

Process Control: Viral Inactivation (VI)

The Process Automation System (PAS) utilizes an automated monitoring strategy to ensure the drug substance is correctly processed during the viral inactivation stage. The system monitors pH levels at both the inlet and outlet of the unit. If the measured pH falls outside of the predefined high or low tolerance setpoints for a specific amount of time, the system automatically triggers a "drain" response. This involves switching the valve path to a dedicated waste line (VI Inlet or Outlet Drain) to prevent out-of-specification material from continuing through the manufacturing process. Once the pH returns to the acceptable range and stabilizes, the system automatically redirects the flow back to the collection path to resume normal operations