AEGIS LIFESCIENCES
PROTECTION THROUGH PERFECTION

Signature Not Verified

Dokument podpisany przez Juliusz Paskal Biegalski
Data: 2024.06.07 14:20:27 CEST

CE 2460 ISO 13485

Date: 02-Jan-2023

To whomsoever it may concern

Subject: Statement/Justification with reference to the complete absorption/degradation/resorption of the product Surgi-ORC® (Oxidized Regenerated Cellulose Haemostat) at the implant site.

- We, Aegis Lifesciences Pvt. Ltd., located at 215/216, Mahagujarat Industrial Estate-382213, Ahmedabad, Gujarat, India, hereby declare that the Surgi-ORC® (Oxidized Regenerated Cellulose Haemostat) absorption/degradation/resorption is completed in "substantial absorption- 7-14 days" & "complete absorption- 28 days" with no any evident traces of the product at the implant site.
- In vitro degradation study for the ORC products were carried out and the weight loss and visual observation at selected time points (Initial, 7th day, 14th Day and 28th Day) was observed. It was noted that the ORC haemostat samples were degraded to a larger extent by day 7. At 14th day, only non-measurable/negligible residue/fibres of ORC haemostat were visible in the test tubes. At the end of the 28th day, all products were degraded to non-detectable forms with no visible traces or fibers in the test tube.

Enclosed –

- In-vitro Degradation Study Test Report (report No. – AL/IVD/ORC/01).

Signature

Vivek Kumar Shahi

Mr. Vivek Kumar Shahi

Regulatory Affairs Assistant

Aegis Lifesciences Pvt. Ltd.

Place: Ahmedabad, India

TEST REPORT

REPORT NO –AL/IVD/ORC/01

DATE –July 25, 2017

Test	In-vitro Degradation Study(28 Days)
Product Name	Oxidized Regenerated Cellulose Haemostat
Test Facility	Aegis Lifesciences Pvt. Ltd., Ahmedabad
References	ASTM F1635 - 16 Standard Test Method for in vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants

Name	**Jaydeep Ratani**	**Bhavin Trivedi**	**Piyush Patel**
Signature			
Date	25/07/17	25/07/17	25/07/2017
	Prepared By	**Reviewed By**	**Approved By**

1. Purpose

The purpose of this study is to evaluate the time required for degradation of Oxidized Regenerated Cellulose (ORC) Haemostat under the influence of simulated environmental conditions.

2. Equipment, Materials and Samples

Equipment:

Thermometer (Equip. ID) : AL/QC/30
pH Meter (Equip. ID) : AL/QC/01
Weighing Balance (Equip. ID) : AL/QC/06
Oven (Equip. ID) : AL/QC/05
Incubator Shaker (Equip. ID) : AL/QC/17

Material:

Phosphate Buffer Saline (Soaking Solution) pH 7.4 ± 0.2
Glass Test Tubes

Samples:

Surgi-ORC Variant	Batch No.	Sample Dimensions (cm)	Quantity
Original	ORC0517002	5 X 5	3
Knit	ORC0517005	5 X 5	3
Fibril	ORC0517009	5 X 5	3
Non-Woven	ORC0517012	5 X 5	3

3. Procedure

a. Weigh the dry samples prior to placement in PBS solution and note it as initial weight (W0) in test data sheet for each sample.
b. Capture the photographs of samples.
c. Place the individual samples in separate test tubes previously rinsed with PBS solution and label them.
d. Transfer the freshly prepared PBS solution in cleaned test tubes and labeled them.
e. Maintain the temperature of PBS solution at 37±2 ° C by water bath.
f. Transfer the individual samples in separate test tubes.
g. Keep these test tubes in the incubator shaker and adjust the speed at 100+/-10 rpm and temperature at37 ± 2° C.
h. Monitor the pH of PBS solution on daily basis and change the PBS solution periodically at least after every week to maintain pH 7.4±0.2.
i. Note start time as T0.
j. Upon completion of specific time interval i.e. 0, 1, 7, 14 and 28 days, remove each sample and rinse with sufficient de-ionized water to remove saline.

k. Dry the samples to constant weight in oven and note the weight as Wi in test data sheet.

l. Capture the photographs of samples to evaluate the morphological changes occurs aftereach time interval.

m. Calculate the % weight loss by the formula;

% Weight Loss = 100 × (W0 - Wt)/W0

Where; W0 = Initial weight of samples

Wt = Weight after each time interval

4. Observations

Please refer Annex I for weight loss details and visual observations.

5. Conclusions

In vitro degradation study for the ORC products were carried out and the weight loss and visual observation at selected time points (Initial, 7th day, 14th Day and 28th Day) was observed. It was noted that the ORC haemostat samples were degraded to a larger extent by day 7.

At 14th day, only non-measurable/negligible residue/fibres of ORC haemostat were visible in the test tubes.

At the end of the 28th day, all products were degraded to non-detectable forms with no visible traces or fibres in the test tube.

Annex I- Observations

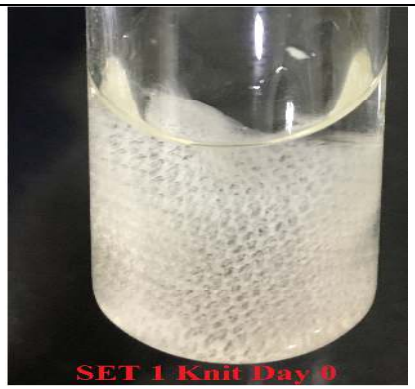
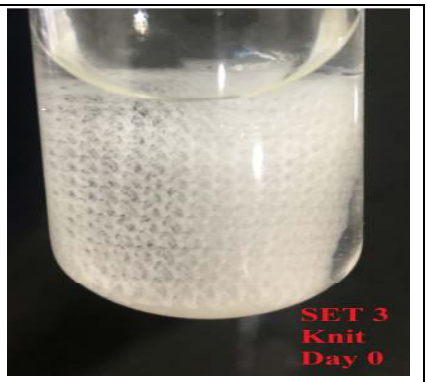
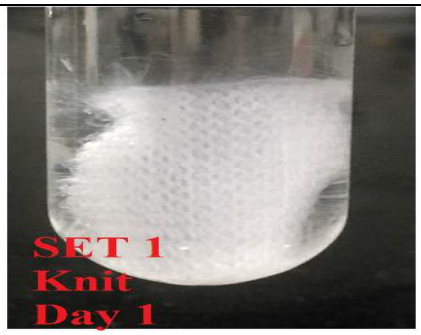
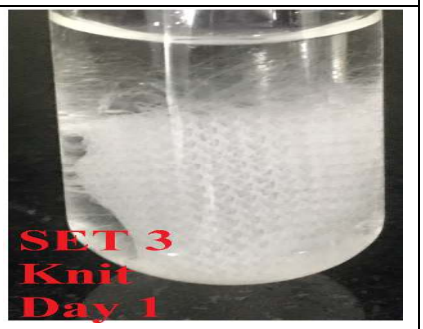
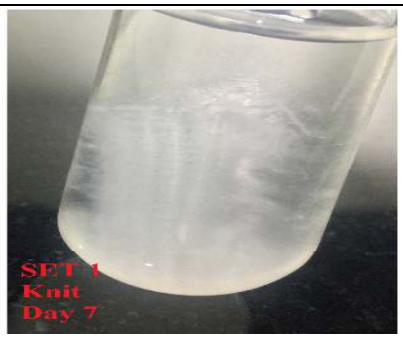
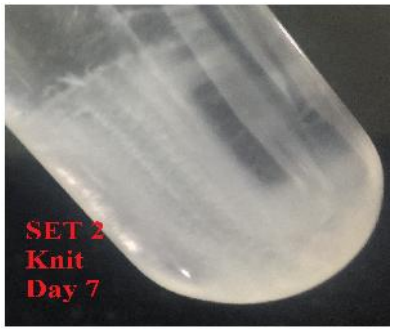
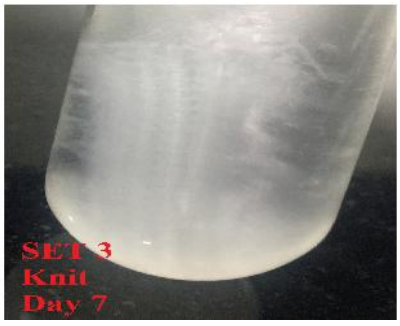
A. Weight Loss

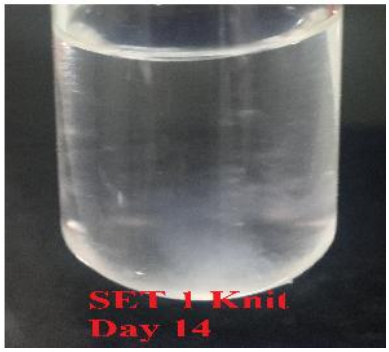
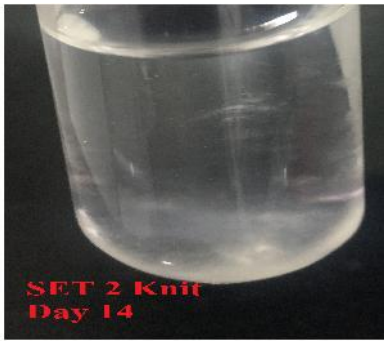
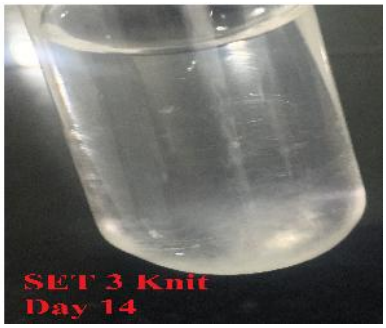
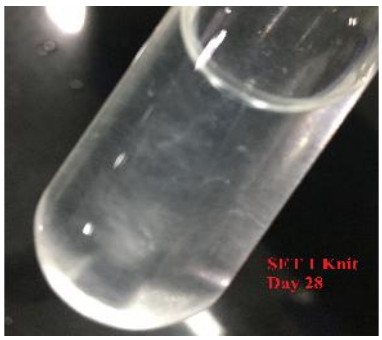
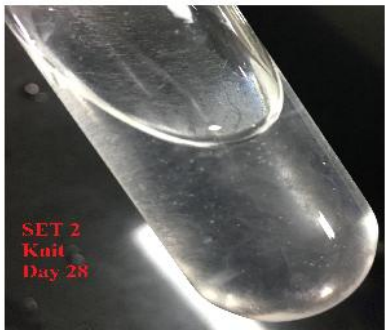
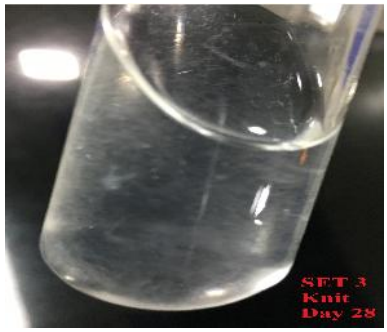
Sample ID	Sample Weights (mg)					Cumulative Weight Loss (%)					Avg. Wt. Loss in 28 Days (%)
	W0	W1	W7	W14	W28	W0	W1	W7	W14	W28	
ORIGINAL1	155	124	35	-	-	0	20.00	77.42	100	-	100
ORIGINAL2	154	125	33	-	-	0	18.83	78.57	100	-	
ORIGINAL3	155	121	36	-	-	0	21.94	76.77	100	-	
KNIT 1	289	232	56	-	-	0	19.72	80.62	100	-	100
KNIT 2	290	232	58	-	-	0	20.00	80.00	100	-	
KNIT 3	292	235	61	-	-	0	19.52	79.11	100	-	
FIBRIL 1	203	163	46	-	-	0	19.70	77.34	100	-	100
FIBRIL 2	203	166	42	-	-	0	18.23	79.31	100	-	
FIBRIL 3	205	162	47	-	-	0	20.98	77.07	100	-	
NON-WOVEN 1	178	143	31	-	-	0	19.66	82.58	100	-	100
NON-WOVEN 2	180	144	30	-	-	0	20.00	83.33	100	-	
NON-WOVEN 3	180	141	31	-	-	0	21.67	82.78	100	-	

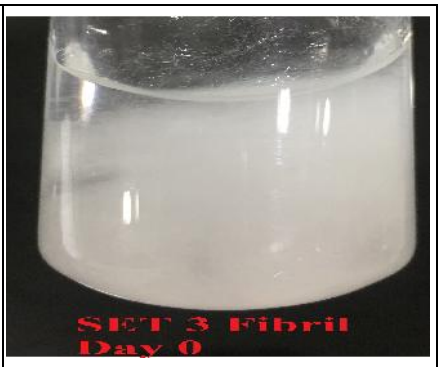
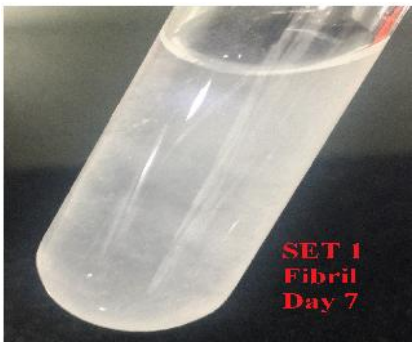
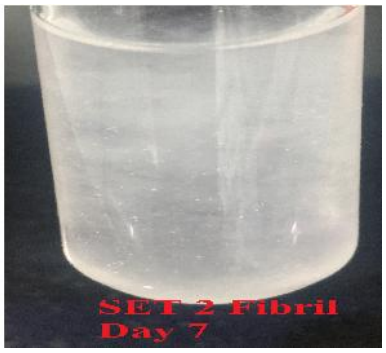
A. Visual Observations

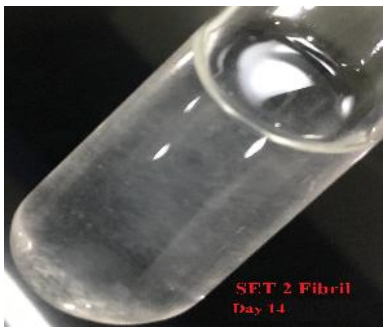
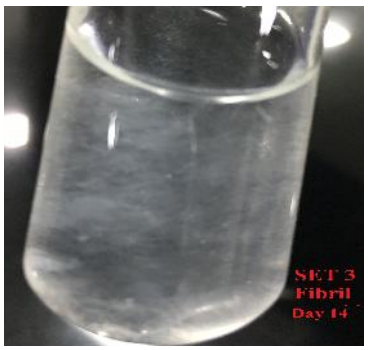
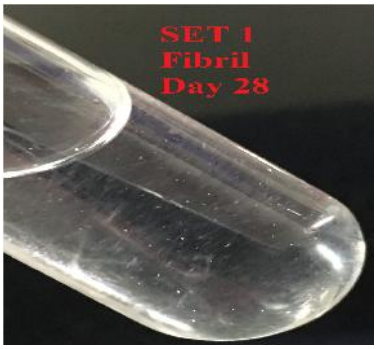
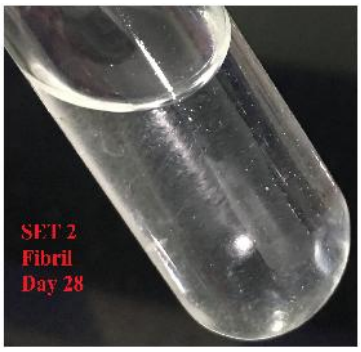
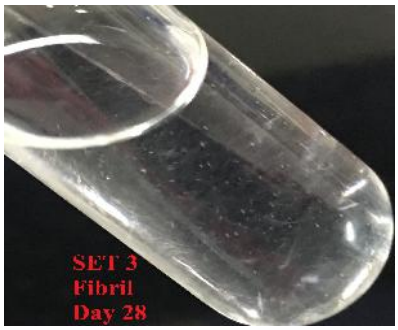
Day 0- ORIGINAL			
Day 1- ORIGINAL			

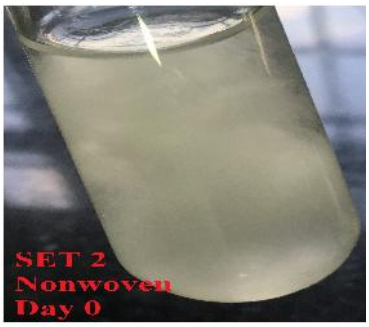
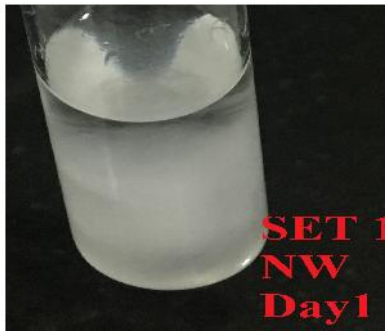
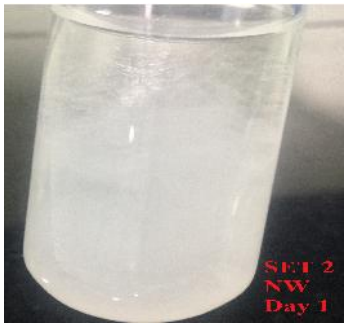
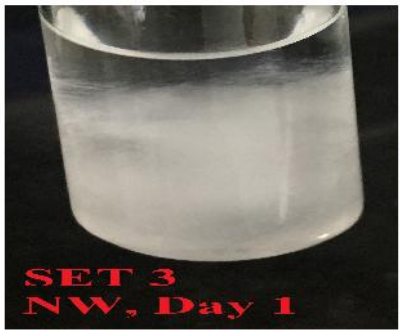
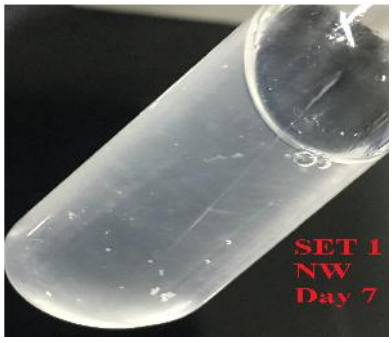
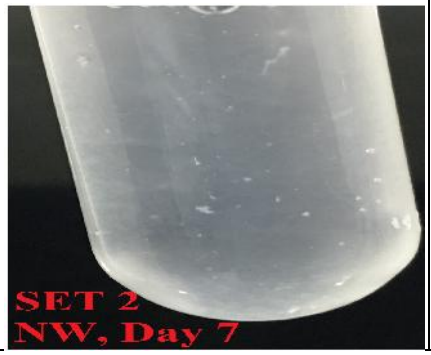
Day 7- ORIGINAL			
Day 14- ORIGINAL			
Day 28- ORIGINAL			

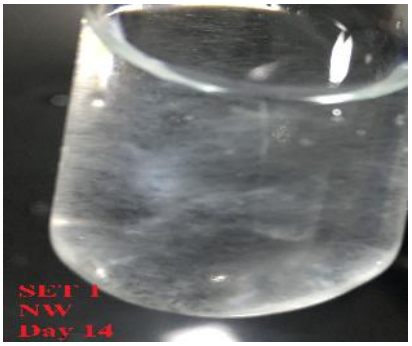
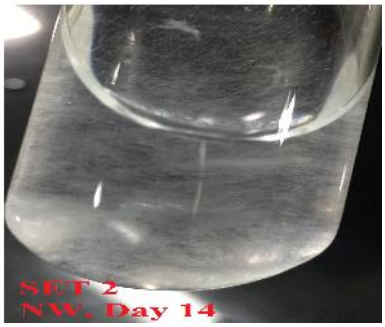
Day 0- KNIT			
Day 1- KNIT			
Day 7- KNIT			

Day 14- KNIT			
Day 28- KNIT			

Day 0- FIBRIL			
Day 1- FIBRIL			
Day 7- FIBRIL			

Day 14- FIBRIL			
Day 28- FIBRIL			

Day 0- NON-WOVEN			
Day 1- NON-WOVEN			
Day 7- NON-WOVEN			

Day 14- NONW-WOVEN			
Day 28- NON-WOVEN