



February 18, 2021

Subject: Detrex 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 a direct synthesis process. In this manufacturing process, Detrex only uses high purity hydrogen, chlorine and water. We purify our water on-site with a high purity DI water system. The hydrochloric acid product from our process is chemically pure, with very few trace contaminants, especially all elemental impurities.

Detrex does not utilize any metal catalysts in the production of their 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 handwritten signature in black ink that reads "Dave Morgan". The signature is written in a cursive style with a large, looped initial "D".

Dave Morgan
Global Product Manager, Hydrochloric Acid
Detrex Chemicals