



August 1, 2017

Subject: Elemental Impurities Statement

To whom it may concern,

Elemental impurities in drug products may arise from several sources; they may be added intentionally in synthesis, or may be present as contaminants (e.g., through interactions with processing equipment or by being present in components of the drug product) and are consequently detectable in the drug product. Since elemental impurities do not provide any therapeutic benefit to the patient, element impurity levels should be controlled within acceptable limits in the drug product. In accordance with *International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use* (ICH) guideline Q3D, the elemental impurities of concern are heavy metals.

Detrex Chemicals Hydrochloric Acid products are made using the hydrochloric acid direct synthesis process. In this manufacturing process, Detrex Chemicals only uses high purity Hydrogen and Chlorine, and water, which we purify on-site, to produce Hydrochloric Acid. The hydrochloric acid product from our process is chemically pure, with very few trace contaminants, especially any elemental impurities.

Detrex Chemicals does not utilize any metal catalysts in the production of our Hydrochloric Acid products, such as palladium. Heavy metals, such as lead, mercury, cadmium, and hexavalent chromium are not intentionally added during any of our manufacturing, storage, or packaging processes, and are not present in any of the processing equipment or packaging materials.

The United States Pharmacopeia (USP), the National Formulary (NF), and the Food Chemical Codex (FCC) all set a limit of 5 parts per million (PPM) for metals in Hydrochloric Acid. Detrex routinely conducts analysis of their products for metals using advanced analytical processes and equipment, such as ICP Mass Spectrometry as an on-going verification our product meets or exceeds the USP / NF / FCC specification for metals.

Sincerely,

A blue ink handwritten signature, appearing to read "Jim Vence", is written over the word "Sincerely,".

Jim Vence  
Technical Director  
Detrex Chemicals