



March 1, 2023

Subject: Detrex Food and Drug Guarantee Statement

To whom it may concern,

Detrex Chemical produces bulk hydrochloric acid at their Ashtabula, OH facility in accordance with the applicable requirements of 21 CFR § 10 and §211 for drug grade and 21 CFR §117 for food grade. These regulations are known at the U.S. Food and Drug Administration's (FDA) Good Manufacturing Practices for Human Drugs and Human Food respectively. Our food grade hydrochloric acid operations are conducted in accordance with a hazard-based food safety plan we have developed, implemented, and managed under the guidance of certified Preventive Control Qualified Individual(s) (PCQI).

Since Detrex hydrochloric acid products can be, and are, used as both drug and food products our manufacturing and compliance programs integrate all aspects of both drug and food grade regulations.

This means the bulk hydrochloric acid we produce at Ashtabula, OH meets or exceeds all United States Pharmacopeia (USP) and Food Chemical Codex (FCC) specifications for drug grade and food grade hydrochloric acid. Each batch of finished hydrochloric acid we produce is analyzed by our on-site laboratory staff to confirm that batch meets or exceeds all applicable USP / NF analytical requirements. This analytical work is performed prior to release of any product for distribution. In addition, periodically we utilize the services of a third-party laboratory to independently confirm our internal analytical results.

Our Ashtabula, OH site is registered with the U.S. Food and Drug Administration as a human food production site and as a human drug manufacturing facility. Detrex Chemical maintains all appropriate production, analytical, and distribution documentation as required by the applicable FDA regulations for both grades of product.

This document is our product guarantee that Detrex Chemical shall only provide hydrochloric acid from our Ashtabula, OH production facility to those customers requesting either drug or food grade which meets or exceeds the applicable USP or NF specifications for drug or food grade hydrochloric acid products. Additionally, all our drug and food grade hydrochloric acid products are manufactured in compliance with the applicable FDA regulations for human drug and human food products.

Sincerely,

Dave Morgan  
Global Product Manager, Hydrochloric Acid  
Detrex Chemicals