

Peptide Bioprocessing Purification

Using Advanced Flow and Pressure Sensors

Advancements in bioprocessing prioritize developing scalable and efficient production methods to meet the growing global demand for biologically derived therapeutics. By employing synthesis techniques that replicate natural cellular processes, complex peptides with essential modifications can be produced effectively. Ensuring sterility and compliance depends on precise control of filtration parameters such as pressure and flow, which safeguard product quality and minimize contamination risks. High-precision monitoring instruments improve process reliability, reduce contamination threats, and facilitate adherence to regulatory standards in biopharmaceutical manufacturing.

Background

Bioprocessing evolves to meet the urgent need for efficient and cost-effective production methods capable of addressing the growing global demand for biopharmaceuticals. The core objective of bioprocess development is to facilitate large-scale manufacturing that can effectively address this increasing demand, especially in light of the rising prevalence of infectious diseases worldwide. Biological peptide synthesis is a pivotal component in this landscape, involving the biosynthesis of peptides within living cells that closely mimic natural processes. This method offers several significant advantages, including the ability to produce complex peptides with essential post-translational modifications, scalability suitable for industrial-scale production, and enhanced sustainability and cost efficiency. Consequently, biological peptide synthesis is widely adopted in pharmaceutical and biotechnology sectors for the manufacture of therapeutic peptides, research reagents, and vaccine constituents. It is particularly valuable for synthesizing peptides that are challenging to produce through chemical synthesis or that require specific biological modifications.





Process

The biopharmaceutical manufacturing process consists of upstream and downstream stages. Upstream involves growing cells from small flasks to large bioreactors. Downstream includes purification steps like cell harvesting, filtration, chromatography, viral inactivation, and final formulation¹.

Sterile filtration plays a crucial role in this process by removing microbial contaminants to ensure product safety and regulatory compliance before aseptic packaging. It maintains the quality and efficacy of protein and peptide therapeutics by using membrane filters with pore sizes of 0.22 microns or smaller to effectively eliminate microorganisms such as bacteria and yeast, thereby protecting sensitive products throughout processing^{2,3}.

Challenges

To achieve optimal sterile filtration performance and maintain appropriate flow rates, it is essential to manage several critical factors carefully. Continuous monitoring of flow rate and pressure is crucial, as excessive pressure risks damaging the filter membrane and allowing contaminants to penetrate, while low pressure could indicate clogging, reducing filtration effectiveness. Incorrect flow rates can lead to incomplete microbial removal or longer processing times, and pressure spikes risk leaks that introduce contaminants or damage sensitive biologics. Lack of proper monitoring undermines process validation, risking regulatory non-compliance and costly batch recalls. Operating outside recommended pressure limits shortens filter life, increasing costs, and pressure buildup can pose safety

hazards to equipment and personnel. Best practices include using pressure gauges and flow sensors with alarm thresholds, regular integrity testing, and thorough data logging to ensure precise control throughout sterile filtration^{2,3}.

Solutions by METTLER TOLEDO

Single-Use Flow Meter Sensor

Flow meters play a crucial role in numerous purification processes by delivering highly accurate flow measurements with a precision of 1%. METTLER TOLEDO Pendotech sensors are available as singleuse components to reduce the risk of cross-contamination or as reusable units. Their design, which lacks moving parts, prevents particle generation, making them ideal for environments where maintaining cleanliness is essential. Furthermore, the incorporation of DSP technology enhances bubble resistance. These flow meters integrate seamlessly with OEM equipment, providing ease of use for various organizations. The materials in single-use sensors are made from biocompatible, gamma-sterilizable polypropylene (PP) that meets FDA, USP-VI, BSE/TSE standards, and animal-free certifications.



Single-Use Pressure Sensor

METTLER TOLEDO Pendotech Single-Use Pressure Sensors incorporate cutting-edge bioprocessing technology. Equipped with High Accuracy Pressure (MEMS-HAP™) chips, these sensors deliver precise measurements of both static and dynamic pressure for gases and liquids. They connect effortlessly to monitors through an integrated connector and are fully compatible with our PressureMAT™ and PressureMAT PLUS monitor/transmitters. as well as the DIN rail mount PTR Pressure Transmitter. With an operational range from -11.5 to 75 psi (-0.79 to 5.2 bar) and accuracy specifications spanning -10 to 60 psi (-0.69 to 4.14 bar), these sensors are an excellent solution for organizations aiming to enhance their bioprocessing workflows using advanced technology.





Conclusion

To ensure optimal performance and reliability in bioprocessing, integrating advanced flow and pressure sensors into sterile filtration systems is highly beneficial. These sensors offer precise real-time monitoring, allowing for meticulous control of essential parameters like pressure and flow rate, which are crucial for preserving product purity, preventing membrane damage, and minimizing contamination risks. Employing high-accuracy instruments improves process efficiency and safety, supports regulatory compliance, and helps reduce the likelihood of costly batch failures. Adopting this technology is vital for organizations striving for robust, scalable, and consistent biopharmaceutical manufacturing.

References:

- 1. <u>Bioactive Peptides: Synthesis, Sources, Applications, and Proposed Mechanisms of Action</u>
- Mastering Sterile Filtration: Essential Guide for Bioburden Control in Cell Culture and Downstream Processing - Loyal
- 3. Sterile Filtration and Bioburden Control for the Processing of Biologics

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