



August 1, 2017

Subject: 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) and the Food Chemical Codex requirements in the U.S. 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 Chemicals drug grade hydrochloric acid is tested to ensure it conforms to these requirements and limits.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jim Vence", with a large, stylized flourish at the end.

Jim Vence
Technical Director
Detrex Chemicals