

Pfanstiehl Launches New cGMP Histidine and Histidine HCl

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Pfanstiehl Launches New cGMP-produced, Parenteral Grade Histidine and Histidine HCl For Biopharmaceutical Formulations



Following a record 100th year in business, Pfanstiehl has launched high purity, low endotoxin, low metal L-Histidine and L-Histidine Hydrochloride Monohydrate and established a new quality standard for amino acids.

Amino acids are critical components utilized in bioprocessing for both upstream and downstream applications. With the ever-increasing regulatory requirements placed on bioprocessing components, there is a drive towards using higher-quality products when available. Availability of high-quality amino acids for the biopharma market has been a challenge, which is why many customers enlisted Pfanstiehl to help develop a better alternative.

Pfanstiehl's new L-Histidine High Purity / Low Endotoxin-Low Metals-USP, EP, JP, ChP (H-116) and L-Histidine Hydrochloride Monohydrate, High Purity / Low Endotoxin-Low Metals, EP, JP, ChP (H-117) products have market leading specifications which show a tight control of endotoxin and trace metal impurities reflected with Elemental Impurity Data in parts per billion on their specifications. These products are suitable for bioprocessing, solubilization and stabilization applications.

"Pfanstiehl's amino acid specifications exceed regulatory requirements and reflect our leadership in setting high quality industry standards for the biopharma market" – Hemasunder Reddy, Director of Business Development APAC

As a US-based manufacturer, Pfanstiehl's Quality Systems are based on ICH Q7 "Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients" guidelines. Pfanstiehl has Drug Master Files in process for these products.

Prior to launching any new product, Pfanstiehl completes full product characterization while validation is done at full scale. Pfanstiehl offers complimentary product characterization data to their customers, understanding the criticality of such information. This shows their commitment to customers' success, as they deliver world-class levels of quality and consistency.

Commercial material and samples for both Histidine products are now available for customer qualification and manufacturing, along with product profiles and regulatory documentation.

In everything they do, Pfanstiehl is motivated by a concern for both product quality and commitment to their valued customers.