



September 9, 2019

Subject: Detrex Impurity Profile Statement

To whom it may concern,

According to the *International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use* (ICH) guideline Q3A drug substances such as the HCl manufactured by Detrex should contain specifications for 1) Organic Impurities, 2) Residual Solvents, and 3) Inorganic Impurities.

Detrex Chemicals' drug grade hydrochloric acid meets the analytical specifications of the United States Pharmacopeia (USP), the European Pharmacopeia (EP), the British Pharmacopeia (BP), the India Pharmacopeia (IP), the Japanese Pharmacopeia (JP), the Chinese Pharmacopeia (ChP) and the U.S. Food Chemical Codex specification. 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 hydrochloric acid products. Each batch of Detrex drug grade hydrochloric acid is tested to ensure conformance to these requirements and limits.

Sincerely,

A handwritten signature in black ink that reads "Dave Morgan". The signature is fluid and cursive, with the first name "Dave" and last name "Morgan" clearly distinguishable.

Dave Morgan
Global Product Manager, Hydrochloric Acid
Detrex Chemicals