

March 1, 2023

Subject: Conformance to Good Manufacturing Practices for Drugs and Foods

To whom it may concern,

The Detrex Corporation hereby affirms that the production facilities, manufacturing methods, quality systems and preventive controls, and analytical methods used to manufacture, store, package, label, and analyze our Hydrochloric Acid products conform to the following United States Food and Drug Administration regulatory requirements.

- Title 21, Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs: General
- Title 21, Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals
- Title 21 Part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Additionally, Detrex Hydrochloric Acid products are continuously analyzed for conformance to key global analytical monograph requirements. The Detrex Ashtabula facility uses a variety of sophisticated analytical techniques, which are validated and qualified to demonstrate they are equal or superior to official analytical monograph requirements. Detrex products meet or exceed the requirements stated in the following product monographs;

- United States Pharmacopeia monograph for Hydrochloric Acid NF
- United States Pharmacopeia monograph Food Chemical Codex monograph for Food Grade Hydrochloric Acid
- European Pharmacopeia monograph for Hydrochloric Acid (concentrated)
- Japanese Pharmacopeia monograph for Hydrochloric Acid

Sincerely,

Dave Morgan

Global Product Manager, High Purity Hydrochloric Acid

**Detrex Chemicals** 

