3P pharma equipment

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EXPANDING THE VISCOSITY LIMITS OF PERISTALTIC DOSING

Development and evaluation of a high-accuracy pump for liquids up to 2000 cP

A new **peristaltic dosing pump** has been developed by 3P innovation and is now in routine operation at manufacturing sites in both clinical and commercial environments. This paper presents performance data from controlled laboratory evaluations, focusing on dose accuracy across a wide viscosity range.

The new design demonstrates up to a **tenfold improvement in volumetric accuracy** compared to an industry-standard peristaltic pump, while maintaining accurate dosing at viscosities exceeding 2000 cP - more than twenty times higher than typical operational limits for conventional peristaltic systems (≈100 cP).

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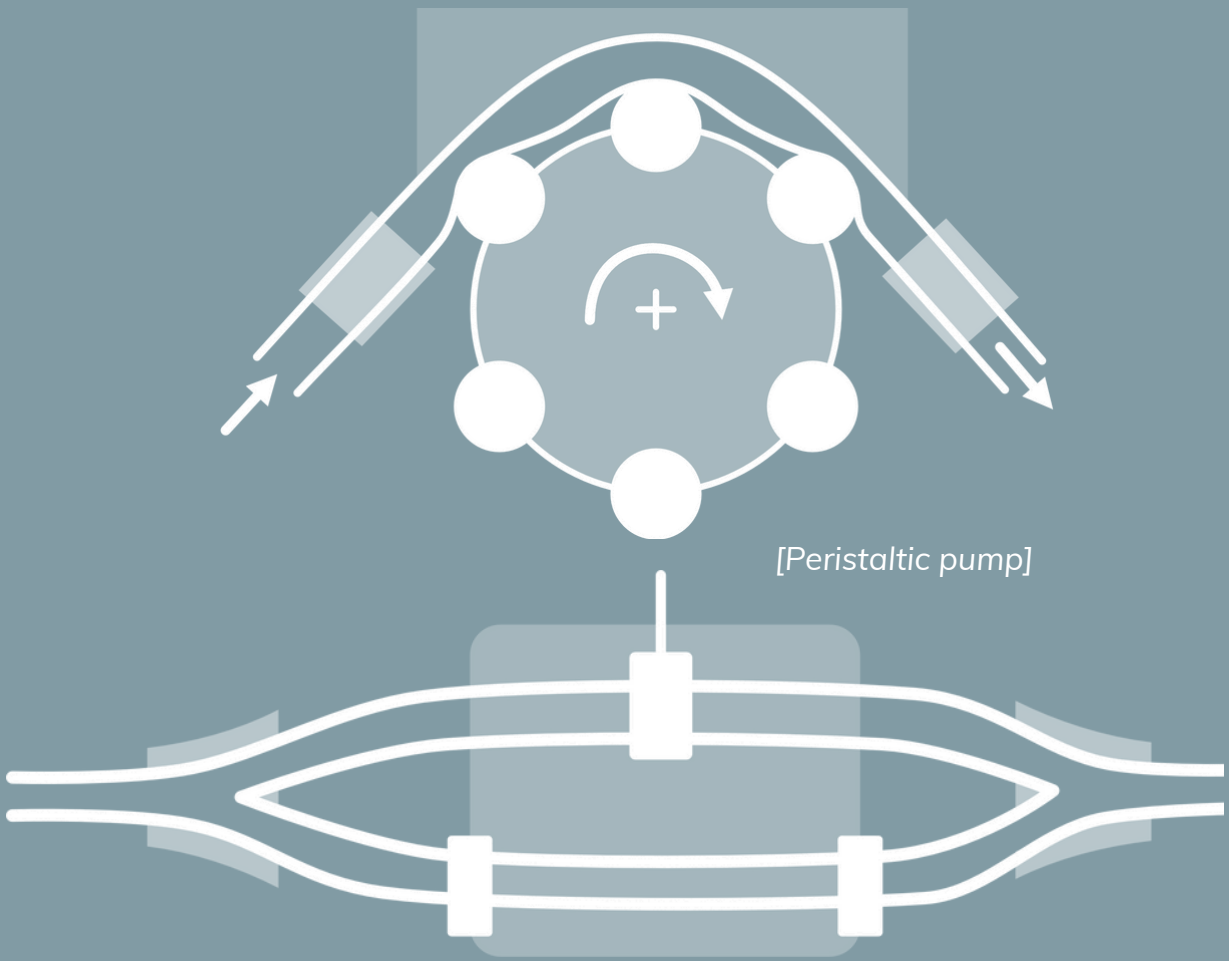
1. Introduction

Peristaltic pumps are widely employed across the biopharmaceutical, food, and chemical industries due to their non-contact and contamination-free mode of fluid transfer. Operation is based on sequential compression of a flexible tube by external rollers, which displace discrete fluid volumes through a closed flow path. Between roller passes, the tubing must elastically recover to its original geometry, drawing in the next fluid segment.

At elevated viscosities, this elastic recovery becomes progressively impaired, leading to flow inconsistencies, diminished accuracy, and increased tube wear [ref1]. For this reason, conventional peristaltic systems are generally limited to fluids below approximately 100 cP before performance degradation becomes significant.

Modern injectable formulations are trending toward higher concentrations and correspondingly higher viscosities. Protein-based therapeutics, for instance, may exhibit intermolecular interactions and transient aggregation, increasing both apparent viscosity and shear dependence. Current advanced therapies - particularly in cell and gene therapy - can reach or exceed 200 cP, typically requiring piston-driven filling technologies [ref2]. However, piston systems introduce drawbacks, including fixed fluid paths, complex cleaning validation, and potential cross-contamination risk [ref3].

To address these limitations, 3P innovation has developed a peristaltic pump capable of dosing liquids up to 2000 cP while maintaining high volumetric accuracy. This represents an expansion of peristaltic pump capabilities into viscosity ranges previously dominated by piston systems, while preserving the advantages of disposable fluid paths and straightforward aseptic integration.



[Peristaltic pump]

2. The challenges of viscosity

High-viscosity fluids present mechanical and rheological challenges for peristaltic pumping, primarily through increased internal resistance to deformation and delayed elastic response of the tubing. These effects can manifest in several ways:

- **Tube deformation and expansion:** Elevated discharge pressures can cause transient tube expansion, altering internal volume and leading to time-dependent dosing variability.
- **Restoration delay:** Slower elastic recovery between roller compressions produces inconsistent chamber volumes, particularly at higher rotational speeds.
- **Viscous bridging:** Viscous adhesion can prevent clean break-off between doses, creating variability in fill weight.

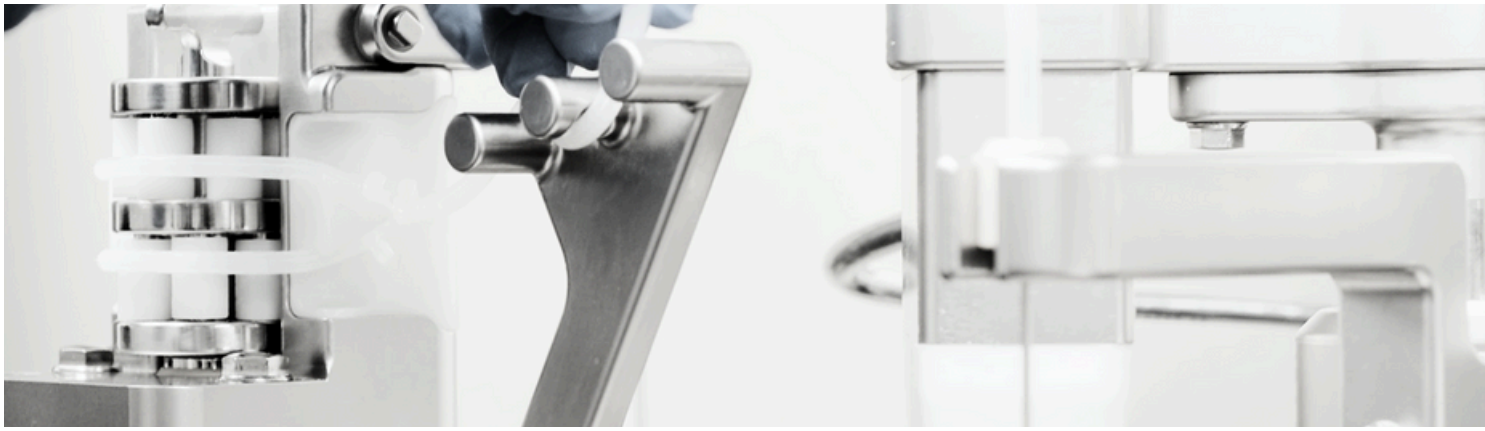
These effects collectively limit the practical viscosity range of conventional peristaltic dosing systems.

3. 3P innovation's peristaltic pump

The 3P innovation peristaltic pump integrates several mechanical and control innovations, to enhance dosing performance at high viscosities. Following extensive development, the system is now implemented across multiple automated fill–finish platforms in clinical and commercial production environments.

Key design features include:

- **Closed-loop control:** continuous feedback from an integrated high-precision weigh cell enables adaptive control. The software continuously optimises pump dynamics using:
    - Zero-Loss Priming to eliminate startup material waste;
    - Tube Wear Drift Correction to compensate for gradual changes in tube elasticity over the course of a batch;
    - Top-up correction for underfilled doses, improving batch yield.



- **Rotor geometry:** A reduced-pitch rotor design smooths the flow profile and maintains accuracy at smaller dose volumes. The rotor assembly is modular and compatible with multiple tubing materials, simplifying cleaning and replacement.
- **Precision control:** A precision industrial servo motor provides fine dynamic control, allowing rapid yet controlled acceleration, shutoff, and pullback. These factors improve drip break-off and inter-dose consistency.
- **Rigid static saddle:** The saddle structure remains stable under high compression forces, maintaining consistent tube occlusion and predictable displacement per revolution even with viscous fluids.

4. Comparative evaluation

A comparative study was conducted between the 3P innovation peristaltic pump and a conventiona;l, industry standard Watson-Marlow PF6 unit. The PF6 was selected for its widespread use in aseptic filling operations; although the newer PF7 model exists, its mechanical characteristics are equivalent for dosing performance.

Tests were designed to evaluate volumetric accuracy as a function of viscosity, dose volume, and speed. To maintain relevance to automated fill–finish process conditions, dosing duration was limited to 2 seconds per dose. Each test consisted of 50 replicates, providing a statistically representative dataset.

Accuracy was quantified using 3 × Relative Standard Deviation % (RSD) of dose weights. For a normal distribution, this metric encompasses 99.7% of all doses for a given configuration, thus giving a reasonable estimate of the range of a full population set, while allowing cross-comparison between dose sizes.

4.1 Dose Accuracy with Water

Initial benchmarking was performed using water at 0.25 ml, 1 ml, and 5 ml fill volumes. Across all volumes, the 3P peristlatic pump (labelled 3PPP) demonstrated accuracy up to three times higher than the PF6, with no condition where performance fell below a 2.5× improvement (Figure 1)

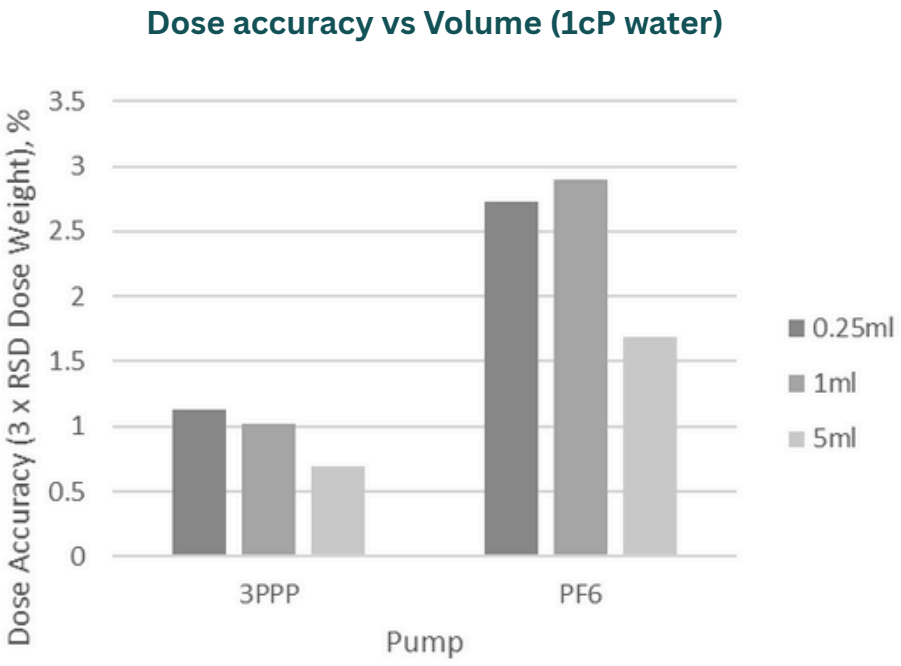
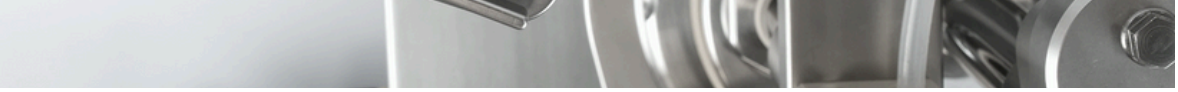


Figure 1: Comparison of pump accuracy across a range of dose sizes (water)



4.2 Dose Accuracy Across Viscosity Range

Subsequent tests assessed performance at increasing viscosities using 1 ml target volumes. Low-viscosity fluids were prepared with water–glycerol mixtures, while high-viscosity samples (>1000 cP) used water–hyaluronic acid formulations. The PF6 demonstrated increasing inaccuracy above 90 cP, exceeding ±10% accuracy at 93.9 cP. In contrast, the 3P innovation pump maintained ±3.75% accuracy at 950 cP and continued to operate reliably up to 2000 cP (Figure 2).

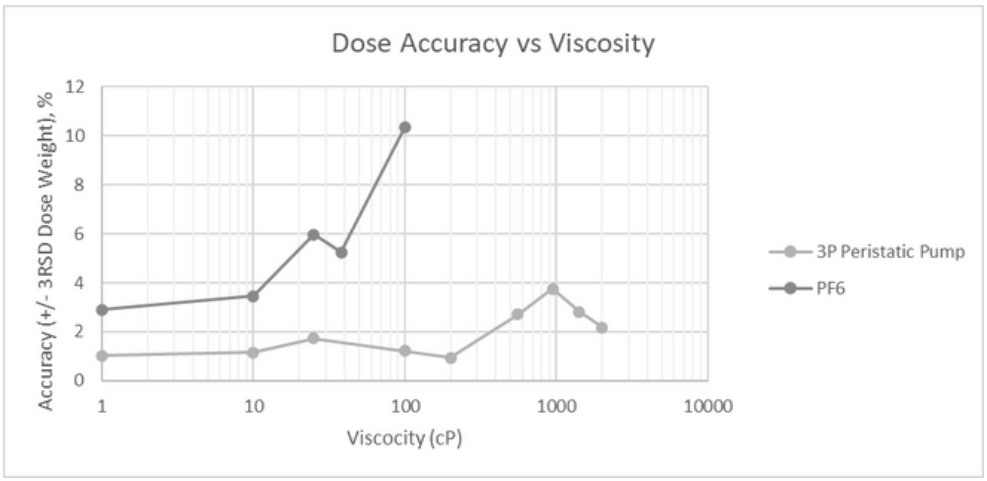


Figure 2: Comparison of pump accuracy across a range of viscosities

4.3 Tube Wear and Long-Term Stability

To assess performance stability over course of a typical batch, the 3P innovation pump underwent an accelerated wear test. The system was operated continuously for 10,000 doses with a 2137 cP hyaluronic acid - water mixture. Dose accuracy was evaluated before and after this endurance test.

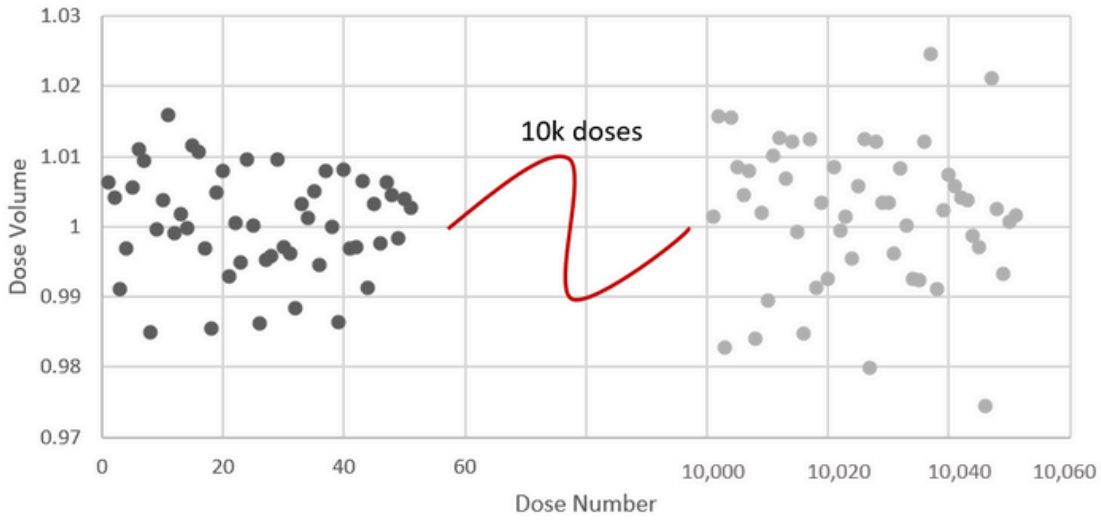


Figure 3: Results from wearing a tube set across 10,000 doses

Table 1: A table showing the accuracy (3RSD) of a 2137cP dose in a new and worn tube set

Initial Accuracy +/- 3RSD%	No. of Simulated Wearing Doses	Final Accuracy +/- 3RSD%
2.12%	10,000	3.06%

While a modest increase in dose spread was observed after extended operation, the overall accuracy remained within acceptable limits for high-viscosity aseptic filling (Figure 3).

Conclusion

The 3P innovation peristaltic pump demonstrates significant performance improvements over conventional peristaltic systems, maintaining high dosing accuracy across a viscosity range from 1 to 2000 cP. The combination of closed-loop feedback control, servo-driven actuation, and stable mechanical architecture enables precision dosing previously achievable only with piston-based systems.

The design includes removable components suitable for Grade A sterilisation methods (vaporised hydrogen peroxide or autoclave) and features a compact footprint for integration into automated fill–finish environments. This expanded operating envelope allows peristaltic technology to address a wider range of modern biopharmaceutical formulations without compromising sterility, process efficiency, or material yield.

References

[ref1] https://eagleelastomer.com/industry-news-blog/life-expectancy-of-a-peristaltic-pump-tube/

[ref2]https://www.sigmaaldrich.com/deepweb/assets/sigmaaldrich/product/documents/273/572/viscosity-reduction-wp8385en-mk.pdf

[ref3] https://www.pharmtech.com/view/dispensing-biopharmaceuticals-piston-and-peristaltic-pumps

[ref4] https://www.sharpservices.com/expert-content/the-science-of-viscous-drug-product-filling-pumps-pressure-and-process-optimization-2/