



# Preventing Metal Contamination

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**Using metal detectors in the packaging process can help ensure product quality by locating and rejecting contaminated products.**

**E**ach year metal contamination prompts warning letters and recalls of pharmaceutical products. This problem can be minimized through the use of metal detectors at critical points in the pharmaceutical and packaging process.

Today's highly sensitive units not only can detect minute particles of ferrous and nonferrous metals as well as nonmagnetic stainless steel, but also can locate contaminants in products packaged in foil or metallized film.

Metal contaminants are classified as ferrous (magnetic), nonferrous (highly conductive nonmagnetic metals such as copper, aluminum, and brass), and nonmagnetic stainless steel. Ferrous contaminants are the easiest to detect and 300 series stainless steel contaminants (such as those commonly used in pharmaceu-

tical processing and packaging machinery) are the most difficult to locate because the material is not particularly conductive or magnetic.

## Characteristics of metal detectors

A metal detector features an aperture, or tunnel, through which the product passes and a user interface-control system, which generally is housed separately but may be integrated in some models. Typical designs configure the unit around a conveyor or a pipe carrying a product or ingredient. The aperture is sealed to protect the components inside and is lined with a nonmetallic material. Within the aperture, a transmitter coil emits a radio frequency signal and generates an electromagnetic field. Receiver coils on either side of the unit detect disturbances in the field caused by magnetic or electrically conductive material. This configuration often is described as a "balanced coil" system.

The size, shape, and orientation of the particle and type of material determine the strength of the signal. Ferrous contaminants generate the strongest signal, followed by nonferrous and nonmagnetic

stainless steel. Spherical particles are the easiest contaminants to identify. Wire-shaped contaminants can be extremely difficult to detect because the signal varies depending on the orientation of the metal piece. Many units today can detect contaminants as small as 1 mm.

Detection becomes complicated when the product creates a magnetic or conductive signal for which the unit must compensate. As a result, products typically are classified as *dry* (nonconductive) or *wet* (conductive) and units are designed for automatic calibration, which is sometimes called *phasing*, to differentiate between signals generated by the product and any contaminants. Wet products are more challenging to scan than dry products.

A unit capable of detecting a 1-mm ferrous or nonferrous metal fragment in a dry product can not perform at the same standard when checking a wet product. To generate the same signal strength in a wet product, a ferrous contaminant would have to measure 1.5 mm, a nonferrous fragment would have to measure ~ 2 mm, and stainless steel might not be detectable at sizes smaller than 2.5 mm.

In addition to product effect, contaminant size, and orientation, metal detector sensitivity is influenced by the metal-free area surrounding the detector and the unit's aperture size. In general, unit sensitivity is proportional to the size of the aperture (i.e., a small size indicates higher sensitivity). A unit with a 50-mm-high aperture can locate ferrous and nonferrous contaminants in dry products as small as 1 mm, but a 200-mm-high aperture will limit sensitivity to a 2-mm fragment.

However, there are exceptions to this rule. More-challenging applications such as metallized film packaging, packages with iron oxide-based oxygen scavengers, and highly conductive products may be examined more effectively by units with larger aperture openings.

Metal detectors tend to be most sensitive at the edges of the aperture and least sensitive at the center. As a result, system challenges should be conducted with the product passing through the geometric center of the aperture. Testing protocols should be documented in standard operating pro-

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### Many metal detectors today can detect contaminants as small as 1 mm.

cedures (SOPs) and should mirror production conditions. Recommended test frequency is once every hour at least and at shift starts and product changeovers as well as after the repair, maintenance, adjustment, or relocation of a unit. For proper testing, contaminants should be placed in a fresh, contaminant-free product because an older product may not exhibit the same properties. Many metal detector suppliers provide contaminant samples of a specific size and composition for use in testing programs.

SOPs also should outline what happens when a product is rejected by the metal detector, which usually involves confirming that a metal contaminant is present, identifying the contaminant and locating it, and correcting the cause.

#### Various types of detectors

Several metal detectors are designed specifically for the examination of tablets and capsules. These detectors typically are positioned to check product either pre- or postfilling, but sometimes a unit is installed to inspect the product before filling and another unit is used to double check filled containers. In some cases, metal detectors may be integrated with checkweighers to provide another quality-control function.

Metal detectors designed to be integrated with tablet presses and dedusters are built to the strict hygiene standards of the pharmaceutical industry. These designs can detect very small particles of metal, including stainless steel-sieve wire and metal flakes from the punch and die sets of tablet presses.

One such detector (Safeline PharmX, Safeline Metal Detection, Tampa, FL) has a detection head mounted on three axes to easily adjust to the tablet press outlet without tools. Product contact parts are constructed from mirror-polished stainless steel and food-grade plastic and

quickly disassemble for cleaning. A variety of aperture sizes and reject mechanisms accommodate a wide range of pill sizes and help provide throughput rates <10,000 tablets/min. A reject confirmation feature alerts the operator if a contaminated product is not ejected. Should the power fail, the diverter automatically switches to reject mode to ensure no off-spec product slips by. Finally, validation software notifies operators when testing should be performed, and a self-check capability provides a warning if sensitivity drifts outside set parameters.

Another metal detector designed specifically to check tablets (Phantom Pharmaceutical Metal Detector, Fortress Technology Inc., Scarborough, ON) offers full validation documentation and can run multiple search heads from a single microprocessor

controller. This controller interfaces with other equipment, accommodates data logging, and holds product readings in memory for quick setup. An automatic on-the-fly or one-button “learn” function compensates for readings generated by the product itself and simplifies changeover and a digital signal processor delivers the highest level of sensitivity.



**Figure 1:** E-Z Tec Pharmaceutical Metal Detector from Eriez.

**Figure 2:** Goring Kerr DSP IP metal detector from Thermo Goring Kerr.



### Today's highly sensitive units can even locate contaminants in products packaged in foil or metallized film.

A failsafe reject mechanism and easily dismantled product chute and reject device characterize another metal detector that is capable of checking <10,000 tablets/min (Loma Pharmaceutical System, Loma Systems, Carol Stream, IL). The unit may be ordered with 100 × 20 mm or 100 × 38 mm apertures.

Another tablet–capsule detector has an expedited start-up feature that allows operators to pass through and test sample product and begin production in less than five minutes (E-Z Tec Pharmaceutical Metal Detector, Eriez, Erie, PA). Start-up efficiency also is supported by an easy-clean chute to speed changeovers and the position of the detector's head, which is fixed at a slope of 30° to eliminate lengthy timing adjustments of downstream reject equipment (see Figure 1).

A metal detector capable of withstanding high-pressure washdown conditions (Goring Kerr DSP IP, Thermo Goring Kerr, Minneapolis, MN) is watertight against jets of 80 °C at 1450 psi. The detector's design eliminates the most water-sensitive areas of standard detectors, which usually must be covered during washdown and then cleaned separately by hand. Water-resistant features include an etched steel-membrane keyboard and an integrated detector head and control box. In addition, flanged seals are designed to deflect the water. Integrating the power supply and input–output into the detection head not only eliminates the need for a control box and attendant wiring between the two, but also results in a more compact unit (see Figure 2).

Locating ferrous contaminants in foil packaging is possible with some units, which actually magnetize the contaminant

to enable identification. One such metal detector can automatically adjust sensitivity to accommodate production variations and eliminate false rejects (Autosearch II Plus Ferrossearch, Cintex of America Inc., Kenosha, WI). The machine also can automatically recalibrate for new products to reduce changeover and setup time. The Management Information Control System makes the equipment networkable and records production data for validation and other purposes. An integral Autocheck system continuously monitors all electronic circuits and provides diagnostic information if a fault occurs or sensitivity deviates outside fixed parameters. A battery backup protects stored data.

New custom-designed, Windows CE–based software enables Lock MET 30+ metal detectors (21 CFR Part 11 Pharmaceutical Metal Detection System, Lock Inspection Systems Inc., Fitchburg, MA) to meet 21 CFR Part 11 requirements and provides full batch traceability. The software includes security access controls, user identification, and audit trails. The data can be accessed by a remote personal computer (PC) or a PC panel integrated into the metal detector itself. The latter replaces the standard operator interface so that 21 CFR Part 11 compliance, tests, diagnostics, and equipment setup and operation are handled from one location. The remote PC configuration accommodates operations with multiple metal detectors (see Figure 3).

#### X-ray inspection systems

Although the installation of a metal detector is a well-established method to identify and reject metal contamination, it is not the only way to accomplish quality control. X-ray inspection systems can identify metal contamination and fragments of materials such as glass or rubber. X-ray systems also can check product



**Figure 3:** Lock MET 30+ metal detector from Lock Inspection Systems, Inc.

count, product size, product mass, container fill level, product–package condition, and package insert presence. Some metal detector suppliers offer this type of equipment also. **PT**

#### FYI

##### Pharmaceutical sciences web portal

The American Association of Pharmaceutical Scientists (AAPS) has launched a web portal, AAPS Pharmaceutica ([www.aapspharmaceutica.com](http://www.aapspharmaceutica.com)).

The project is the result of more than 18 months of study and design with input from the AAPS Portal Task Force. The web portal features additional functionality and content in addition to the member directory, information on AAPS meetings, a press room, career network, and daily pharmaceutical news. Late this summer members can look forward to new e-commerce capabilities for faster registration, membership renewals, and purchases.

AAPS is a professional, scientific society of more than 11,000 members.