Fristam
Hygienic Pumping Experts

DEMONSTRATING THE SUPERIOR PERFORMANCE OF THE FRISTAM FDS TWIN SCREW PUMP

Testing conducted by

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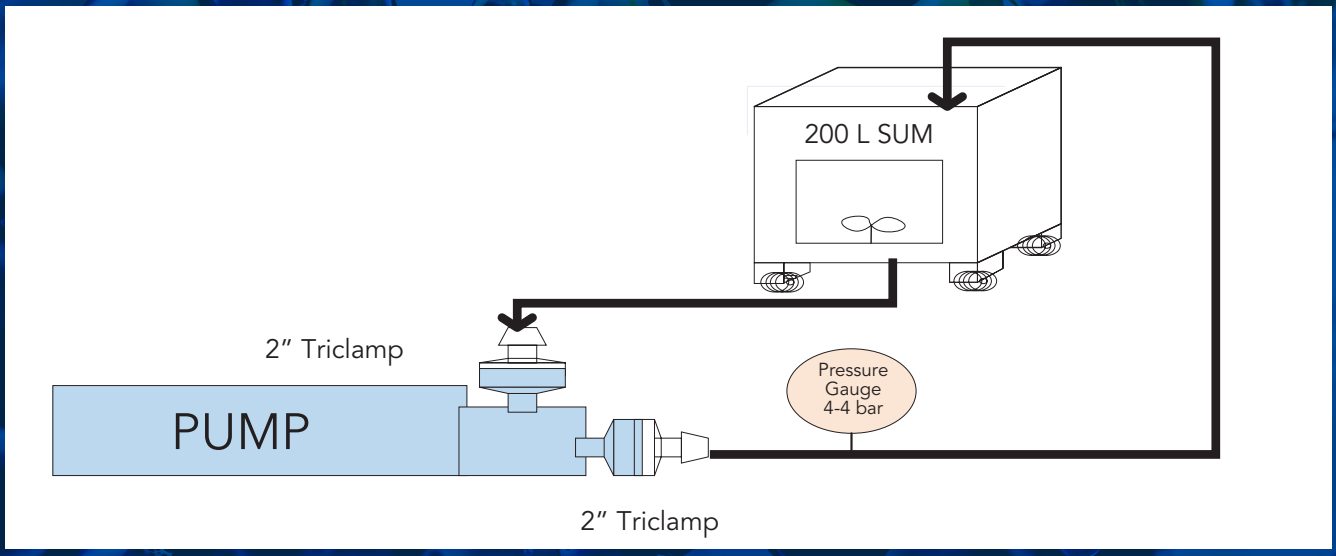
DEMONSTRATING THE SUPERIOR PERFORMANCE OF THE FRISTAM FDS TWIN SCREW PUMP

EXECUTIVE SUMMARY

The Fristam FDS multi-use twin screw pump has undergone rigorous testing at the bioX Applications Lab in Salem New Hampshire to assess its mechanical shear, hemolysis, pulsation, and protein denaturing effects. These tests were part of a comprehensive evaluation aimed at understanding the pump's suitability for critical fluid processing applications, particularly in the pharmaceutical and life sciences sectors. The bioX Applications Lab, renowned for its expertise in conducting physical, mechanical, biological, and chemical testing, provided the ideal environment for this detailed assessment. The results highlighted the Fristam FDS pump's exceptional performance across all flow rates and pressures, demonstrating minimal mechanical shear, low pulsation, and negligible hemolysis. For over two hours of continuous operation, the pump's impact on red blood cell integrity was less than 5%. Additionally, protein stability tests conducted at bioX revealed only a minor 4% reduction in Immunoglobulin G (IgG) concentration, a significant improvement over other pump technologies such as rotary lobe and peristaltic pumps, which can cause denaturation of 8-16%. With these results, the Fristam FDS pump stands out as a superior choice for sensitive fluid handling, ensuring minimal process variability and optimal product quality in critical applications.

RECIRCULATION LOOP TEST SETUP

A recirculating test loop was designed to accommodate variable flow rates and pressures throughout each testing phase. System pressure was monitored using a 0–100 psi gauge, while pump speed was precisely controlled via a variable frequency drive (VFD) to regulate potential product shear conditions effectively.



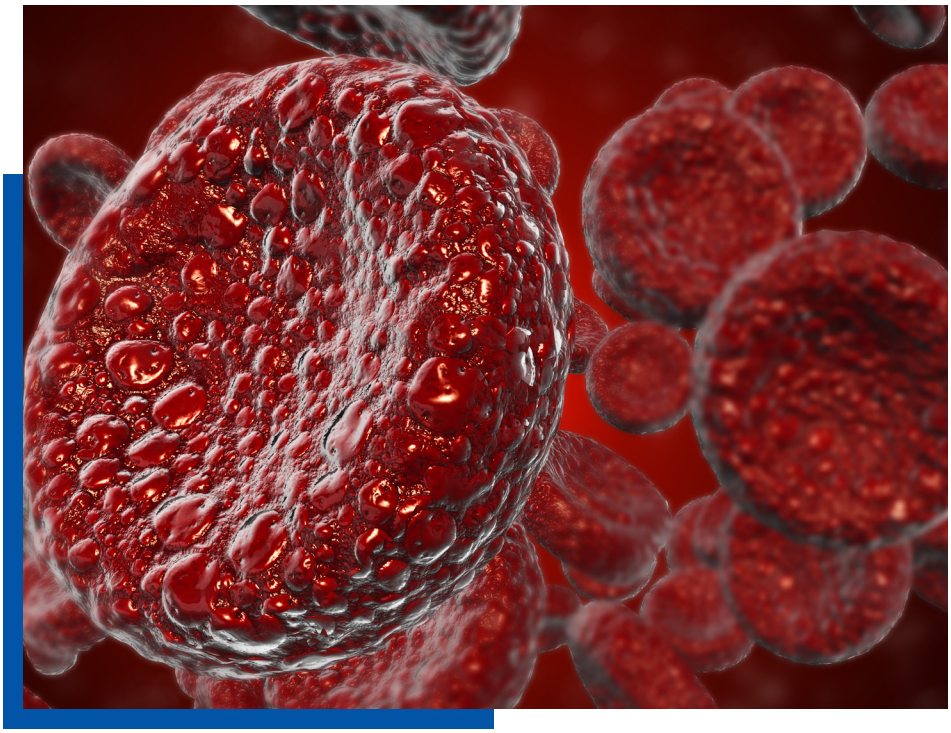
1. INTRODUCTION

Manufacturing processes in the pharmaceutical and life science industries require highly precise and controlled fluid handling to maintain the integrity of sensitive biological materials. The Fristam FDS twin screw pump is designed to meet these needs by providing a robust solution that minimizes mechanical shear, pulsation, and protein denaturation. These factors are critical to ensuring consistency in biological product quality, particularly during the production of cell cultures, drug substances, and drug products. This whitepaper presents the results from an extensive set of performance tests that confirm the superior handling capabilities of the Fristam FDS pump.

2. TEST METHODOLOGY AND INSTRUMENTATION

2.1. MECHANICAL SHEAR TESTING

Mechanical shear forces can negatively impact cell viability, product formation, and consistency in biological manufacturing processes. To assess the shear impact of the Fristam FDS pump, Sauter Mean Diameter (SMD) testing was employed, a well-established method for evaluating the mechanical shear imposed on fluids during pump operation. The test setup included the Mettler Toledo FBRM (Focused Beam Reflectance Measurement) sensor, which offers real-time particle size measurement with high precision. This allowed for the accurate determination of shear forces and their effect on the fluid stream.



2.2. HEMOLYSIS TESTING

Hemolysis testing is a key metric for evaluating the impact of pumps on cell integrity, especially when handling red blood cells. Hemolysis was quantified by measuring both free hemoglobin levels and intact red blood cells using the Attune Acoustic Focusing Cytometer. The testing was conducted in accordance with ASTM F756, with a focus on determining the maximum acceptable hemolysis levels during the pump's operation under varying conditions.

2.3. PROTEIN STABILITY TESTING

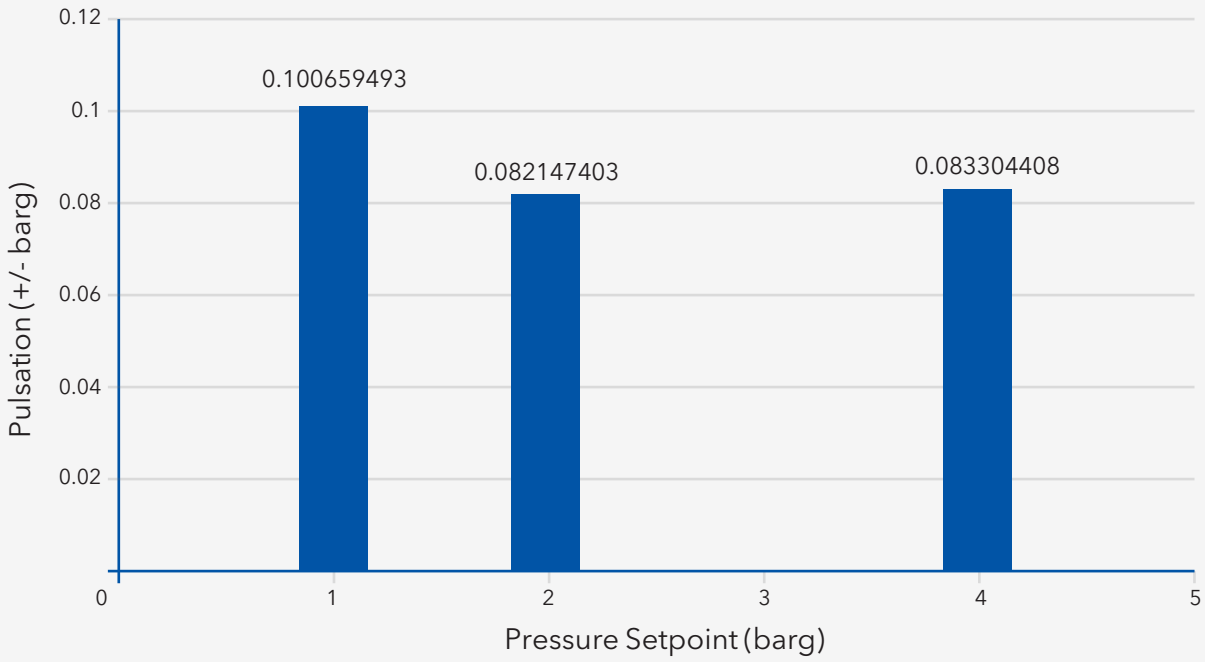
Protein stability is a major concern when handling biological materials such as antibodies. To assess the Fristam FDS pump's impact on protein denaturation, a series of Immunoglobulin G (IgG) stability tests were conducted. IgG at a concentration of 10g/L was recirculated through the pump at various pressures (2 bar) and flow rates (50% output) for one hour. The results were compared to similar tests conducted using rotary lobe and peristaltic pumps.

3. TEST RESULTS AND ANALYSIS

3.1. MECHANICAL SHEAR

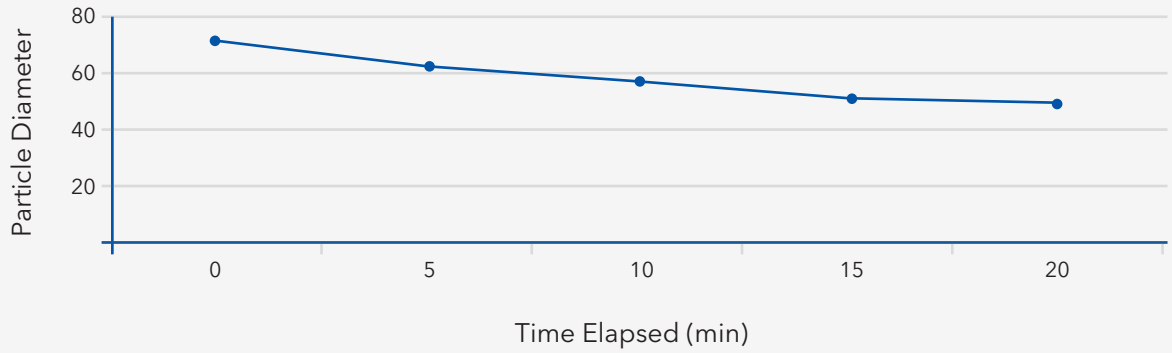
The Fristam FDS pump was found to generate significantly lower mechanical shear compared to other commonly used pump technologies. The Sauter Mean Diameter (SMD) tests showed that the FDS pump maintained stable particle size distributions across a wide range of flow rates (10%, 50%, 90% of maximum) and pressures (1 bar, 2 bar, 4 bar). This performance ensures minimal disruption to fluid streams, making the Fristam FDS pump an ideal choice for processes that require delicate handling of biological products.

PULSATION PRESSURE AT SETPOINTS



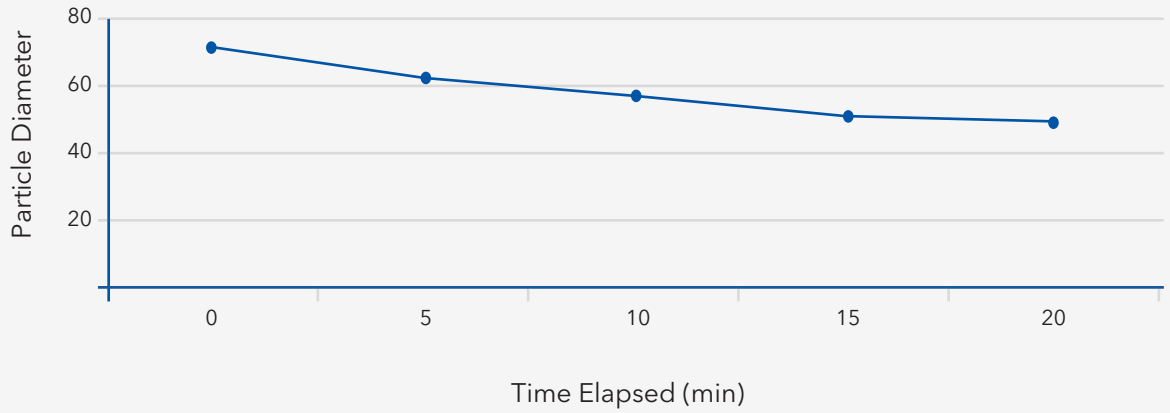
Pulsation data at 1, 2, and 4 barg.

1-BAR MEAN SAUTER DIAMETER RESULTS



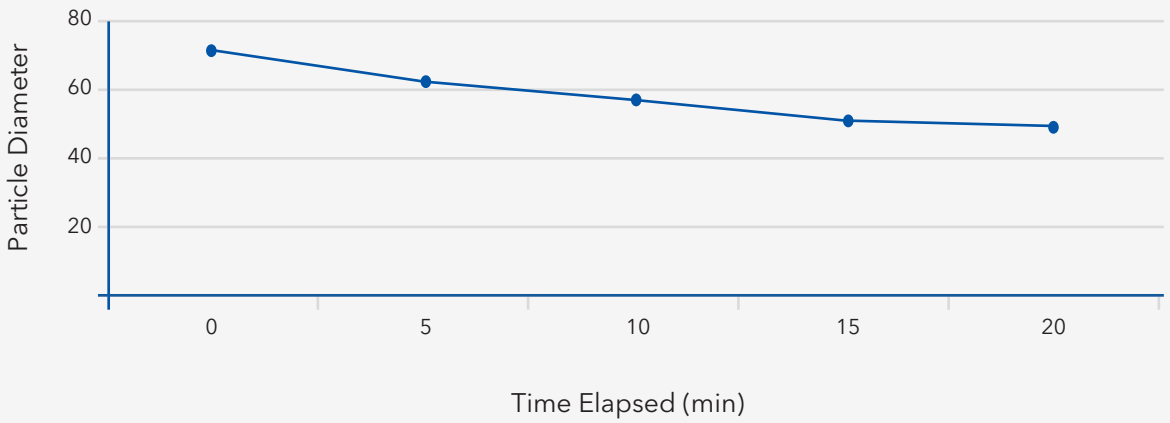
Particle diameters over time at pressure setpoint of 1bar.

2-BAR MEAN SAUTER DIAMETER RESULTS



Particle diameters over time at pressure setpoint of 2 bar.

4-BAR MEAN SAUTER DIAMETER RESULTS

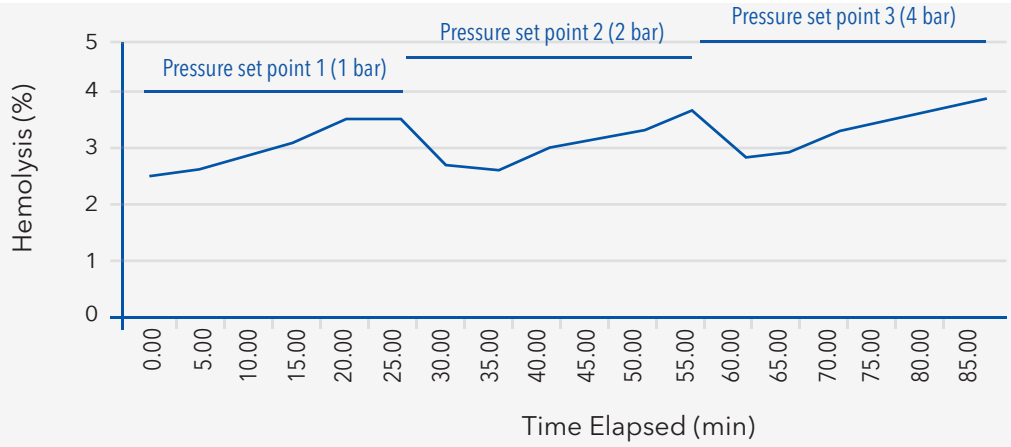


Particle diameter over time at pressure setpoint of 4 bar.

3.2. HEMOLYSIS

Hemolysis testing demonstrated the Fristam FDS pump's superior ability to minimize red blood cell degradation. After two hours of continuous pumping at varying flow rates and pressures, the pump induced less than 5% hemolysis. For comparison, other pump technologies often result in higher hemolysis rates, making the FDS pump an excellent choice for critical applications where cell integrity is essential.

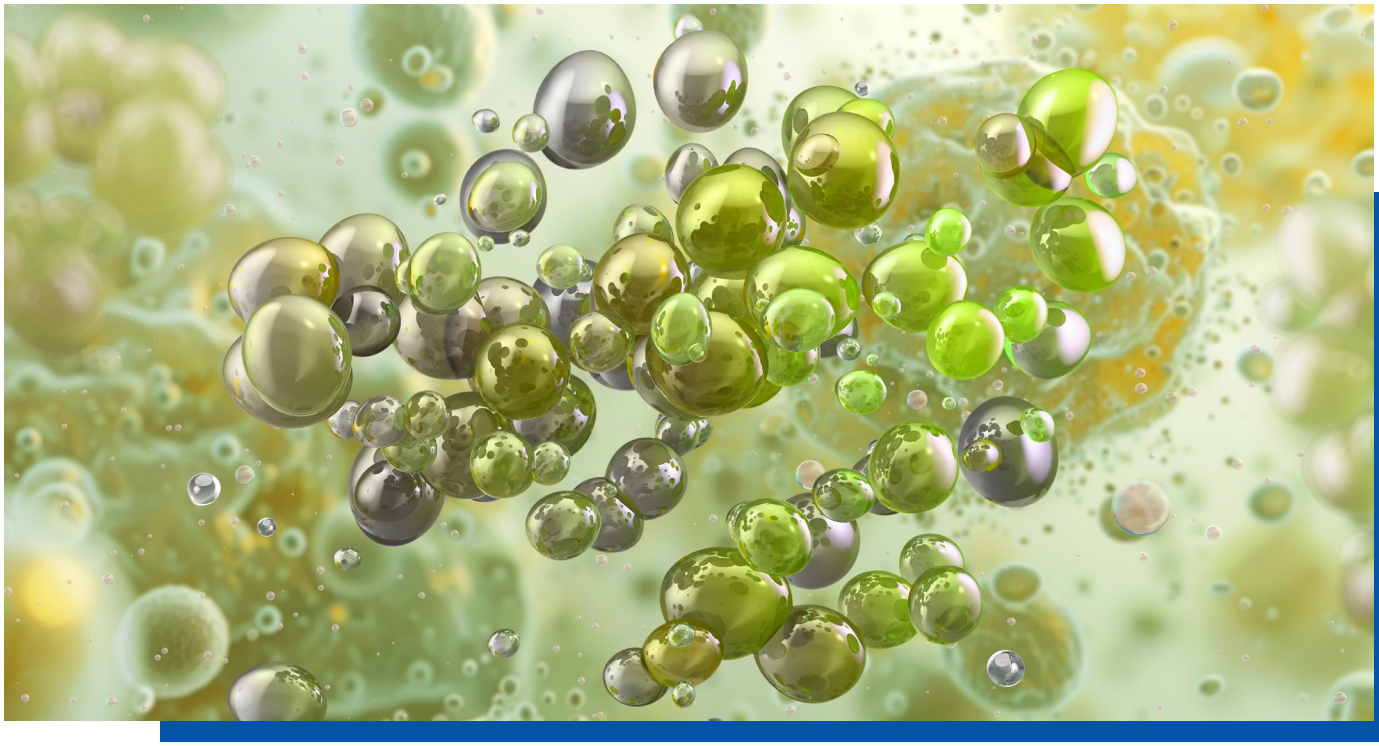
HEMOLYSIS RESULTS



Hemolysis trend over 85 minutes of pumping and 3 pressure setpoints

3.3. PULSATION

Pulsation, as highlighted in section 3.1, is a common challenge with certain pump types, which can lead to inconsistent fluid flow and affect product quality. However, the Fristam FDS pump exhibited minimal pulsation across all test conditions. The pulsation levels were significantly lower than those observed with other pumps, contributing to a more stable and predictable fluid flow—ideal for applications requiring precise fluid delivery.



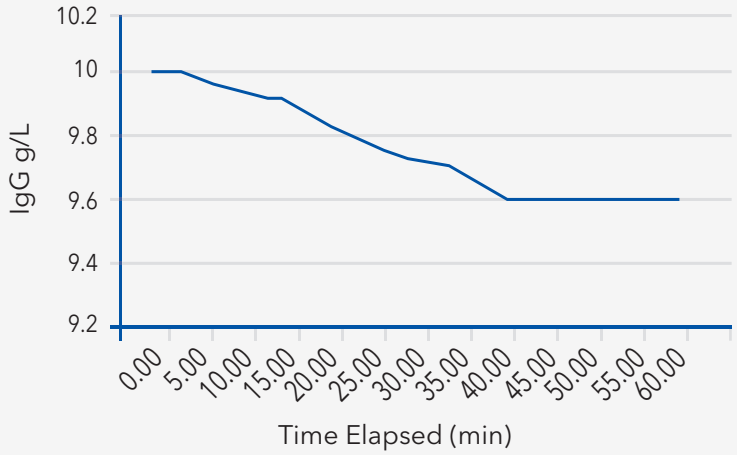
3.4. PROTEIN STABILITY

Protein stability testing revealed that the Fristam FDS pump had minimal impact on the integrity of Immunoglobulin G (IgG). After one hour of recirculation at 50% output and 2 bar pressure, the concentration of IgG decreased by only 4%, indicating excellent preservation of protein structure during processing.

PROTEIN STABILITY TESTING

Immunoglobulin G (IgG) was tested at 10g/L and recirculated for 1 hour at 50% output and 2 bar pressure.

PROTEIN DENATURING IGG @ 10G/L AND 2 BAR PRESSURE



IgG 10g/L Denaturation Testing

4. CONCLUSION

The Fristam FDS twin screw pump has demonstrated outstanding performance in mechanical shear, hemolysis, pulsation, and protein denaturation testing. Its ability to minimize shear forces, reduce hemolysis, and maintain protein integrity makes it a standout choice for applications involving sensitive biological fluids. Moreover, the pulsations are significantly low, making it an optimal pump technology for applications involving filtration, such as Tangential Flow Filtration (TFF) and chromatography. The Fristam FDS pump is an ideal solution for pharmaceutical and life science manufacturing processes, where consistency, quality, and process optimization are paramount.

To learn more about how the Fristam FDS twin screw pump can enhance your production processes, optimize fluid handling, and maintain the highest standards of quality, reach out to one of our hygienic pumping experts today for a consultation or request a demo. Let us help you achieve superior results in your pharmaceutical and life science applications.

Fristam

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