Detrex®
CHEMICALS DIVISION

February 18, 2021

Subject: Detrex Good Manufacturing Practice Compliance Statement

To whom it may concern,

Detrex drug grade HCl meets or exceeds the analytical monograph specifications of the United States Pharmacopeia (USP), the European Pharmacopeia (EP), and the U.S. Food Chemical Codex. Each of these analytical monographs contain specifications and limits for Organic and Inorganic impurities, as well as Residual Solvents. These drug monographs serve as the impurity profile for our HCl product. Each batch of Detrex drug grade HCl is tested to ensure conformance to these requirements and limits.

Detrex HCl products are manufactured, stored, packed, and tested in conformance with FDA and EU (current) Good Manufacturing Practices applicable to our business, products, and facilities. Our Ashtabula, OH production facility is FDA registered and inspected site. Detrex HCl operations conform to the GMP guidance in the ICH Publication Q7 – Good Manufacturing Practice for Active Pharmaceutical Ingredients in producing our HCl products, and we conform to the regulatory requirements in 21 CFR part 211 for the storage, testing, and packaging of our HCL products. Our state-of-the-art water purification system used to produce our HCl products meets all applicable USP requirements for purified water systems.

Sincerely,

Dave Morgan
Global Product Manager, Hydrochloric Acid
Detrex Chemicals

1000 Belt Line Street / Cleveland, Ohio 44109
PHONE: 216.749.2605 / (800) 321.0467 / FAX: 216.749.7462
www.detrexchemicals.com

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