

## **Manganese Contamination in Neonatal Parenteral Nutrition**

**Performer:** Neonatal Research Institute

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**Project Duration:** 9/15/18 – 9/14/21

### **Regulatory Science Challenge**

Parenteral nutrition (PN) (administration of nutrition through a vein) has become standard and essential to the care of preterm neonates in the neonatal intensive care unit (NICU). Health benefits of PN include positive nitrogen balance, weight gain, and reduced neurodevelopmental impairment. However, the daily provision of PN to pre-term neonates involves numerous safety risks. Among these risks are side effects from ingredient formulations not ideally suited for this vulnerable population. The trace element manganese is one example. Manganese is added to PN, but manganese is also present in other PN ingredients. So, the amount of manganese given to pre-term neonates receiving PN can far exceed the amount that would be consumed through breastmilk.<sup>i</sup>

### **Project Description**

This project will evaluate the sources of manganese in approved products used to prepare neonatal PN. These sources of manganese will be identified by testing a variety of PN components. The second part of the project will determine whether preventing potential harm from PN manganese overexposure can be done reliably and safely through creative product selection during the PN compounding process.

### **Project Goals**

The specific goals for this project are to:

- Quantify manganese in commercially available ingredients commonly used to prepare neonatal PN.
- Design neonatal PN formulations capable of providing recommended daily trace element intakes using a “no manganese added” strategy. That is, the manganese present will be from PN components not specifically intended to contain manganese.
- Evaluate the safety of a PN with no added manganese compared to standard PN in hospitalized premature neonates  $\leq 32$  weeks gestational age using whole blood manganese monitoring.

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<sup>i</sup> Aschner JL, Aschner M. Nutritional Aspects of Manganese Homeostasis. *Mol Aspects Med.* 2005;26(4-5):353-62.