Rapid, Aseptic Sampling Supports FDA Validation of Tamarack's UV Pasteurization System

Why is precise, high-frequency sampling critical when demonstrating log-reduction performance to meet FDA pasteurization requirements?

> *"QualiTru's TruDraw® Sterile Single Sampler gave us the precise, time-point data we needed for FDA validation of our UV pasteurization system."*

CHALLENGE

Tamarack Biotics developed a thin-film, high-turbulence UV pasteurization system and needed to verify the log reduction achieved for a wide range of pathogens found in milk—data that would ultimately support FDA evaluation of the technology as a potential alternative to thermal pasteurization. Due to the system's efficiency, a 5-log reduction for many pathogens occurred in 60 seconds or less. Therefore, after inoculating a pathogen or surrogate to 1×10^7 CFU/mL, samples needed to be collected every 20 seconds to track the log-reduction curve through sample plating.

SOLUTION

Tamarack chose QualiTru's TruDraw® Sterile Single Samplers for rapid sample collection through multiple QualiTru TruStream™ stainless steel ports and septa. An inoculation septum was installed at the low-pressure inlet side of the pump in a closed-loop recirculating system that included Tamarack's UV pasteurizing Turbulator. Two TruStream septa were installed at the high-pressure side of the pump to enable fast collection, ensuring accurate timing. Once the UV lamp reached full warm-up, a syringe containing the inoculum was inserted into the inoculation septum, and an operator consistently injected the inoculum over the 4-second recirculation time. After waiting 3 seconds for mixing to occur, a zero-time sample was collected, followed by samples every 20 seconds, using the TruDraw. Proper needle insertion into the septum ensured fast, aseptic draws.

Time After Inoculation (sec)	Expected Log Reduction Behavior	Notes
0	0-log reduction (baseline)	Zero-time sample pulled 3 sec after mixing
20	Rapid early reduction	TruDraw used for timed, aseptic sample
40	Approaching 5-log reduction	UV system highly efficient
60	≥5-log reduction achieved	Confirmed across 50+ runs; meets FDA requirement

Sampling Timeline for Log Reduction Validation

RESULTS

To meet the FDA's requirements, Tamarack conducted more than 50 experimental runs with various pathogens. The data demonstrated that Tamarack's UV system achieved at least a 5-log reduction in the most UV-resistant pathogen. The FDA affirmed that Tamarack's UV system met the legal requirements as an alternative to thermal pasteurization in May 2025.

BENEFITS

The combination of QualiTru's TruDraw Single Samplers and TruStream septa allowed Tamarack to capture accurate, repeatable samples at tight intervals, ensuring confidence in their log-reduction curves. This level of precision contributed to the successful regulatory review of their UV system and reinforced its suitability for processors seeking non-thermal pasteurization options.

Applications and Product Guide

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