

Summary - Metal Detection

The decision on whether routine metal detection operations are required for products at their Site should be based on, and not limited to, the following factors:

- Product history of metal contamination incidents (e.g., equipment failures, equipment metal-to-metal contact causing contamination, raw materials with metal contaminants);
- Assessment of manufacturing and/or packaging processes involved in terms of possible metal contamination
- Effectiveness of the metal prevention systems and processes used at the site; and
- Commitments to Regulatory Authorities.

Action Levels for the total number of units (e.g., tablets, capsules, bottles) isolated by the metal detector should be developed by the quality based on the historical data on the number of units contaminated with metal according to product and/or manufacturing or packaging process step.

The Metal Detector should be positioned such that the detector does not interfere with the process and the detector is not in contact with adjacent manufacturing or packaging equipment. Any chutes or conveyors passing through detectors should be aligned to not interfere with reject gate operation.

All Metal Detectors used in Packaging Operations should be qualified and subsequently set-up and operated such that the detectors will, 100 percent of the time, detect and isolate spherical 1.0mm ferrous, spherical 1.0mm non-ferrous, and spherical 1.5mm stainless steel metal embedded in discs or cylinder carriers that are used to challenge the system.

Product Units (e.g., Tablets, Capsules, Packaged Units) that are isolated by the metal detector reject mechanism should not be returned to the acceptable units of the lot unless an investigation reveals an assignable cause associated with the metal detector. Product units that are isolated by the metal detector during re-inspection should be rejected and not returned to the acceptable units.

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