# VIRAL CLEARANCE CONSIDERATIONS FOR CONTINUOUS VIRAL INACTIVATION

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Continuous low pH viral inactivation has been considered by Boehringer Ingelheim, Pfizer, and other companies who are investing in integrated processing. In continuous viral inactivation, a critical parameter that poses a new challenge is the exact incubation time of the product stream. In a continuous space, the concept of time translates in the product flow rate, incubation volume, and dispersion effects. To address dispersion, we define the minimum residence time, $t_{min}$, as the time when the first product element exits the tubular chamber. In this work, we characterize the $t_{min}$ for a novel, scalable, and sturdy tubular reactor design that can serve as an incubation chamber for a process capable to produce >1kg of product. In addition, we provide robust data for a scale down model suitable for viral studies. We propose an innovative in-line spiking methodology to validate the minimum residence time using viruses. This methodology can be used as a viral clearance platform for continuous low pH virus inactivation. Finally, we propose a trace response method to be used as a way to verify that the process was properly set up.