

January 2023

## **ELEMENTAL IMPURITIES USP & EP - MALTRIN<sup>®</sup> NF Products**


United States Pharmacopeia (USP) replaced the Heavy Metals procedure in General Chapter <231> with the new General Chapters <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures. European Pharmacopeia deleted chapter 2.4.8 Heavy Metals from individual monographs and implemented chapter 5.20- Elemental Impurities and chapter 2.4.20 – Determination of Elemental Impurities to align with the guidelines and principles of ICH Q3D. Grain Processing Corporation (GPC) does not knowingly add or create elemental impurities in the manufacturing process of MALTRIN<sup>®</sup> maltodextrin and corn syrup solids products.

Testing has been completed on random lots on a yearly basis. The data from the historical testing indicates the following elemental impurities have not been detected in the finished products: arsenic, cadmium, lead, mercury, chromium, molybdenum, nickel, cobalt, copper, iron, zinc, and aluminum. The compliance statement above regarding the US and European Pharmacopeia Elemental Impurities will be based on knowledge of the manufacturing process and supported by the data obtained from the annual random finished product testing.

Metal catalysts or reagents are not used in the manufacturing process; therefore, the following elemental impurities should not be present: iridium, osmium, palladium, platinum, rhodium, and vanadium. Although no metal catalysts or reagents are used, these impurities have been added to the annual testing protocol for verification. The additional impurities listed above have not been detected.

Please do not hesitate to contact GPC, if additional information or clarification is required.

Kind Regards,



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This document is valid for one year from the date of issue.