Reducing compliance costs in the life sciences industry

Eurotherm®

Tablet coating process

Eurotherm™ provides a range of products, digital engineered solutions and services throughout the world. Our expertise in life sciences allows us to supply solutions that suit the scale of your manufacturing requirements, while helping to maximize efficiency, productivity, and ultimately your return on investment.

Our solutions support regulatory compliance and help create a safer world.

Compliance

We empower our customers to help maintain regulatory compliance and minimize audit costs by providing a Data Integrity layer with open IoT platforms that support the digital transformation to Pharma 4.0.

Safer world

Specialists in managing critical data and contextual metadata to efficiently manage the quality, safety and authenticity of manufactured goods.

We have application expertise in:

- Control and sequencing
- Recipe management
- Batch control and reporting
- Setpoint programming
- Graphics based on situational awareness concepts
- Alarm management
- FDA 21 CFR Part 11 and EudraLex Annex 11 compliance
  - Electronic signatures
  - Electronic records
  - Audit trail
- Data Integrity ALCOA+ concept
- ISPE GAMP® 5 guidelines
  - Good engineering practice (GEP)
  - Qualification practices
  - Risk based approach
  - Quality management
- System lifecycle support services

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Tablet coating overview

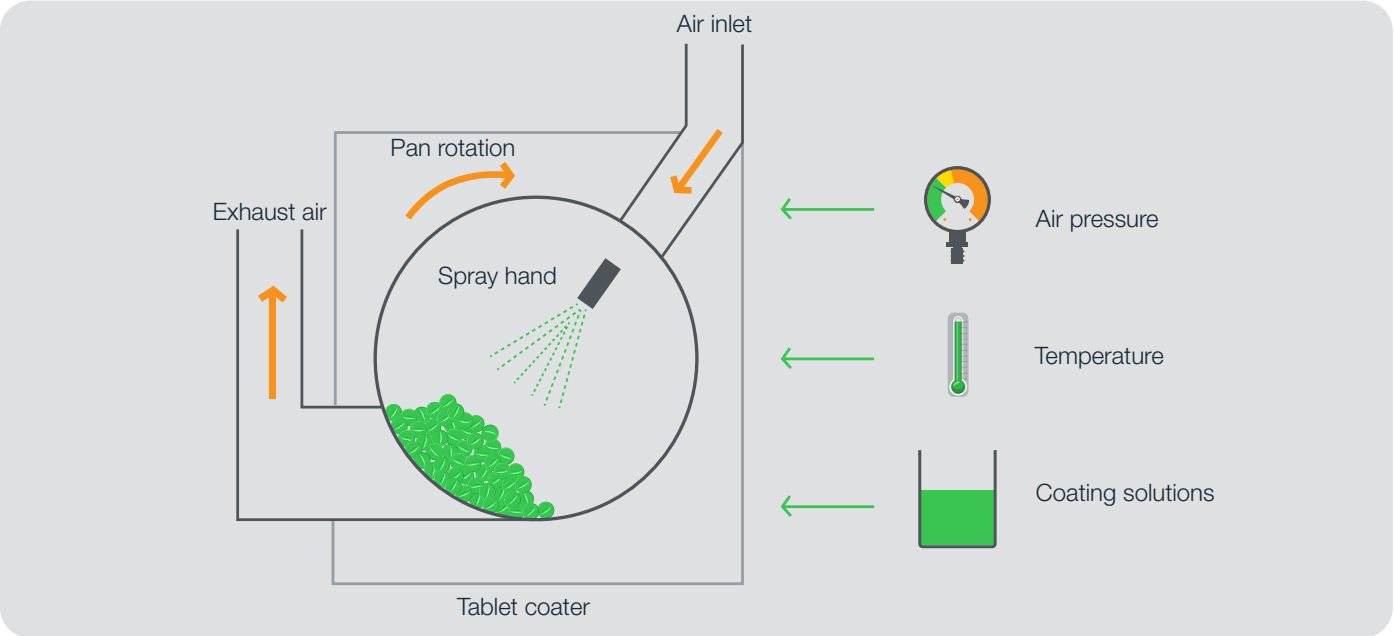
A tablet is a pharmaceutical dosage form. It comprises a mixture of active substances and excipients, usually in powder form, compressed or compacted into a solid. Coating is the last unit operation where a tablet's external features can be modified. This process is used for multiple reasons:

- Appearance: to change the color for branding purposes or other aesthetic reasons
- Stability: to protect the active ingredient from moisture, light, and/or acidic environment of the stomach
- Taste and/or odor masking: to provide an easy to swallow tablet without the bitter taste of many active ingredients
- Release characteristics: many film coating materials have functional properties which enable the creation of sustained or delayed (enteric) release dosage forms

Tablet coating process design and control

Tablet coating is the process of applying a suspension or solution containing the components needed for the coating formation, on a moving bed of tablets, keeping a constant temperature in the bed. It takes place within a controlled atmosphere inside a perforated rotating drum. Angled baffles fitted into the drum and air-flow inside the drum provide means of mixing the tablet bed. As a result, the tablets are lifted and turned from the sides into the center of the drum, exposing each tablet surface to an even amount of deposited/sprayed coating.

The liquid spray coating is then dried onto the tablets by heated air blown through the tablet bed from an inlet fan. The air-flow is regulated for temperature and volume to provide controlled drying and extracting rates, and at the same time, maintaining a slightly negative drum pressure relative to the room to provide an isolated process atmosphere.



Non-uniform coating created by inefficient mixing is one of the main issues that can occur during coating. There are several variables to consider:

- Air temperature and flow (the air temperature is controlled by the steam valve, while the air flow is regulated by the exhaust fan)
- Pan pressure and exhaust air volume (controls the speed of the exhaust fan)
- Pan rotation speed (a control loop with logic functions enables jogging and continuous blending motions, enabling each tablet to be brought into the spray zone frequently)
- Exhaust air temperature (used to control the spray solution pump. For a given pan speed and spray rate, the coating uniformity is related to the efficiency of the spray coater)

The coating process is usually a batch driven task consisting of the following phases:

- Batch identification and recipe selection (film or sugar coating). Multiple recipes can be configured to define tablet size, batch size (in weight), process time, etc.
- Loading/dispensing (accurate dosing of all required raw materials)

- Warming
- Spraying (application and rolling are carried out simultaneously)
- Drying (the duration of this phase depends on the type of coating, the tablet composition, and the batch size)
- Cooling
- Unloading and emptying the pan. This phase can be followed by a clean in place (CIP) stage, where the whole system is cleaned and put in a hold mode to accept a new batch

Eurotherm solution:

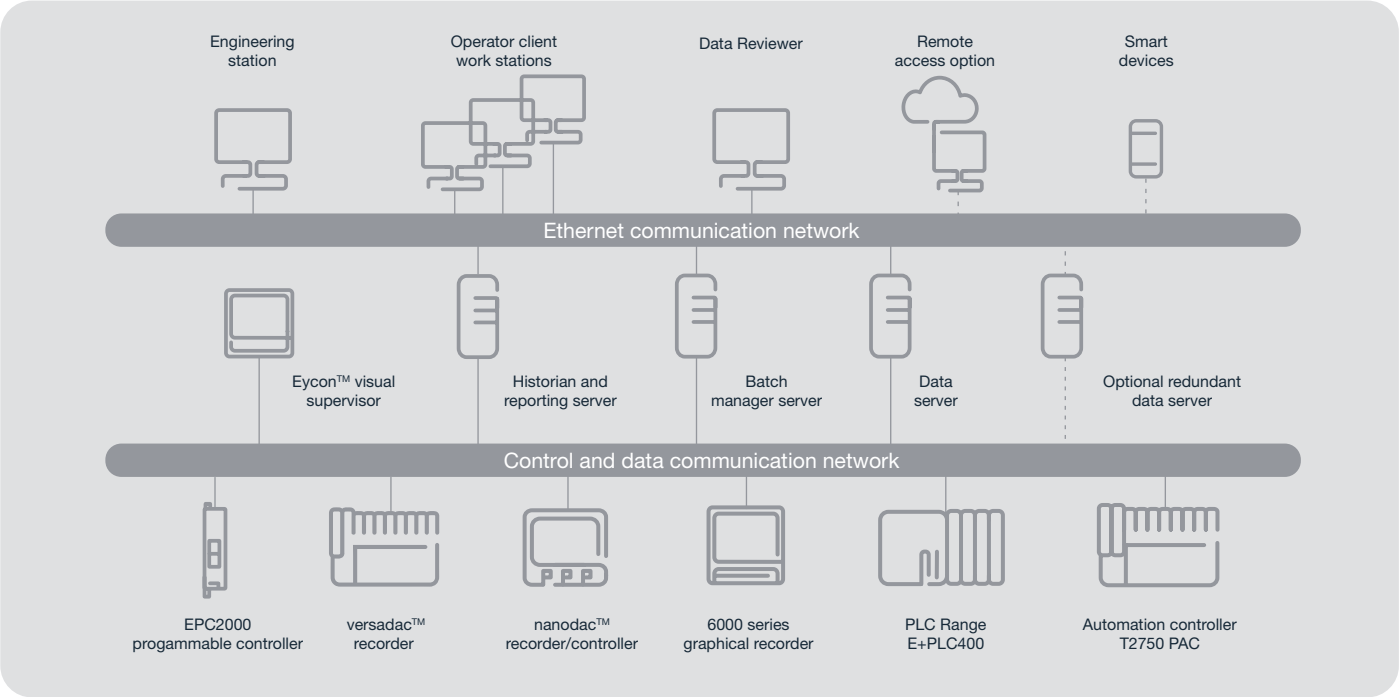
- Distributed control system with configuration lock
- Fast acting control accuracy, and process repeatability
- Batch/recipe management
- Data management based on ALCOA+ principles
- Power control for electric heaters
- Local HMIs to full SCADA solutions
- High availability architecture (redundant solutions and 'Store and Forward' feature)
- Data analysis
- Historian and reporting server
- Reporting

FDA 21 CFR part 11 and EU EudraLex Annex 11 regulations compliancy

As an automation and information technology leader our solutions meet the Electronic Record and Electronic Signature requirements as defined by the US and EU regulatory bodies.

Data Integrity ALCOA+ guidelines

To make sound decisions, you need to trust your data. Key regulatory bodies (FDA, EMA, WHO) and some advisory bodies (PIC/S, ISPE) have agreed on the Data Integrity related ALCOA+ concept. ALCOA+ defines that data should be Attributable, Legible, Contemporaneous, Original, and Accurate + Complete, Consistent, Enduring, and Available. As an experienced solution supplier, well established in life science processes, Eurotherm is a main supporter of that vision and contributed to the definition and the revision of some of these guidelines.



A 21st century risk-based approach

Business investments should be future-proof and audits hassle free. Eurotherm has developed and widely applied a set of good engineering practise (GEP) qualification documents based on ISPE GAMP 5 guidelines to assist with achieving these goals. Qualification documents can be maintained in electronic format. Industry is progressing from manual standard operating procedure (SOP) based manufacturing operations to a digitalized paperless quality systems approach based on FDA and ICH guidelines.

Quality by design

In a quality by design (QbD) approach, product quality is continuously monitored and controlled at the earliest stages, rather than waiting for a process to end. Pharmaceutical manufacturers need to focus on identifying, controlling, and validating process variables that could cause a non-compliant result. This is accomplished by managing the quality target product profile (QTPP), the critical quality attributes (CQA), and the critical process parameters (CPP). As defined by the process analytical technology (PAT) approach, Eurotherm can assist with measurement and performance analytics on CQAs and help manage CPP deviations, providing time-stamped evidence for correlation of parameter behaviors at their occurrence.

Pharma 4.0 ready technology

Eurotherm control and data recording solutions are IoT ready, providing a data integrity layer within open IoT platform system architectures and aiding the digital transformation to Pharma 4.0 technology.

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