

Enhancing Product Purity and Yield

Innovative pH and Pressure Sensors

Chromatographic techniques are essential for separating complex mixtures in pharmaceutical and biomedical research. These methods enable precise qualitative and quantitative analysis, critical for drug development and quality control. Key factors such as pH and pressure stability greatly influence separation efficiency and product purity. In downstream bioprocessing, maintaining consistent pH and pressure is vital for effective protein purification and process reliability. Advanced single-use pH and pressure sensors, combined with intelligent transmitters, offer accurate, real-time monitoring and seamless integration for sterile operations, enhancing control and compliance in biopharmaceutical workflows.

Background

Chromatography unit operations are vital in pharmaceutical and biomedical research, encompassing a variety of methods such as liquid chromatography (LC), gas chromatography (GC), thin-layer chromatography (TLC), and high-performance liquid chromatography (HPLC). These techniques enable precise separation of complex mixtures. LC and HPLC are extensively used for sensitive analysis of pharmaceutical compounds and biological samples. At the same time, GC is preferred for volatile substances, and TLC serves as a quick, cost-effective preliminary tool. Together, these chromatographic methods are indispensable for drug development, quality control, and biomedical research, ensuring product safety, efficacy, and advancing scientific understanding (1).



Process

Chromatography separates components of a mixture based on their differing interactions with the stationary and mobile phases. As the mobile phase transports the sample through the stationary phase, compounds with greater affinity move more slowly, leading to effective separation. Each substance elutes at a distinct retention time, allowing for qualitative identification, while the peak areas in the chromatogram enable accurate quantification (2).

Flow rate and pH are critical parameters for optimizing loading and elution during chromatographic separation. Proper control of flow and pressure ensures the process stream moves efficiently through the column, promoting sharp peak resolution, minimizing peak broadening, and preserving the integrity of the stationary phase or packed bed. Insufficient pressure leads to low flow rates, resulting in poor separation and longer processing times. In contrast, excessive pressure can cause high flow rates, column overloading, and potential damage to the column packing material (3).

Challenges

In downstream biopharmaceutical processes, pH and ionic strength in the buffered mobile phase are crucial for effective protein purification during chromatography. These factors influence interactions between the mobile and stationary phases, directly impacting separation efficiency and the distinction between product and impurities. Variations in buffer preparation and pH during large-scale bioprocessing can adversely affect product recovery, purity, and throughput. Additionally, precise pH monitoring during formulation prior to fill-and-finish operations is essential for maintaining product quality (4).

Pressure fluctuations during chromatography negatively affect performance and reliability. They cause inconsistent flow rates, leading to unstable retention times and poor reproducibility. This results in peak broadening, distorted peak shapes, and reduced resolution, undermining both qualitative and quantitative accuracy. Pressure instability also stresses system components such as pump seals, check valves, and columns, increasing wear, maintenance needs, and risk of downtime. Severe pressure issues can cause sample

loss or contamination, compromising product purity and the integrity of the chromatographic process (5).

METTLER TOLEDO Pendotech Solutions

pH Sensor

The advanced single-use pH sensor by METTLER TOLEDO integrates the InSUS line of pH probe technology with a single-use flow cell for precise in-line pH monitoring in downstream bioprocessing. It includes a pH-sensitive electrode, a reference electrode, and a temperature probe, providing rapid, accurate, real-time measurements critical for product purification. Utilizing a factory-determined slope and zero-point, the sensor streamlines setup by requiring only a simple 1-point process calibration, supporting efficient closed-system operations. Available in pre-assembled sizes and compatible with gamma irradiation sterilization, this sensor reduces process downtime by requiring no calibration other than a process calibration. Seamlessly compatible with METTLER TOLEDO transmitters, it offers a reliable, efficient solution for monitoring pH in environments where probe cleaning is challenging, ensuring rapid detection of pH changes.

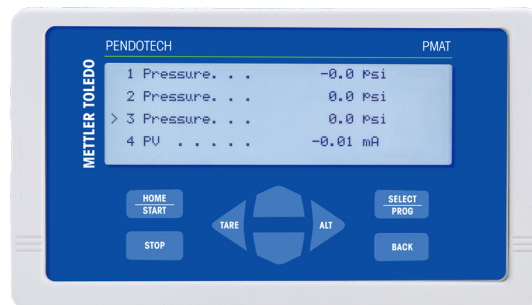


Pressure Sensor and Transmitters

Pendotech's Single-Use Pressure Sensors provide precise, cost-effective pressure measurement tailored for chromatography applications in biopharmaceutical processes. Accurate pressure monitoring is crucial in chromatography to ensure optimal flow conditions, prevent column damage, and maintain consistent separation performance. These sensors, featuring MEMS-HAP high-accuracy pressure chips, reliably measure both static and dynamic pressures within chromatography systems. Their caustic-resistant polysulfone construction supports common cleaning protocols, ensuring durability in harsh environments. With a rating up to 75 psi, they deliver robust performance suited for small- to medium-scale chromatography processes and seamlessly integrate with systems such as PressureMAT™, Pendotech Process Control Systems (PCS), and select third-party monitors, enhancing process control and product quality.



The PressureMAT™ Sensor Transmitter addresses key challenges in chromatography by providing real-time pressure monitoring and alerting capabilities essential for maintaining precise control over chromatographic processes. Its easy-to-read LCD and seamless integration with PCs and control systems enable operators to promptly detect and respond to pressure deviations, preventing potential damage to chromatography columns and ensuring consistent separation quality. The availability of a high-resolution model tailored for low-pressure applications enables sensitive monitoring where even minor pressure changes can impact performance. User-configurable upper and lower pressure limits provide critical safeguards against pressure excursions, enhancing process reliability.



Additionally, accessories such as the handheld PressureMAT DPG Sensor Reader and PC Data Acquisition Software enhance flexibility in data management and facilitate thorough process analysis, helping to optimize chromatography workflows and maintain product integrity.



Pendotech's Single-Use Pressure Sensors, combined with the PressureMAT Sensor Transmitter, provide optimized pressure monitoring specifically for chromatography processes in biopharmaceutical manufacturing. This integrated solution ensures precise pressure control within chromatography systems, helping to maintain consistent flow rates, protect chromatography columns from pressure surges, and improve separation performance. By enabling tight process control and early detection of pressure anomalies, they reduce errors and safeguard product yield. Their design also supports simplified compliance with regulatory requirements, making them highly effective for single-use chromatography applications.

Conclusion

Chromatographic methods are essential tools in biopharmaceutical manufacturing. Achieving optimal separation results depends heavily on precise control of pH and pressure during the process, which directly impact separation efficiency, product purity and yield, and overall process reliability. METTLER TOLEDO Pendotech's advanced single-use sensors and transmitters provide high-precision, real-time monitoring of these vital parameters. Their innovative design supports seamless integration into bioprocess workflows, enhances operational efficiency, and helps maintain stringent regulatory compliance. By delivering consistent and reliable measurements, these technologies contribute significantly to safeguarding product quality and improving control throughout biopharmaceutical production processes.

References

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