Flexsafe® Pro Mixer
The Fast, Flexible and Intelligent Solution for Frozen Paste Dissolution

Delphine Audubey1,*, Adiba Ahmad2,*, Anilkumar Paramathma3
1. Sartorius Stedim FMT S.A.S., ZI des Paluds, Avenue de Jouques – CS 91051, 13781 Aubagne Cedex
2. Sartorius Stedim North America Inc., 545 Johnson Ave, Bohemia, NY 11716
3. Sartorius Stedim India Pvt. Ltd., #69/2-69/3, NH 48, Jakkasandra, Nelamangala Tq, 562 123 Bangalore, India
*Correspondence
E-Mail: delphine.audubey@sartorius-stedim.com

Abstract

Flexsafe® Pro Mixer is a unique single-use technology fitting all mixing steps from buffer and media preparations, downstream steps to final formulation. Flexsafe® Pro Mixer ergonomic design enables intuitive, modular and agile use to achieve fast installation and mixing operations. Additionally, the Flexsafe® film offers high standards quality attributes such as Biocompatibility, Integrity and Supply network.

This application study presents performance data of the 50 L Pro Mixer for frozen paste dissolution.

The dilution of frozen paste is often required in blood product application where frozen plasma needs to be dissolved. Ice blocks were used to simulate frozen paste

The performances of the single-use mixing system are assessed by checking the robustness of the impeller during the test.

The impeller showed good stability during the test, no significant damages visible by eyes or via scanning method and was able to mix 4.4 kg of salt-water ice blocks in less than 20 min at 25°C.
Introduction

The manufacturing of plasma derived product like factor VIII often requires a dissolving step of frozen plasma.

The purpose of this application study is to assess the performances and the robustness of the single-use Pro Mixer to dissolve ice blocks used to simulate frozen paste.

In the test, 4.4 kg of ice blocks were inserted in 25 L of water at 25°C and mixed at 375 rpm in a 50 L Flexsafe® for Pro Mixer. The impeller is then thoroughly inspected and tested for potential damages.

Materials and Methods

Materials

Consumable

- Standard 50 L Flexsafe® Bags for Pro Mixer
- 4 salt-water ice blocks of 1.1 kg each, made with NaCl to produce 9% weight/weight sodium chloride solution
- Deionized water

Equipment

- Weighing Palletank for Mixing
- Pro Mixer drive unit
- Thermometer
- Temperature probe

Method

1. Partially fill the bag up to 25 L with water at 25°C.

2. Start mixing at 375 rpm.

3. Add 4 times 1.1 kg of ice blocks every 6 minutes.

4. Total dissolution time is recorded when all the ice is melted for information.

5. When all the ice is melted, drain the bag and take the impeller out of it to perform an inspection for any visible damage. Carefully inspect and record pictures of each part of the impeller (side, top, bottom...) looking for potential damages like cracks or breaks.

6. Properly pack the impeller according to SSB internal SOPs and ship it to Sartorius Stedim Plastics for in-depth analysis with CT scan.

7. CT scan of the impeller is performed to locate any cracks that may have occurred during testing.

8. This test is pass or fail, fail meaning destruction or significant damage of the impeller.

Results

During the test, impeller was able to draw ice blocks down with robust stability (fig. 1).

Apart from light scuffs at tip of impeller blades, no significant visual damage to the impeller was observed (fig. 2).
CT-scan analysis confirmed no distortion nor cracks of the impeller (fig. 3).

Flexsafe® Pro Mixer system passed successfully this impeller robustness test and was able to achieve a complete dissolution of 4.4 kg of water-salt ice blocks in less than 20 minutes (table 1) with good stability and no significant damages of the impeller.

<table>
<thead>
<tr>
<th>Solution</th>
<th>Typical application</th>
<th>Characteristics</th>
<th>Dissolution time and rotation speed</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.4 kg of Salt-water</td>
<td>Frozen plasma</td>
<td>Hard blocks of ice potentially</td>
<td>&lt; 20 minutes</td>
</tr>
<tr>
<td>ice blocks in 25 L of</td>
<td></td>
<td>causing impeller instability</td>
<td></td>
</tr>
<tr>
<td>water at 25°C</td>
<td></td>
<td>and significant damages</td>
<td></td>
</tr>
</tbody>
</table>

Table 1: Ice blocks characteristics and dissolution performance of the Pro Mixer System

Conclusion

Flexsafe® Pro Mixer is a unique single-use technology platform fitting all mixing steps from buffer and media preparations, downstream steps to final formulation in 50 L, 100 L, 200 L, 400 L, 650 L and 1,000 L volumes.

Flexsafe® Pro Mixer ergonomic design enables intuitive, modular and agile use to achieve fast installation and mixing operations. Thanks to its high efficiency, the Flexsafe® Pro Mixer system was able to achieve short dissolution time and prove impeller stability robustness even against ice blocks of frozen salt water, making it adequate for frozen paste dissolution applications like in processes involving frozen plasma.
Europe

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Göttingen
Phone +49.551.308.0

Sartorius Stedim Systems GmbH
Robert-Bosch-Strasse 5 – 7
34302 Guxhagen
Phone +49.5565.407.0

France
Sartorius Stedim FMT S.A.S.
ZI des Paluds
Avenue de Jouques – CS 91051
13781 Aubagne Cedex
Phone +33.442.845600

Sartorius Stedim France SAS
ZI des Paluds
Avenue de Jouques – CS 71058
13781 Aubagne Cedex
Phone +33.442.845600

Austria
Sartorius Stedim Austria GmbH
Modecenterstrasse 22
1030 Vienna
Phone +43.1.7965763.18

Belgium
Sartorius Stedim Belgium N.V.
Rue Colonel Bourg 105
1030 Bruxelles
Phone +32.2.756.06.80

Hungary
Sartorius Stedim Hungária Kft.
Kaigyő u. 5
2092 Budakeszi
Phone +36.23.457.227

Italy
Sartorius Stedim Italy S.r.l.
Via dell’Antella, 76/A
50012 Antella-Bagni a Ripoli (FI)
Phone +39.055.63.40.41

Netherlands
Sartorius Stedim Netherlands B.V.
Phone +31.30.60.25.080
filtratie.nederland@sartorius-stedim.com

Poland
Sartorius Stedim Poland Sp. z o.o.
ul. Wrzesinska 70
62-025 Kostrzyn
Phone +48.61.647.38.40

Russian Federation
LLC “Sartorius Stedim RUS”
Vasilyevsky Island
5th line 70, Lit. A
199178 St. Petersburg
Phone +7.812.327.53.27

Spain
Sartorius Stedim Spain, S.A.U.
Avda. de la Industria, 32
8317 Tagelswangen
Phone +34.913.586.098

Switzerland
Sartorius Stedim Switzerland AG
Ringstrasse 24 a
8317 Tagelswangen
Phone +41.52.354.36.36

U.K.
Sartorius Stedim UK Ltd.
Longmead Business Centre
Blenheim Road, Epsom
Surrey KT19 9 QG
Phone +44.1372.737159

Ukraine
LLC “Sartorius Stedim RUS”
Post Box 440 “B”
01001 Kiev, Ukraine
Phone +380.44.411.4918

Africa

Republic of South Africa
Sartorius South Africa (Pty) Ltd
Unit 4, Alphen Square South
853 16th Road
Midrand 1685, RSA
Phone +27.11.315.5444

Americas

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1.800.368.7178

Argentina
Sartorius Argentina S.A.
Int. A. Ávalos 4251
B1605CSM Munro
Buenos Aires
Phone +54.11.4721.0505

Brazil
Sartorius do Brasil Ltda
Avenida Senator Vergueiro 2962
São Bernardo do Campo
CEP 09600-000 - SP- Brasil
Phone +55.11.4362.8900

Mexico
Sartorius de México, S.A. de C.V.
Libramiento Norte de Tepoztlan s/n,
Colonia Barrio Tlacateco,
Municipio de Tepoztlan,
Estado de México,
C.P. 54605
Phone +52.55.5562.1102
leadsmex@sartorius.com

Asia/Pacific

Australia
Sartorius Stedim Australia Pty. Ltd.
Unit 5, 7-11 Rodeo Drive
Dandenong South Vic 3175
Phone +61.3.8762.1800

China
Sartorius Stedim (Shanghai)
Trading Co., Ltd.
3rd Floor, North Wing, Tower 1
No. 4560 Jinke Road
Zhangjiang Hi-Tech Park
Pudong District
Shanghai 201210, P.R. China
Phone +86.21.6878.2300

India
Sartorius Stedim India Pvt. Ltd.
#69/2-69/3, NH 48, Jakkasandra
Nelamangala Tq
562 123 Bangalore, India
Phone +91.80.4350.5250

Japan
Sartorius Stedim Japan K.K.
4th Fl., Daiwa Shinagawa North Bldg.
8-11, Kita-Shinagawa 1-chome
Shinagawa-ku, Tokyo, 140-0001 Japan
Phone +81.3.4331.4300

Malaysia
Sartorius Stedim Malaysia Sdn. Bhd.
Lot L3-E-3B, Enterprise 4
Technology Park Malaysia
Bukit Jalil
57000 Kuala Lumpur, Malaysia
Phone +60.3.8996.0622

Singapore
Sartorius Stedim Singapore Pte. Ltd.
10 Science Park Rd
The Alpha #02-13/14
Singapore Science Park II
Singapore 117684
Phone +65.6872.3966

South Korea
Sartorius Korea Biotech Co., Ltd.
8th Floor, Solid Space 8/D,
PanyoYeok-Ro 220, Bundang-Gu
SeongNam-Si, GyeonggiDo,
463-400
Phone +82.31.622.5700

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