

Health and Beauty

Checkweighing, Metal Detection and X-ray Inspection



1 News

GARVENS

Checkweighing

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Metal Detection & X-ray Inspection

X-ray Inspection at Pfizer Pharmaceuticals Ensures Superior Quality

Pfizer Pharmaceuticals, LLC produces both prescription and over-the-counter drugs. Pfizer's state-of-the-art manufacturing facility in Puerto Rico is their largest plant with 800,000 square feet and 13 production lines. Here they rely on METTLER TOLEDO SAFELINE X-ray to ensure their product quality.

Pfizer understand the importance of product quality in protecting their brand and maintaining their reputation for high quality. The Technical Service Specialist, Francisco Collazo, responsible for managing all floor operations, noticed that one of their over-the-counter blister packaging lines had a problem with broken tablets and occasionally crushed or folded blister packs inside the packaging.

Solving the problem

Pfizer turned to METTLER TOLEDO SAFELINE X-ray and chose a PowerChek* x-ray inspection system that not only detects and rejects multiple contaminants, but also verifies product and package integrity. After installing the PowerChek at the

end of the packaging line, they no longer have any problems.

"Since we purchased the SAFELINE PowerChek x-ray system, customer complaints about missing or partial tablets or crunched packages has been eliminated," remarks Collazo.

Tablets are dropped into formed plastic blisters and sent through a vision system that checks that all tablets are present. After the printed foil seals the package, the blister pack goes through a perforator, then are cut into desired pack sizes and dropped into a sorter that can be set into stacks of one, two or four. Running at up to 300 packs per minute, they are then put into the final packaging and through the PowerChek x-ray unit where any packages with



METTLER TOLEDO

broken, damaged or missing tablets or crushed blisters are air-jetted into a separate lockable bin for analysis.

Finding a supplier

“When we were searching for an x-ray system, we turned to METTLER TOLEDO SAFELINE X-ray as they were the only manufacturer that could inspect blister packs stacked up to four deep,” says Collazo. “All other systems would only guarantee two layers.”

The SAFELINE PowerChek x-ray system features superior image processing technology that optimises the performance of the system. With an intuitive operator interface and innovative auto-learn function that automates set-up and makes frequent calibration unnecessary, the PowerChek x-ray system is easy to set-up and operate. Despite Pfizer running 13 – 15 different products on their production line product changeover takes only seconds as the system stores multiple product profiles.

We purchased the SAFELINE PowerChek x-ray two years ago and we have had no problems whatsoever,” says Collazo. “Reliability is fantastic; we are so pleased with the METTLER TOLEDO SAFELINE X-ray system.”

► www.mt.com/safeline-xray

*PowerChek is marketed under the name T10 X-ray Inspection System outside the US.

Outsourced Metal Detector Qualification Reduces Manufacturing Costs

Meeting metal detection equipment validation and qualification demands is critical for pharmaceutical manufacturers. Many companies employ dedicated internal resources to satisfy these needs but there is an alternative solution.

Stricter regulations driven by the FDA, HACCP, GMP and ISO standards continue to provide new challenges for dwindling resources within manufacturing operations. Outsourcing of the initial qualification and re-qualification processes to external specialists can be a cost effective option. METTLER TOLEDO has a team of trained service engineers ready to address this need.

EQ Pac provides the answer

As the equipment manufacturer, METTLER TOLEDO SAFELINE has the in-depth knowledge of how the metal detector works. This expertise has been used to write the qualification SOP’s, relieving manufacturers of this time consuming task.

Qualified engineers from METTLER TOLEDO are able to conduct qualification procedures and complete the necessary documentation quickly and effectively resulting in reduced demands on internal resources, minimised down time and increased plant efficiency.

The EQ Pac package includes:

- Factory acceptance certification (FAT)
- Installation qualification report confirming satisfactory installation
- Operation qualification report confirming satisfactory operation
- Performance qualification report confirming system operation with respect to customer production
- Operator familiarisation training covering basic operation, user settings and maintenance routines

A comprehensive qualification package

Manufacturer URS requirements are matched to the product specification in order to meet the needs of the Design Qualification (DQ) The requirements of the Installation, Operational, Performance and Maintenance Qualification (IQ, OQ,



Easing the strain of validation and qualification

PQ/MQ) are met with fully documented protocols in a comprehensive single binder for each piece of equipment.

Maintaining ongoing performance levels

The initial qualification procedure can be executed by a trained engineer and a performance verification certificate can be issued. Guidance on the frequency of routine testing applicable to the manufacturing processes is included as part of the document package. This is accompanied by a proposal and schedule for continuous performance verification and a system maintenance log.

The ongoing performance of equipment can be verified throughout the life of the equipment using certified test pieces from a test kit which is provided as part of the EQ Package.

Tablex, Tablex 2 and Pharma GF pharmaceutical inspection systems from METTLER TOLEDO SAFELINE are available with EQ Pac.

► www.mt.com/metaldetection



METTLER TOLEDO Helps AstraZeneca Ensure Patient Safety and Regulatory Compliance

Clinical drug trials provide a precisely-calibrated daily dose to participants: too little and the trial data is useless; too much and the patient is in danger. METTLER TOLEDO have worked with AstraZeneca to provide solutions which allow precise measurement of packaged medication.



AstraZeneca production line

The Investigational Products (IPS) group, part of Pharmaceutical and Analytical R&D function located at the AstraZeneca plant in Newark, Delaware, USA, has a bottle-filling line that is utilised for the packaging of clinical trials. Prior to installing the METTLER TOLEDO checkweighers, bottle count verification was performed by visual inspection and by manually weighing in-process samples. This process required a high amount of resources and was affecting the efficiency of the bottle-filling operation.

Accuracy is paramount

“Accuracy is critical in this application,” commented Senior Delivery Technologist David Flynn. “We need to maintain good compliance with the clinical trial, so instead of having 50 or 100 tablets per bottle (as on a normal pharmaceutical filling line), we had just three or four – a patient’s one-day dose. The patient opens the bottle and swallows everything inside. One more or less tablet makes a big difference in this application.”

Patient safety and compliance are a major concern with these fills.

Variability in the weight of these square plastic bottles, which was not normally a significant factor, became an issue because of the precision required on this line. To obtain the required accuracy, the IPS group needed to precisely weigh each bottle they were filling twice.

Providing the solution

METTLER TOLEDO provided the solution by first weighing the empty bottle to establish the tare weight prior to filling. After filling they were then weighed again to establish the gross weight. The two checkweighers communicate with each other so each bottle’s tare weight is deducted from the gross weight, thus eliminating any bottle weight variability in the final weight. This allows precise measurement of the materials packaged inside the bottle. The filling line is capable of speeds of 45 to 50 bottles per minute and the margin of error was less than a quarter of a gram per bottle.

Customised solution

Furthermore, this precision weighing had to take place in a corner of the filling line. Here the checkweigher would have to change the direction of the bottles by 270 degrees, rather than the usual 360 and work in a tight space. The Starweigh checkweighers were customised to make less than a full turn, fit into the two foot-square space available and straddled over the existing conveyor belt so that it was not necessary to cut the line.

“METTLER TOLEDO were the only company that could do this,” Flynn said. “They adapted their checkweigher to our particular application and it took considerable engineering to make it work. They also provided a machine that didn’t require us to change parts



StarWeigh weighing empty bottles

when we changed bottle size. This was a significant factor during product changeovers in reducing downtime and improving efficiency. This feature was also greatly welcomed by the operator.”

Dispelling the Myths of X-ray Unleashing the Potential

When x-ray inspection systems appeared in the pharmaceutical, nutraceutical and food industry about twenty years ago, some thought the days of metal detection could be numbered. But x-ray has not displaced metal detection. Even in the sectors for which it is the more suitable technology, metal detection often reigns. In no small part, argues Nick Bridger, Technical Manager at METTLER TOLEDO SAFELINE X-ray, because its features and benefits simply aren't fully understood.

Compared to the global market for metal detectors, x-ray is undoubtedly smaller. However, x-ray technology is developing quickly and growth has accelerated significantly. The speed and extent of this expansion is dependent on improving the understanding of x-ray, dispelling the myths surrounding it and clarifying its role and suitability for different applications.



X-ray: A new force in quality control

Most people are introduced to x-ray at the dentist, in hospital or at an airport. Used for decades in these environments, it started making inroads into the pharmaceutical, nutraceutical and food industry in the early 1990s. The driving force behind this was the increasing number of foreign bodies like glass, rubber, stone or plastic which could not be identified by traditional inspection methods. A further benefit of x-ray is its ability to carry out other types of inspection, including component counting, the identification of misshapen parts, mass and zoned mass verification, fill level control and seal integrity inspection as well as the detection of the presence of instruction leaflets in for example blister packs.

The role of the metal detector

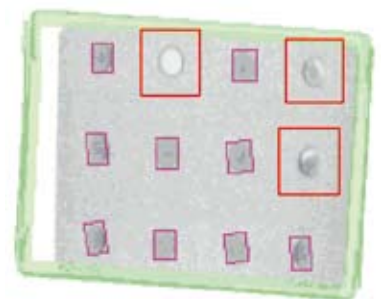
Apart from the cost implication of installing a new inspection system, the main reason behind the enduring prevalence of metal detectors is that, for many manufacturers, they remain an effective “first line of defense”. If there is minimal risk of non-metallic contamination in the product, a metal detector will consistently and accurately identify the most likely foreign bodies – swarf, filings, nuts, bolts, etc. Similarly, due to more rigorous demands from

their customers and legislation, many processors require inspection systems at various points on their production lines.

Often these will be early on, for incoming ingredients; after mixing / immediately prior to primary packing; and just before dispatch.

Fear of the unknown

Some manufacturers, whose processes are suited to x-ray inspection, have concerns over installing new equipment. There is a relatively widespread, although unfounded, perception that x-ray systems are difficult to set up and operate due to far more complex technology. However, x-ray technology is surprisingly simple – the machine looks for objects that are denser than the surrounding product. With a highly intuitive user interface



X-ray image shows a blister pack with one tablet missing and two partially missing

and touch screens, the equipment is also very easy to navigate. The safety of the equipment is also a subject of discussion



Compared to other inspection equipment, x-ray is relatively immune to product effects and similar physical interactions, including:

- The effects of metallised film and foil packaging.
- The presence of metallic items such as premium inserts, pouring spouts, clips, etc.
- The effects of conductivity or polarised molecules.
- Temperature - products can be inspected at temperatures between -20°C and +90°C.
- Vibrations from surrounding equipment.
- The proximity of metallic objects, magnetic fields or conductive materials.

when considering x-ray inspection systems. X-ray beams (which are electromagnetic rays, as are microwaves and visible light) are contained within the machine and do not pose any risk to human health or safety. No protective clothing or equipment is required and no impact on health has been found among operators who have used x-ray machines for extended periods of time.

Installing the right inspection equipment

The choice of inspection equipment is based on many variables, including the potential contaminants, the product itself, its packaging material, the physical space available and of course, budget. As a result, it is advisable to



X-ray image shows contaminated lipstick

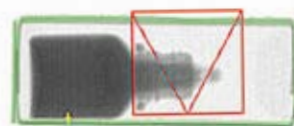


X-ray image shows product trapped in the packaging seal

speaking with suppliers who offer a range of solutions rather than only one product. It is not uncommon for manufacturers to have three or four different machines installed at different positions on the line. A gravity fall metal detector or pipeline x-ray machine to inspect incoming materials may be followed by a vertical packaging detector between weighing and bagging. Then, after a checkweigher, an x-ray machine or metal detector may be employed to conduct a final check on the case-packed product.

Starting to work with x-ray

There is no doubt that x-ray inspection has considerable advantages in many processing environments. Easy to install, safe and simple to use, even without previous experience, x-ray offers comprehensive contaminant detection and much more. It quickly



X-ray image highlights missing cap on a bottle of eye drops

and consistently identifies substandard products, reducing product recall, customer returns and complaints, therefore protecting manufacturers' brands. Furthermore x-ray helps to demonstrate due diligence, complies with HACCP, industry standards and legislation, retailers' QC requirements and national and international regulations. The use of x-ray can improve customer confidence, satisfaction and retention and assist in the generation of new business. With all these benefits on offer, and reassurance about installing and using x-ray systems, the future is looking bright for this innovative and exciting technology.

► www.mt.com/safeline-xray

MEDA Quality is Assured With Tablex 2 Metal Detectors



MEDA Manufacturing GmbH in Cologne is a subsidiary of the Swedish MEDA AB Group, an international company with expertise in specialist pharmaceutical products. The company is focused on the development and manufacture of market-driven products.

MEDA Cologne specialises in pharmaceutical contract manufacturing, both for home and export markets. The company provides a range of business activities, ranging from innovative, new product development to up-scaling of process batches through to shipping of patient-specific medicines. The company's high standard in the area of quality and services is reinforced by a comprehensive quality assurance system that meets international standards.

MEDA manufactures, fills and packages medicines under GMP-compliant conditions using modern processing and packaging machinery and technology. For many years, quality-focused MEDA Cologne has been putting its trust

in metal detectors from METTLER TOLEDO SAFELINE, the world's leading supplier of metal detectors and x-ray inspection systems.

Metal contaminant detection

The company uses SAFELINE Tablex 2 machines at the end of its process lines. These fully integrated metal detection systems specifically developed for detecting contaminants in tablets and capsules, ensure MEDA are able to reliably detect impurities in its products and automatically remove them from the production flow.

The Tablex 2 product monitoring system enables reliable detection of all types of metal including those which are difficult



Tablex 2 with lift flap reject mechanism

to detect, such as non-magnetic stainless steel, as well as thin pieces of wire and swarf. The machines are available with a choice of interchangeable side diverter and lift flap reject mechanisms.

Global service support

"Above all, it is the comprehensive range of services offered by METTLER TOLEDO that has impressed us," explains Gregor Bertram, a production engineer at MEDA. As well as a 24-hour on-site service, METTLER TOLEDO also offers global service support, which includes validation, qualification, training and installation to meet industry standard requirements.



Ensuring tablets are metal free everytime

► www.mt.com/metaldefection



Orthomol Rely on METTLER TOLEDO GARVENS To Provide Accurate Weighing Technology

Since 1991 Orthomol Pharmazeutische Vertriebs GmbH has been developing and marketing products on the basis of orthomolecular nutritional medicine, i.e. balanced dosage and diagnosis-based micronutrient compositions for special medical purposes – so-called supplementary balanced diets and food supplements.



These balanced dosage products include vitamins, minerals, trace elements and secondary plant compounds and are produced as granules for making drinks and tablets/capsules and as ready-made drinks.



Large operator-friendly touchscreen

Annually over 50 million pouches and 12 million bottles leave the site in Langenfeld where it is home not just to the company's R&D, medicine and marketing departments, but also to quality assurance, which is a key focus within the company.

Orthomol is setting new standards in terms of quality. The Langenfeld-based enterprise is the first of its kind to achieve ISO 22000:2005 certification. This comprehensive standard for food safety ensures the highest quality and safety, from development and raw material selection, right up to the finished product.

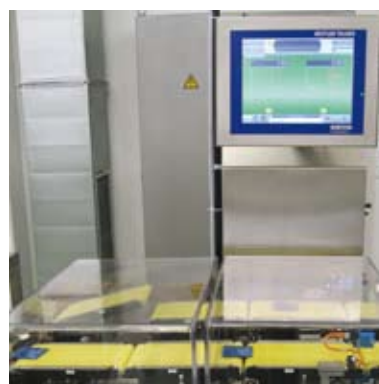
The innovative company has been putting its trust in weighing technology

from METTLER TOLEDO GARVENS for over a decade." A trusting relationship with our suppliers is important to us," explains Michael Grimm, responsible for quality management in technical operations. "We have found a partner in METTLER TOLEDO GARVENS who meet our strict quality standards."

The S2 and XS2 checkweighers used verify the weight of Orthomol products packaged in flat pouches in a secure and reliable manner. Overweight or underweight products are identified and removed by the fast-action lift gate conveyors. Additionally, to ensure the highly reflective pouches are reliably detected, special light barriers are used.

A double lane XS2 system with a clearly laid out weighing terminal checks the correct weight of up to 120 sachets per minute achieving an accuracy of 30 mg. Orthomol uses this system to check up to 15 different products manufactured in the form of capsules, such as Orthomol Vital f® - which has been developed for the nutrition-based medical treatment of women with chronic fatigue, burn-out syndrome and stress-related illnesses.

Single lane XS2 checkweighers ensure that the weight of pouches with granules and tablets or capsules are correct. One such product is Orthomol Immun®, which is used for the dietary treatment of acute and chronic infections and is available as granules, tablets/capsules or



Two lane XS2 checkweigher

ready-to-drink vials. In the production line the checkweigher inspects 80 pouches per minute at a conveyor belt speed of 23m/min. The XS2 achieves an accuracy of 30 mg and can be switched over to a new product with ease enabling up to 10 different products to be checked on this line.

Across the 10 production lines, all GARVENS checkweighers are controlled by the remote access tool CW-ReAct II and are networked accordingly allowing the monitoring and archiving of checkweigher information. This allows the user access to the data at one central location.



ServiceXXL

Tailored Services

METTLER TOLEDO offers a full range of standard or customised service contracts, enabling you to select the type of agreement which best suits your application and production requirements.



Field based local engineer network

The most comprehensive network of field based technicians and engineers for rapid local service.

Equipment installation and performance verification packages

Maximise the performance of your equipment from day one with our unique IPac, commissioning and regular audit packages.

Modular training programmes

Maximising the benefits of your investment through the development of operator skills, with customised training courses to suit all skill levels.

Spare parts at your disposal

Spare parts and customised spare part kits are available for express despatch.

Certified test samples and weights

A comprehensive range of certified contaminant test samples and weights to aid equipment qualification and performance verification.

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