

Rottendorf Pharma Advanced Technology



ROTTENDORF
PHARMA

Delivers High Quality

Rottendorf Pharma GmbH is an international pharmaceutical manufacturer that specialises in contract manufacturing. As a specialist manufacturer of tablets and capsules Rottendorf provides its customers with a range of services, from the development and manufacture of the product, to its packaging and distribution; taking responsibility for the entire process across the complete supply chain.

Rottendorf uses GMP and FDA-compliant systems and advanced technologies such as reliable metal detection systems from METTLER TOLEDO to achieve this. Tablex-PRO systems are highly sensitive, reliable metal detection solutions for the inspection of tablets and capsules. The Tablex-PRO was developed to meet the special requirements of pharmaceutical production.

Each tablet produced is inspected for metal contamination before packaging. The Tablex-PRO is capable of detecting ferrous,

non-ferrous and stainless steel contaminants as small as 0.3mm, and automatically removing contaminated products from the production process.

"The Tablex-PRO not only improves the quality of our products, it also reduces production costs thanks to its accurate rejection process and quick setup," explains Michael Barton, Head of Tablets and Coating at Rottendorf Pharma.

The Tablex-PRO can be set up quickly for each new batch, maximising valuable production



The Tablex-PRO from Mettler-Toledo reliably inspects each tablet produced.

METTLER TOLEDO

time. The quick setup time is especially important for a subcontractor like Rottendorf Pharma, which produces up to 90 different products in a week.

Scheduled performance verification tests are conducted before and after each new batch of products produced. Authorized Rottendorf employees log on with their individual user name and password to perform the verification tests, apply new settings or prepare a batch change. This provides full audit traceability supporting the requirements of 21 CFR part 11. The Tablex-PRO generates reports with access time stamps and employee names and provides Michael Barton with valuable information on all operative settings including process times and compliance of the processes.

Typically up to three batch changeovers are performed in one production day at Rottendorf Pharma. At peak times, the contract producer can make up to 400,000 tablets per hour. False rejects or unnecessary downtime can greatly impact the efficiency of production processes, especially

for a subcontractor like Rottendorf Pharma.

In addition to extraordinary operational stability and high availability, the Tablex-PRO metal detection solution also has a condition monitoring function. Unplanned downtime can be prevented because the Tablex-PRO system provides advanced warning of potential problems prior to failure. The Tablex-PRO continually analyses the performance of its most important components and identifies any negative trends. Full colour histograms are utilised to give an early warning of any changes in detector sensitivity, allowing the operator time to plan for corrective maintenance to be completed.

All recorded metal detection data is collected and can be accessed via an integral Ethernet adapter, enabling connection to the company's factory management system. Data can also be accessed manually via a USB interface for documentation purposes. All recorded data and processes, including electronic signatures are captured and stored for quality

management. Thanks to the documentation and data recording functions, the Tablex-PRO helps Rottendorf Pharma meet its quality requirements in order to comply with GMP and FDA regulations.



Automatic rejection of contaminated products by the Tablex-PRO.

About the Company

Rottendorf have worked in partnership with global pharmaceutical clients for over 80 years to actively develop, manufacture and package pharmaceutical products in solid dosage form. The service portfolio of the pharmaceutical specialist ranges from the development of processes and formulas to upscaling and large-scale production.



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