



As your Active Pharmaceutical Ingredient (API) supplier, Mallinckrodt is dedicated to your complete satisfaction with everything we do. Our promise to customers is reflected in our four core values: quality, performance, supply continuity and customer service. When you choose Mallinckrodt for your APIs, you get the peace of mind that comes from working with a trusted source. We want you to expect more – in fact, we insist on it.

Quality Update: Technological Strategy for Microscopic Foreign Matter Control

Mallinckrodt has developed a three-pronged process to help eliminate trace amounts of foreign matter from our products. Our scientists and engineers examined every step of the production process to prevent and remove trace metal that can come from processing equipment. This additional effort in our quality process significantly reduces trace metal.

Prevention

- Reducing trace metal has yielded the greatest measurable improvement since we implemented these new controls. Our Failure Mode and Effect Analysis (FMEA) assessments utilize innovative tools designed to identify potential sources of foreign matter. The FMEA process incorporates the input and involvement of our manufacturing operators to fully review and assess the operation, asking the question, “What could go wrong?” By seeking to answer that question before problems occur, we have identified and eliminated a number of potential trace metal sources.

Detection

- As part of our comprehensive control process, prevention measures are augmented by highly refined detection methods. We have expanded the use of metal detection systems in both our Greenville, Illinois, and Raleigh, North Carolina, manufacturing facilities. These state-of-the-art systems are strategically located to provide the maximum protection. These systems have extremely high sensitivity for bulk powder manufacturing operations, have been validated and proper operation is routinely verified and documented.

Removal

- In the rare instances when foreign matter is detected, our enhanced magnet systems remove rogue metallic particles during the manufacturing process. We carefully monitor these magnets to better understand where trace metals occur and how to prevent future incidents. Every kilogram of API from our facilities passes through these magnets prior to release to ensure you receive the highest quality products.

We are committed to continuous improvement to deliver products that meet or exceed the highest international standards. We look forward to servicing your business as your supplier of choice.