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Application Note

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Flexsafe® Pro Mixer

The Fast, Flexible and Intelligent Solution for Frozen Paste Dissolution

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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.

Find out more: www.sartorius.com/flexsafe-pro-mixer

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).

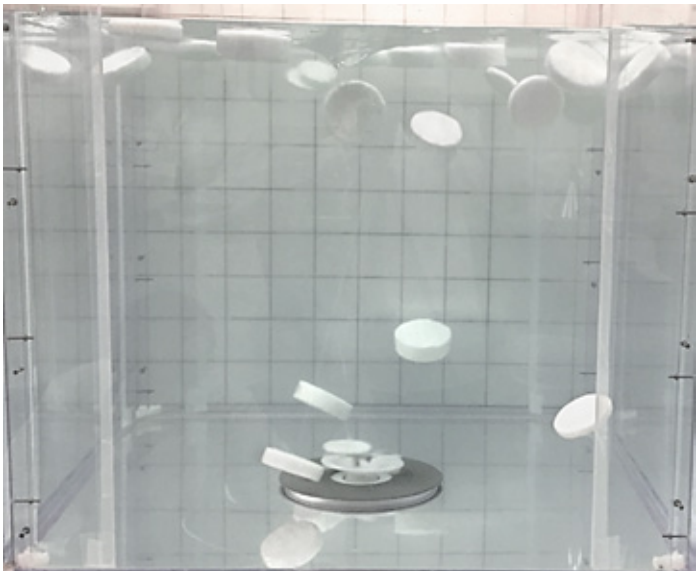

Figure 1: Ice blocks dispersion during pre-test performed at 1000 L

Apart from light scuffs at tip of impeller blades, no significant visual damage to the impeller was observed (fig. 2).

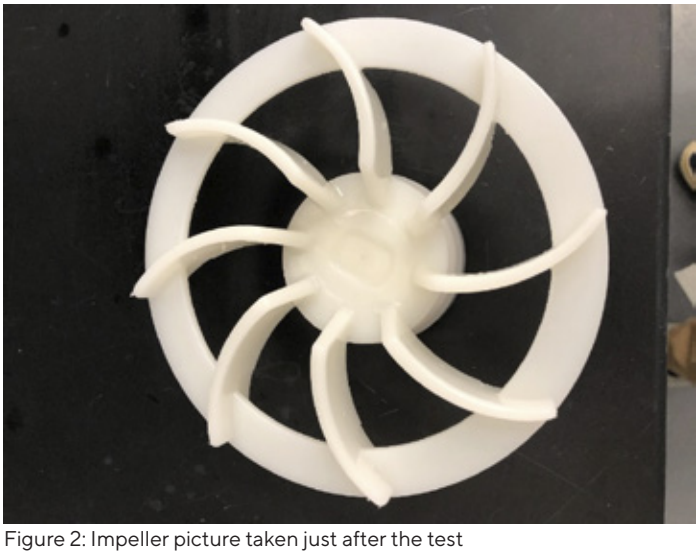

Figure 2: Impeller picture taken just after the test

CT-scan analysis confirmed no distortion nor cracks of the impeller (fig. 3).

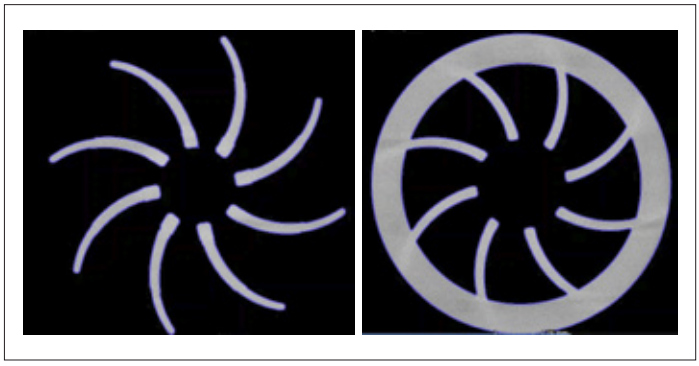

Figure 3: Example of images taken during the scan analysis

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.

Solution	Typical application	Characteristics	Dissolution time and rotation speed
			50 L (375 rpm)
4.4 kg of Salt-water ice blocks in 25 L of water at 25°C	Frozen plasma	Hard blocks of ice potentially causing impeller instability and significant damages	< 20 minutes

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.

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