**FOR IMMEDIATE RELEASE**

**Pfanstiehl LLC Announces the Launch of Glucose (Dextrose) - High Purity Low Endotoxin Low Metals for Upstream Biologic Production**

**Waukegan, IL — October 23, 2024** — Pfanstiehl, Inc., a leading global provider of high-quality, injectable excipients, specialty cGMP bioprocessing components, and active pharmaceutical ingredients (APIs), is excited to announce the launch of its new **High Purity Low Endotoxin Low Metals Glucose (Dextrose)** product (CAS 50-99-7), developed specifically for upstream biologic production in commercial biopharmaceutical manufacturing. This new product ensures the highest quality, consistency, and safety, supporting critical protein production processes with unmatched reliability.

**Why High Purity, Low Endotoxin, and Low Metals Matter in Upstream Biologic Production**

In biologic protein production, especially at the commercial scale, the quality and purity of materials used in the upstream process can significantly impact the final product's efficacy, safety, and regulatory compliance. Contaminants like endotoxins or trace metals can introduce major challenges, including reduced product yield, impaired protein function, and increased risk to patient safety.

- **High Purity**: Pfanstiehl's glucose is of the highest compendial grade, ensuring that it contains no impurities that could interfere with metabolic pathways or negatively affect protein expression. This purity reduces the likelihood of unwanted metabolic byproducts, enhancing overall process efficiency.
- **Low Endotoxin**: Endotoxins can have a detrimental effect on production cell line health. High endotoxin levels can lead to stress responses in cells, reducing their viability and impairing their ability to efficiently produce proteins. This can result in lower protein yields and a decline in protein quality, which can compromise the effectiveness of the final biologic product. Pfanstiehl's High Purity Low Endotoxin Low Metals Glucose minimizes these risks, ensuring a healthier cell culture environment that supports robust protein production, while also meeting stringent regulatory requirements for endotoxin levels.
- **Low Trace Metals**: Even small amounts of trace metals can alter cell metabolism, lead to oxidative stress, and interfere with protein folding or post-translational modifications. Pfanstiehl's High Purity Low Endotoxin Low Metals Glucose helps to avoid such issues by keeping trace metal concentrations below critical thresholds, contributing to higher

product yields and ensuring that the quality of biologic proteins is maintained from batch to batch.

**The Essential Role of Glucose in Biologic Production**

Glucose is a vital component in upstream biologic production, serving multiple functions to support cell growth, protein synthesis, and overall productivity. Key roles include:

- **Primary Energy Source**: Through glycolysis, glucose is metabolized into pyruvate, producing ATP and NADH. These molecules are essential for cellular energy supply, driving protein synthesis and maintaining cell viability.
- **Carbon Source for Biosynthesis**: Glucose provides carbon skeletons for the synthesis of amino acids, nucleotides, lipids, and other biomolecules that are critical for cell growth and protein expression.
- **Regulation of Protein Expression and Post-Translational Modifications**: Adequate glucose levels influence gene expression and modulate metabolic pathways that determine the yield and quality of the target protein. It also affects glycosylation patterns, which are important for the activity and stability of many biologics.

**Optimizing Upstream Bioprocesses**

Pfanstiehl's High Purity Low Endotoxin Low Metals Glucose is designed for use in fed-batch and other controlled feeding strategies, ensuring optimal nutrient supply without leading to byproduct accumulation, such as lactate or acetate, which can inhibit cell growth and productivity. Key benefits include:

- **Consistency and Reliability**: The glucose is produced under strict ICH-Q7 cGMP conditions in the United States, adhering to the highest compendial standards (USP, EP, BP, JP, ChP), ensuring batch-to-batch consistency, a critical factor in biopharmaceutical manufacturing.
- **Customization of Culture Conditions**: By adjusting glucose levels in feed strategies, production conditions can be tailored to maximize protein yield, minimize metabolic stress, and enhance product quality.
- **pH and Osmotic Stabilization**: Glucose helps stabilize pH levels in culture media and maintain osmotic balance, contributing to a stable environment for optimal cell growth and protein production.

**Why Choose Pfanstiehl's Glucose for Your Upstream Biologic Production?**

Pfanstiehl's High Purity Low Endotoxin Low Metals Glucose (Dextrose) offers unmatched quality and performance for upstream biologic feed applications. With stringent production processes and adherence to global pharmacopeial standards, this multicompendial glucose ensures the highest level of safety, purity, and consistency in biopharmaceutical manufacturing. It is specifically tailored for companies looking to optimize their bioprocesses, ensuring both high yield and product quality in therapeutic protein production.

Pfanstiehl's High Purity Low Endotoxin Low Metals Glucose (Dextrose) cGMP is available now for biopharmaceutical and research applications. For more information, visit Pfanstiehl.com/en/

## About Pfanstiehl, Inc.

Pfanstiehl, Inc. is a leading manufacturer and supplier of High Purity, Low Endotoxin, Low Metals (HPLE-LM™), injectable grade excipients, critical cGMP bioprocessing components and APIs for the global biopharmaceutical and pharmaceutical industries. For over 100 years, Pfanstiehl has delivered high-quality biologic building blocks and exceptional service, ensuring the success of life-saving and life-enhancing therapeutics worldwide.

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