 x 14cm dressing. All 3 dressings remove easily - no sticking.			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily Gel is slightly yellow, with skrim, therefore translucent, but is entirely covered in green mesh			
Gel Visual and Colour				
Dressing Odour	Slightly stale smell.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES				

Inspection Date	14-Apr-2010	3wks	Tester	DW
Parameter	Observation			
Pouch Printing				
Pouch Visual Integrity	pouches appear well sealed			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily Gel is slightly yellow, with skrim, therefore translucent, but is entirely covered in green mesh			
Gel Visual and Colour				
Dressing Odour	Slightly stale smell.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES				

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Report Reference: BSN CSH DC2LS/641/C1M(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Condition

Inspection Date	4-May-2010	6wks	Tester	DW
Parameter	Observation			
Pouch Printing				
Dressing Release from Pouch	14 x 14cm dressing. All 3 dressings remove easily - no sticking.			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is slightly yellow, with skrim, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slightly stale smell.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES	No change			

Inspection Date	8-Jun-2010	11wks	Tester	DW
Parameter	Observation			
Pouch Printing				
Pouch Visual Integrity	pouches appear well sealed			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is lightyellow/brown, with skrim, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slightly sharp/stale smell.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES				

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Fast (55°C) Accelerated Storage Conditions

Inspection Date	14-Jul-2010	16wks	Tester	DW
Parameter	Observation			
Pouch Printing				
Dressing Release from Pouch	14 x 14cm dressing. All 3 dressings remove easily- no sticking.			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is light yellow/brown, with skin, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slightly sharp/stale smell.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES				

Inspection Date	Tester
Parameter	Observation
Pouch Printing	
Pouch Visual Integrity	
Dressing Release from Pouch	
Gel Release fr. Top Liner	
Gel Release fr. Substrate Liner	
Gel Adhesion to Mesh	
Border Release fr. liners	
Liner & substrate appearance	
Gel Visual and Colour	
Dressing Odour	
Gel Feel and tack	
Gel Residue	
PHOTO / NOTES	

Conclusions: Assessment of Qualitative Inspections

There are no deleterious changes to the attributes of the product that were qualitatively assessed during this study. Test results PASS.

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Report Reference: BSN CSH DC2LS/641/C1 /I(A,B&C) Storage trial ST10-005

Water Activity - Under Fast (55°C) Accelerated Storage Conditions

Test Method Ramsbury Laboratory SOP: "Water Activity of a Gel or Solution"
(Method used is revision applicable at time of test, following method for each individual sample.)

(Rawdata is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	Water Activity
Mean	0,652
Standard Deviation	0,003
Number of samples	6,000
± 95% Confidence	0,008
Expected Min	0,644
Expected Max	0,659
± 95% Confidence	0,003

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	Water Activity
Min Limit	0	0,64
	16	0,64
Max Limit	0	0,66
	16	0,66

Justification for Acceptance Limits

95% Confidence

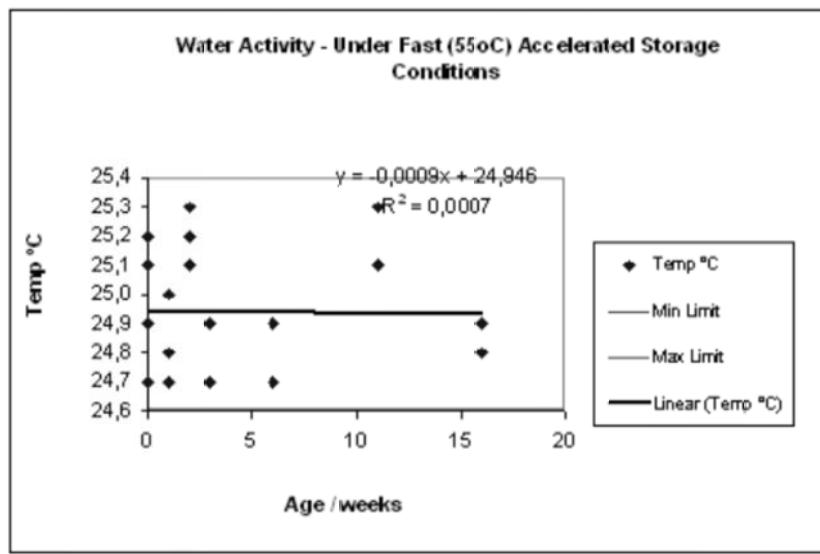
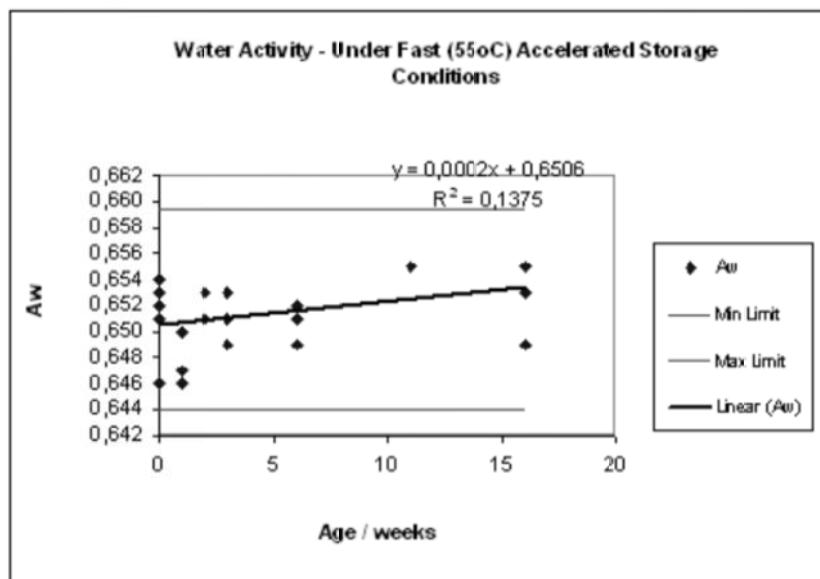
Conclusions: Assessment of Water Activity Properties

There is no change in the water activity throughout the entire duration of the storage trial at 55C. The results at each time point are all within the 95% confidence intervals derived from the benchmark data. TEST RESULT: PASS

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Fast (55°C) Accelerated Storage Conditions**Water Activity Graphs**

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005
Water Activity - Under Fast (55°C) Accelerated Storage Conditions

Base Data

Accelerated Ageing	Weeks	Av	Temp °C	Mean	Test date	Tested by
Sample 1	0	0,654	25,2		23. Mrz 10	DW
Sample 2	0	0,646	25,1		23. Mrz 10	DW
Sample 3	0	0,654	24,7		23. Mrz 10	DW
Sample 4	0	0,651	24,9		25. Mrz 10	AM
Sample 5	0	0,652	24,9		25. Mrz 10	AM
Sample 6	0	0,653	24,9	0,652	25. Mrz 10	AM
Sample 1	1	0,647	24,7		30. Mrz 10	DW
Sample 2	1	0,646	24,8		30. Mrz 10	DW
Sample 3	1	0,650	25,0	0,648	30. Mrz 10	DW
Sample 1	2	0,653	25,1		06. Apr 10	DW
Sample 2	2	0,651	25,2		06. Apr 10	DW
Sample 3	2	0,651	25,3	0,652	06. Apr 10	DW
Sample 1	3	0,651	24,7		13. Apr 10	DW
Sample 2	3	0,653	24,9		13. Apr 10	DW
Sample 3	3	0,649	24,9	0,651	13. Apr 10	DW
Sample 1	6	0,651	24,9		04. Mai 10	DW
Sample 2	6	0,652	24,7		04. Mai 10	DW
Sample 3	6	0,649	24,7	0,651	04. Mai 10	DW
Sample 1	11	0,655	25,1		08. Jun 10	DW
Sample 2	11	0,655	25,1		08. Jun 10	DW
Sample 3	11	0,655	25,3	0,655	08. Jun 10	DW
Sample 1	16	0,649	24,9		13. Jul 10	DW
Sample 2	16	0,653	24,8		13. Jul 10	DW
Sample 3	16	0,655	24,8	0,652	13. Jul 10	DW

Linear Trend Model

Intercept	0,65056394	24,9463
Linear Slope	0,00018347	-0,00095
Standard error in Intercept	0,00071571	0,054113
Standard error in slope	9,7965E-05	0,007407
r^2	0,13750007	0,000747

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FIRST WATER LTD

Report Reference: BSN CSH DC2LS/641/C1 M(A,B&C) Storage trial ST10-005
% Ca/NaCl Saline Uptake - Under Fast (55°C) Accelerated Storage Conditions

Test Method **Ramsbury Laboratory SOP: "% Ca/NaCl Saline Uptake of a Gel"**
(Method used is revision applicable at time of test, following method for each individual sample.

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	% Ca/NaCl Uptake	Initial Wt /g
Mean	1394,696	0,216
Standard Deviation	59,674	0,010
Number of samples	6,000	6,000
± 95% Confidence	153,397	0,026
Expected Min	1241,299	0,191
Expected Max	1548,093	0,242
± 95% Confidence	62,624	0,010

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	% Ca/NaCl Uptake	Initial Wt /g
Min Limit	0	1241	0,095
	16	1241	0,095
Max Limit	0	1548	0,363
	16	1548	0,363

Justification for Acceptance Limits

For saline uptake, use 95% confidence. For weight, showno trends of change.

Conclusions: Assessment of Calcium/Sodium Chloride Saline Uptake Properties

The saline uptake test is a simple but powerful test for evaluating the integrity of the crosslinked polymer network in the hydrogel. The averages at each time point are within ± 95% of the benchmark values. The weight of the samples show no changes during the course of the study. The polymer network is maintaining its integrity over the duration of the study. TEST RESULT: PASS

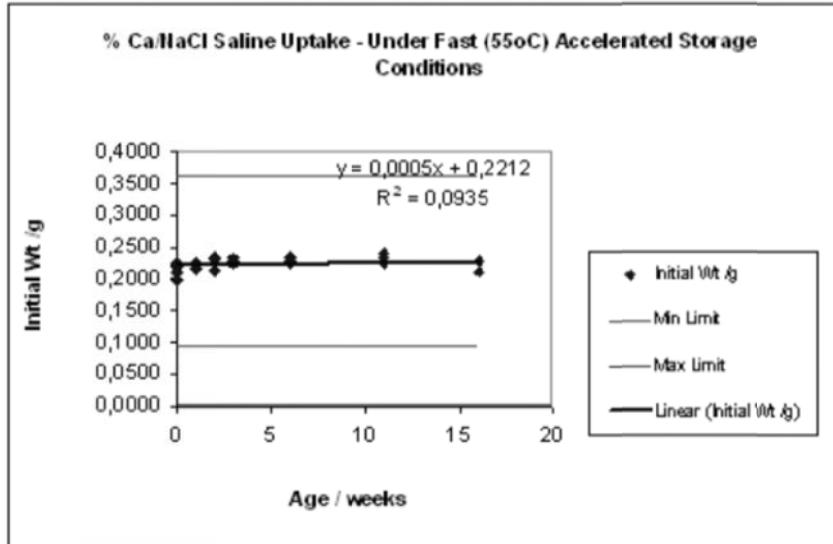
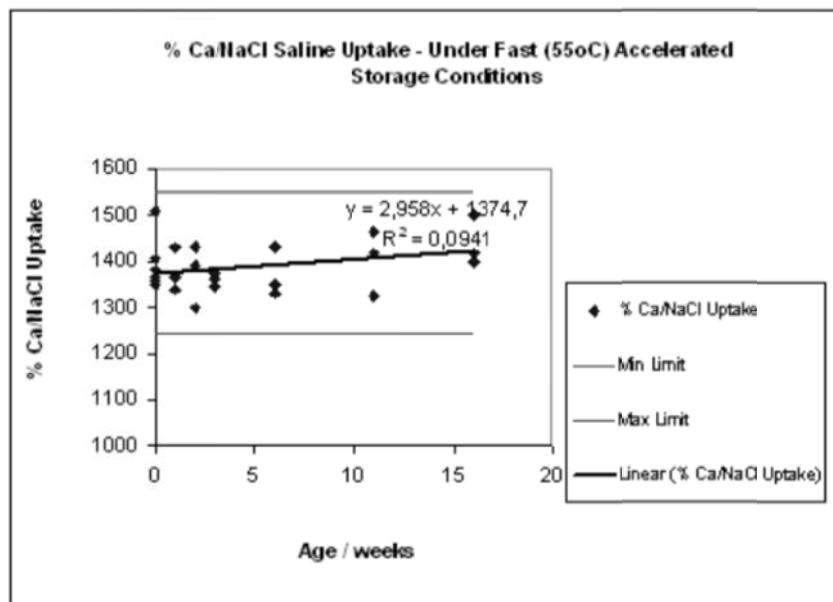
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Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Fast (55°C) Accelerated Storage Conditions

% Ca/NaCl Saline Uptake Graphs



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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Accelerated (40°C) Storage Conditions

Inspection Date	21 April 10	4 wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	Slight smell, but not unpleasant			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

Inspection Date	12 May 2010	7 wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	Slightly stale smell, but not too unpleasant			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Accelerated (40°C) Storage Conditions

Inspection Date	24 Jun 2010	13	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	Slightly stale smell, but not too unpleasant			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

Inspection Date	21st Sept 2010	26 weeks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels mainly dry (x3)			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	Gel is yellowing slightly			
Dressing Odour	Slightly stale smell, but not too unpleasant			
Gel Feel and tack	If fingers are lightly run over the dressing it appears mainly dry, but is slightly sticky around edges of gel island. When slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	As for benchmark			
PHOTO / NOTES				

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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage Under Accelerated (40°C) Storage Conditions

Inspection Date	Due 20th Sept 2011	Tester	
Parameter		Observation	
Pouch Visual Integrity			
Dressing Release fr. Pouch			
Gel Release fr. Top Liner			
Gel Release fr. Substrate Liner			
Gel Adhesion to Mesh			
Border Release fr. liners			
Liner & substrate appearance			
Gel Visual and Colour			
Dressing Odour			
Gel Feel and tack			
Gel Residue			
PHOTO / NOTES			

Conclusions: Assessment of Qualitative Inspections

This trial is still in-progress. The findings after 26 weeks show that there are no deleterious changes in the qualitative attributes of the dressing. RESULT: TEST currently PASSED

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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Accelerated (40°C) Storage Conditions

Test Method **Ramsbury Laboratory SOP: "Water Activity of a Gel or Solution"**
(Method used is revision applicable at time of test, following method for each individual sample.)

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	Water Activity
Mean	0,652
Standard Deviation	0,003
Number of samples	6,000
± 95% Confidence	0,008
Expected Min	0,644
Expected Max	0,659
± 95% Confidence	0,003

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	Water Activity
Min Limit	0	0,644
	52	0,644
Max Limit	0	0,659
	52	0,659

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Water Activity Properties

Trial still in progress: there is no change in the water activity throughout the current duration of the storage trial at 40C. The average at each time point are all within the 95% confidence intervals derived from the benchmark data. Current RESULT: PASS

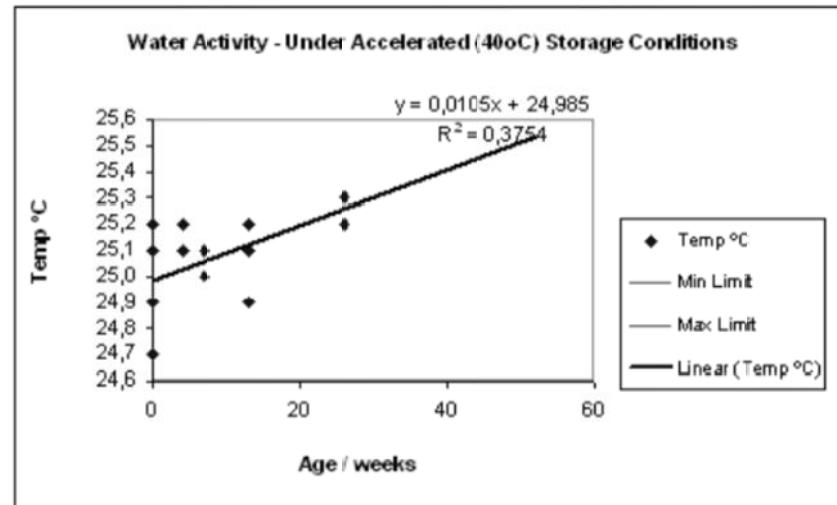
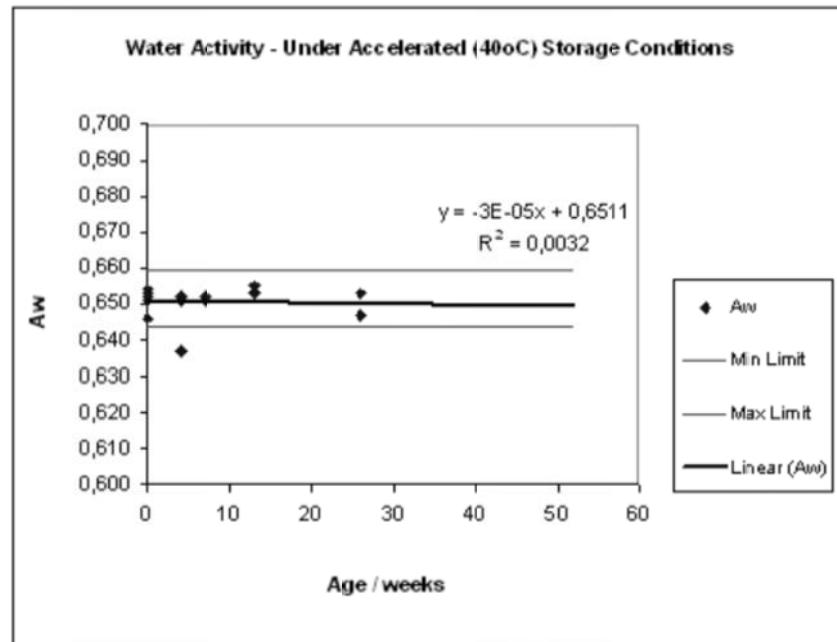
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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Water Activity - Under Accelerated (40°C) Storage Conditions

Water Activity Graphs



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FIRST WATER LTD

Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005
Water Activity - Under Accelerated (40°C) Storage Conditions

Base Data

Accelerated Ageing	Weeks	Av	Temp °C		Test date	Tested by
Sample 1	0	0,654	25,2		23. Mrz 10	DW
Sample 2	0	0,646	25,1		23. Mrz 10	DW
Sample 3	0	0,654	24,7		23. Mrz 10	DW
Sample 4	0	0,651	24,9		25. Mrz 10	AM
Sample 5	0	0,652	24,9		25. Mrz 10	AM
Sample 6	0	0,653	24,9	0,652	25. Mrz 10	AM
Sample 1	4	0,651	25,1		20. Apr 10	DW
Sample 2	4	0,637	25,1		20. Apr 10	DW
Sample 3	4	0,652	25,2	0,647	20. Apr 10	DW
Sample 1	7	0,652	25,1		11. Mai 10	DW
Sample 2	7	0,651	25,1		11. Mai 10	DW
Sample 3	7	0,652	25,0	0,652	11. Mai 10	DW
Sample 1	13	0,653	24,9		22. Jun 10	DW
Sample 2	13	0,655	25,2		22. Jun 10	DW
Sample 3	13	0,655	25,1	0,654	22. Jun 10	DW
Sample 1	26	0,653	25,3		22. Sep 10	DW
Sample 2	26	0,647	25,3		22. Sep 10	DW
Sample 3	26	0,647	25,2	0,649	22. Sep 10	DW
Sample 1	39					
Sample 2	39					
Sample 3	39					
Sample 1	52					
Sample 2	52					
Sample 3	52					

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FIRST WATER LTD

Report Reference: BSN CSH DC2LS/641/C1 M(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Accelerated (40°C) Storage Conditions

Test Method **Ramsbury Laboratory SOP: "% Ca/NaCl Saline Uptake of a Gel"**
(Method used is revision applicable at time of test, following method for each individual sample,

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	% Ca/NaCl Uptake	Initial Wt /g
Mean	1394,696	0,216
Standard Deviation	59,674	0,010
Number of samples	6,000	6,000
± 95% Confidence	153,397	0,026
Expected Min	1241,299	0,191
Expected Max	1548,093	0,242
± 95% Confidence	62,624	0,010

Acceptance Limits*(These limits are not sales specifications)*

Limit Type	Weeks	% Ca/NaCl Uptake	Initial Wt /g
Min Limit	0	1241	0,095
	78	1241	0,095
Max Limit	0	1548	0,363
	78	1548	0,363

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Calcium/Sodium Chloride Saline Uptake Properties

This trial is still in progress: the saline uptake test is a simple but powerful test for evaluating the integrity of the crosslinked polymer network in the hydrogel. The averages at each time point are within ± 95% of the benchmark values. The weight of the samples show no changes during the course of the study. The polymer network is maintaining its integrity over the duration of the study. Current RESULT: PASS

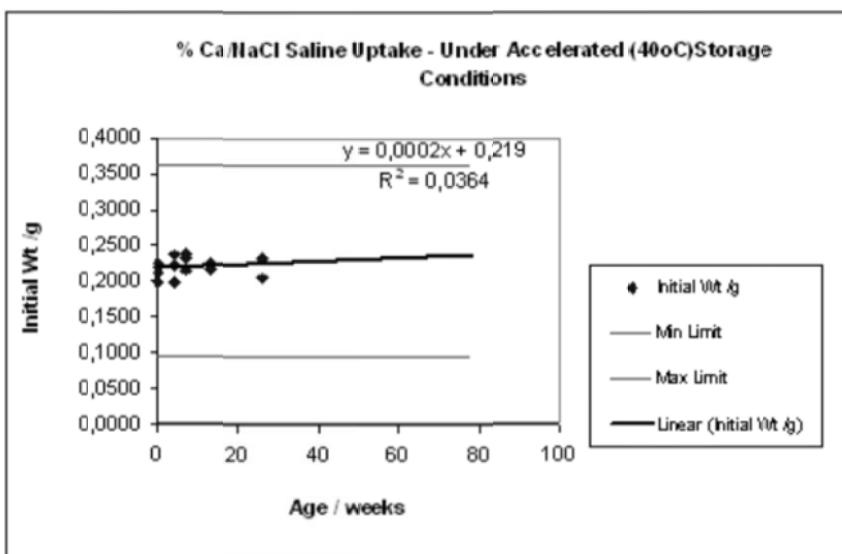
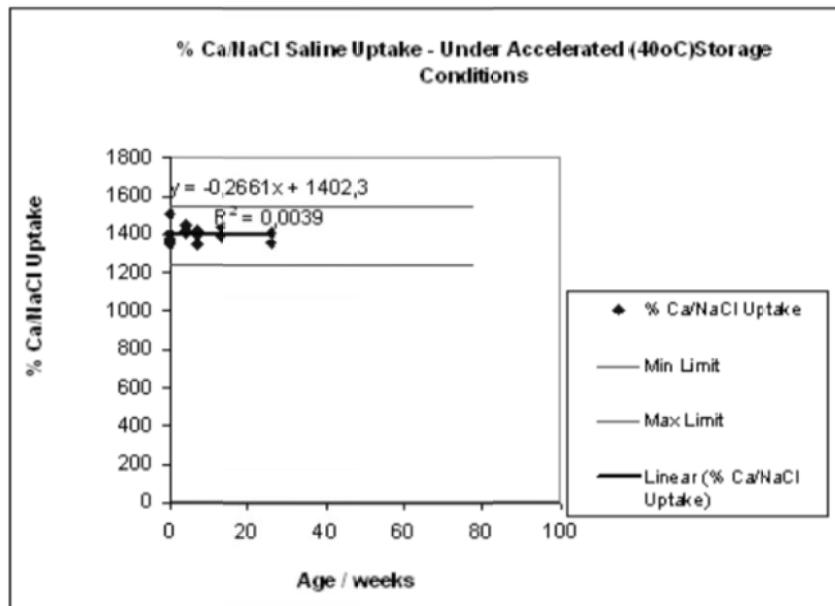
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Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Accelerated (40°C)Storage Conditions

% Ca/NaCl Saline Uptake Graphs



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FIRST WATER LTD

Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Accelerated (40°C)Storage Conditions**Base Data**

Accelerated Ageing	Weeks	% Ca/NaCl Uptake	Initial Wt /g	Final Wt /g	Test date	Tested by
Sample 1	0	1359	0,2193	3,20	24. Mrz 10	DW
Sample 2	0	1380	0,2196	3,25	24. Mrz 10	DW
Sample 3	0	1405	0,2239	3,37	24. Mrz 10	DW
Sample 4	0	1347	0,1983	2,87	25. Mrz 10	AM
Sample 5	0	1510	0,2249	3,62	25. Mrz 10	AM
Sample 6	0	1367	0,2120	3,11	25. Mrz 10	AM
Sample 1	4	1450	0,2368	3,67	21. Apr 10	DW
Sample 2	4	1404	0,1988	2,99	21. Apr 10	DW
Sample 3	4	1416	0,2229	3,38	21. Apr 10	DW
Sample 1	7	1423	0,2390	3,64	12. Mai 10	DW
Sample 2	7	1396	0,2153	3,22	12. Mai 10	DW
Sample 3	7	1349	0,2325	3,37	12. Mai 10	DW
Sample 1	13	1389	0,2250	3,35	23. Jun 10	DW
Sample 2	13	1433	0,2159	3,31	23. Jun 10	DW
Sample 3	13	1401	0,2245	3,37	23. Jun 10	DW
Sample 1	26	1356	0,2054	2,99	23. Sep 10	DW
Sample 2	26	1405	0,2326	3,50	23. Sep 10	DW
Sample 3	26	1411	0,2323	3,51	23. Sep 10	DW
Sample 1	78	#DIV/0!				
Sample 2	78	#DIV/0!				
Sample 3	78	#DIV/0!				

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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	24 Mar 10	Benchmark	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	One pouch from each lot(A,B&C). 20cm x 18.5cm pouch. All 3 pouches appear well sealed			
Dressing Release from Pouch	14 x 14cm dressing. All 3 dressings remove easily - no sticking.			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel is stuck well to mesh, but still feels dry (x3)			
Border Release fr. liners	Mesh is well stuck to the borders (x3)			
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is clear, with skim, therefore translucent, but is entirely covered in green mesh			
Dressing Odour	Slight smell, but not unpleasant - slight almonds.			
Gel Feel and tack	If fingers are lightly run over the dressing it appears dry, but when slight pressure is applied in a single place, it is slightly sticky (x3)			
Gel Residue	No residue (x3)			
PHOTO / NOTES				

Inspection Date	23 Mar 10	Benchmark	Tester	AM
Parameter	Observation			
Pouch Visual Integrity	20 x 21cm pouch. All 3 pouches sealed well			
Dressing Release from Pouch	14 x 14cm dressing. All removed easily from pouch - no sticking			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	Gel stuck to mesh but feels dry. Mesh stuck to borders			
Border Release fr. liners				
Liner & substrate appearance	Back liners remove easily			
Gel Visual and Colour	Gel is clear with skim			
Dressing Odour	Slight almond odour - not unpleasant			
Gel Feel and tack	If fingers are run over the dressing it appears dry. When pressure applied in single place, then feels slightly sticky			
Gel Residue	No residue			
PHOTO / NOTES				

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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	21 April 10	4 wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	As for benchmark			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

Inspection Date	13 July 10	16 wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	As for benchmark			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1M(A,B&C) Storage trial ST10-005
Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	23 Mar 11	52wks	Tester	DW
Parameter	Observation			
Pouch Visual Integrity	As for benchmark			
Dressing Release from Pouch	As for benchmark			
Gel Release fr. Top Liner	N/A			
Gel Release fr. Substrate Liner	N/A			
Gel Adhesion to Mesh	As for benchmark			
Border Release fr. liners	As for benchmark			
Liner & substrate appearance	As for benchmark			
Gel Visual and Colour	As for benchmark			
Dressing Odour	As for benchmark			
Gel Feel and tack	As for benchmark			
Gel Residue	As for benchmark			
PHOTO / NOTES				

Inspection Date		Tester	
Parameter	Observation		
Pouch Visual Integrity			
Dressing Release from Pouch			
Gel Release fr. Top Liner			
Gel Release fr. Substrate Liner			
Gel Adhesion to Mesh			
Border Release fr. liners			
Liner & substrate appearance			
Gel Visual and Colour			
Dressing Odour			
Gel Feel and tack			
Gel Residue			
PHOTO / NOTES			

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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage under Real Time Conditions

Inspection Date	Tester	
Parameter	Observation	
Pouch Visual Integrity		
Dressing Release from Pouch		
Gel Release fr. Top Liner		
Gel Release fr. Substrate Liner		
Gel Adhesion to Mesh		
Border Release fr. liners		
Liner & substrate appearance		
Gel Visual and Colour		
Dressing Odour		
Gel Feel and tack		
Gel Residue		
PHOTO / NOTES		

Inspection Date	Tester	
Parameter	Observation	
Pouch Visual Integrity		
Dressing Release from Pouch		
Gel Release fr. Top Liner		
Gel Release fr. Substrate Liner		
Gel Adhesion to Mesh		
Border Release fr. liners		
Liner & substrate appearance		
Gel Visual and Colour		
Dressing Odour		
Gel Feel and tack		
Gel Residue		
PHOTO / NOTES		

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First Water Ltd

Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005

Qualitative Inspections - Storage under Real Time Conditions

Conclusions: Assessment of Qualitative Inspections

This trial is still in-progress. The findings after 1 year show
that there are no deleterious changes in the qualitative
attributes of the dressing. RESULT: TEST currently PASSED

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FIRST WATER LTD

Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005
Water Activity - Under Real Time Storage Conditions

Test Method **Ramsbury Laboratory SOP: "Water Activity of a Gel or Solution"**
(Method used is revision applicable at time of test, following method for each individual sample)

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	Water Activity
Mean	0,652
Standard Deviation	0,003
Number of samples	6,000
± 95% Confidence	0,008
Expected Min	0,644
Expected Max	0,659
± 95% Confidence	0,003

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	Water Activity
Min Limit	0	0,644
	156	0,644
Max Limit	0	0,659
	156	0,659

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Water Activity Properties

Trial still in progress: there is no change in the water activity throughout the current duration of the storage trial at ambient conditions. The average at each time point are all within the 95% confidence intervals derived from the benchmark data.
 Current RESULT: PASS

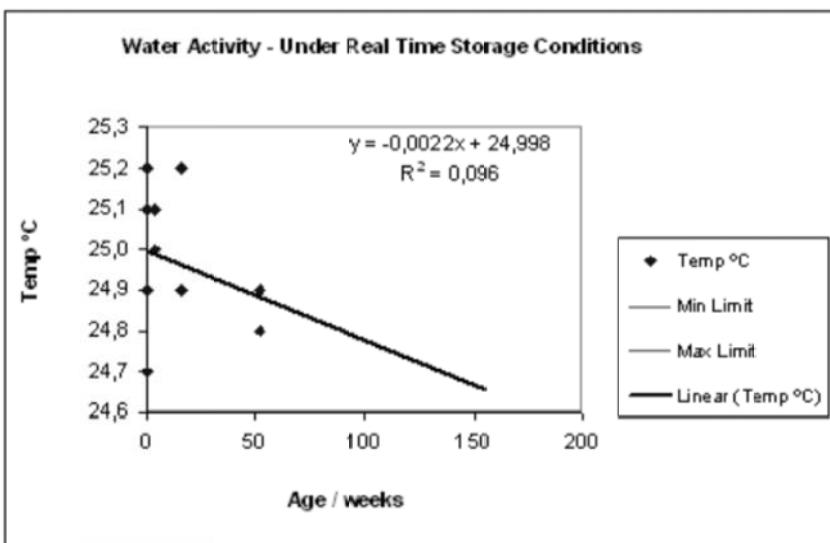
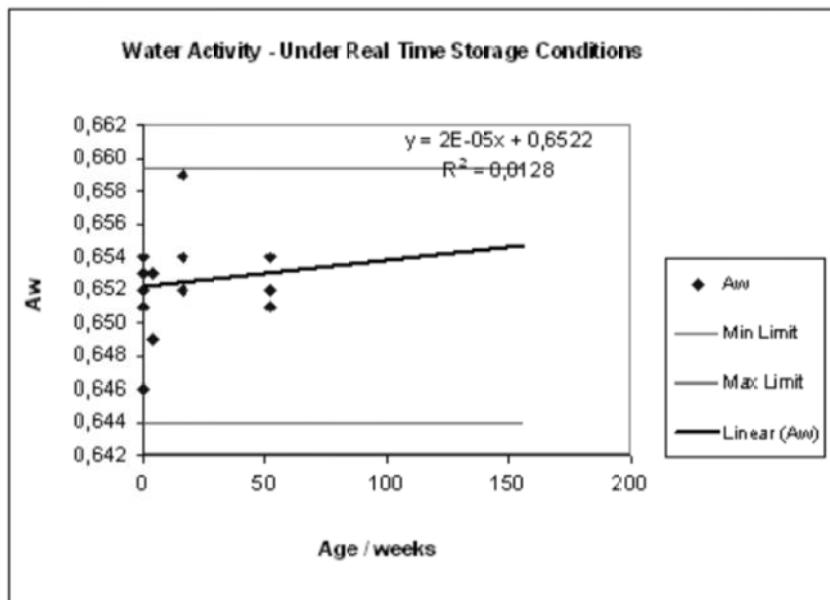
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FIRST WATER LTD

Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005

Water Activity - Under Real Time Storage Conditions

Water Activity Graphs



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FIRST WATER LTD

Report Reference: BSN CSH DC2LS/641/C1/1 (A,B&C) Storage trial ST10-005
Water Activity - Under Real Time Storage Conditions

Base Data

Real Time Ageing	Weeks	Aw	Temp °C		Test date	Tested by
Sample 1	0	0,654	25,2		23. Mrz 10	DW
Sample 2	0	0,646	25,1		23. Mrz 10	DW
Sample 3	0	0,654	24,7		23. Mrz 10	DW
Sample 4	0	0,651	24,9		25. Mrz 10	AM
Sample 5	0	0,652	24,9		25. Mrz 10	AM
Sample 6	0	0,653	24,9		25. Mrz 10	AM
Sample 1	4	0,653	25,1		20. Apr 10	DW
Sample 2	4	0,649	25,0		20. Apr 10	DW
Sample 3	4	0,653	25,1		20. Apr 10	DW
Sample 1	16	0,659	25,2		14. Jul 10	DW
Sample 2	16	0,654	24,9		14. Jul 10	DW
Sample 3	16	0,652	24,9		14. Jul 10	DW
Sample 1	52	0,652	24,9		22. Mrz 11	DW
Sample 2	52	0,651	24,9		22. Mrz 11	DW
Sample 3	52	0,654	24,8		22. Mrz 11	DW
Sample 1	104					
Sample 2	104					
Sample 3	104					
Sample 1	156					
Sample 2	156					
Sample 3	156					

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Report Reference: BSN CSH DC2LS/641/C1/M(A,B&C) Storage trial ST10-005
% Ca/NaCl Saline Uptake - Under Real Time Storage Conditions

Test Method **Ramsbury Laboratory SOP: "% Ca/NaCl Saline Uptake of a Gel"**
(Method used is revision applicable at time of test, following method for each individual sample)

(Raw data is recorded following the graphs and statistical summaries)

Statistical Variation of Initial Properties

	% Ca/NaCl Uptake	Initial Wt /g
Mean	1394,696	0,216
Standard Deviation	59,674	0,010
Number of samples	6,000	6,000
± 95% Confidence	153,397	0,026
Expected Min	1241,299	0,191
Expected Max	1548,093	0,242
± 95% Confidence	62,624	0,010

Acceptance Limits

(These limits are not sales specifications)

Limit Type	Weeks	% Ca/NaCl Uptake	Initial Wt /g
Min Limit	0	1241,299	0,095
	156	1241,299	0,095
Max Limit	0	1548,093	0,363
	156	1548,093	0,363

Justification for Acceptance Limits

95% Confidence

Conclusions: Assessment of Calcium/Sodium Chloride Saline Uptake Properties

This trial is still in progress: the saline uptake test is a simple but powerful test for evaluating the integrity of the crosslinked polymer network in the hydrogel. The averages at each time point are within ± 95% of the benchmark values. The weight of the samples show no changes during the course of the study. The polymer network is maintaining its integrity over the duration of the study. Current RESULT: PASS

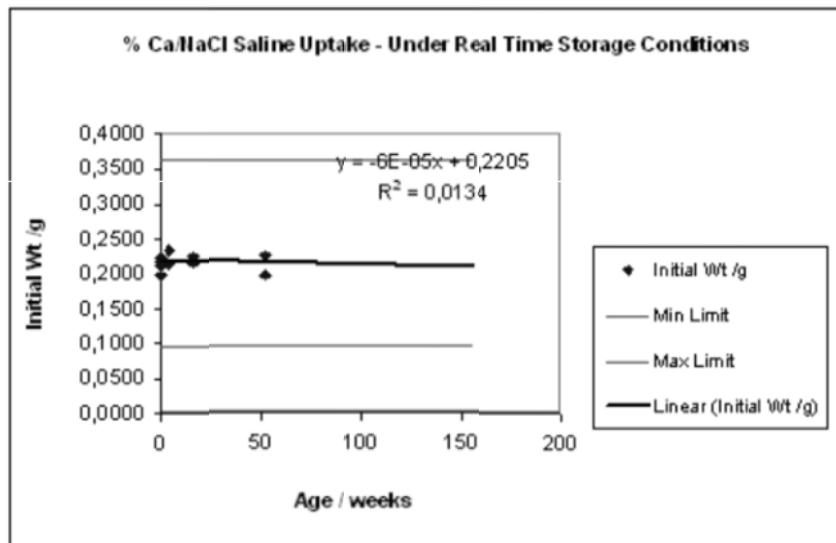
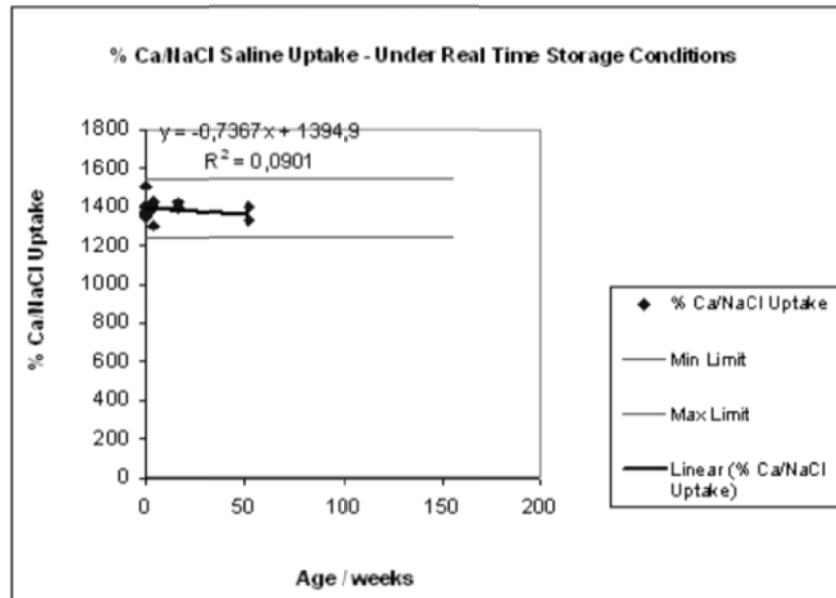
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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Real Time Storage Conditions

% Ca/NaCl Saline Uptake Graphs



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Report Reference: BSN CSH DC2LS/641/C1/1(A,B&C) Storage trial ST10-005

% Ca/NaCl Saline Uptake - Under Real Time Storage Conditions**Base Data**

Real Time Ageing	Weeks	% Ca/NaCl Uptake	Initial Wt /g	Final Wt /g	Test date	Tested by
Sample 1	0	1359	0,2193	3,20	24. Mrz 10	DW
Sample 2	0	1380	0,2196	3,25	24. Mrz 10	DW
Sample 3	0	1405	0,2239	3,37	24. Mrz 10	DW
Sample 4	0	1347	0,1983	2,87	25. Mrz 10	AM
Sample 5	0	1510	0,2249	3,62	25. Mrz 10	AM
Sample 6	0	1367	0,2120	3,11	25. Mrz 10	AM
Sample 1	4	1393	0,2344	3,50	21. Apr 10	DW
Sample 2	4	1426	0,2143	3,27	21. Apr 10	DW
Sample 3	4	1304	0,2343	3,29	21. Apr 10	DW
Sample 1	16	1401	0,2225	3,34	14. Jul 10	DW
Sample 2	16	1397	0,2165	3,24	14. Jul 10	DW
Sample 3	16	1423	0,2258	3,44	14. Jul 10	DW
Sample 1	52	1330	0,2252	3,22	24. Mrz 11	DW
Sample 2	52	1395	0,1973	2,95	24. Mrz 11	DW
Sample 3	52	1327	0,2257	3,22	24. Mrz 11	DW
Sample 1	104	#DIV/0!				
Sample 2	104	#DIV/0!				
Sample 3	104	#DIV/0!				
Sample 1	156	#DIV/0!				
Sample 2	156	#DIV/0!				
Sample 3	156	#DIV/0!				

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