Life Sciences

INDUSTRY

- **Control and sequencing**
- **Recipes**
- **Batch control and reporting**
- **Setpoint programming**
- **Bespoke displays**
- **Alarm management**
- **21 CFR Part 11**

The Tablet Coating Process

Application Note

Many solid pharmaceutical dosage mediums are produced with coatings, either on the external surface of tablets, or on materials dispensed within gelatine capsules. Coating serves a number of purposes:

- Protects the tablet (or the capsule contents) from stomach acids
- Protects the stomach lining from aggressive drugs such as enteric-coated aspirin
- Provides a delayed release of the medication
- Helps maintain the shape of the tablet

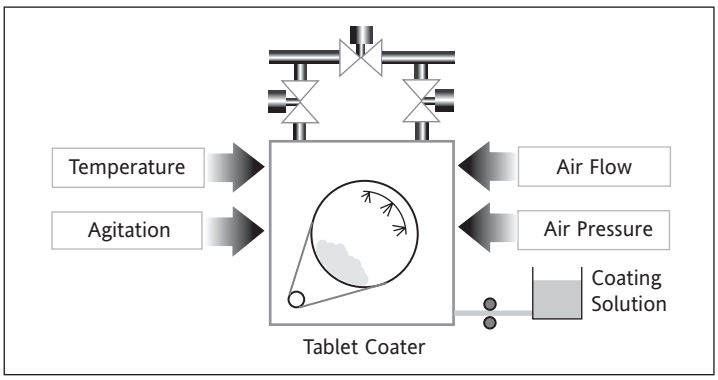
Ideally, the tablet should release the material gradually and the drug should be available for digestion beyond the stomach. The coating can be specially formulated to regulate how fast the tablet dissolves and where the active drugs are to be absorbed into the body after ingestion.

Many factors can affect the end-use properties of pharmaceutical tablets:

- Chemical composition
- Coating process
- Drying time
- Storage and environmental monitoring

Coating process design and control

Tablet coating takes place in 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 centre of the drum, exposing each tablet surface to an even amount of deposited/sprayed coating.



Tablet Coater

The liquid spray coating is then dried onto the tablets by heated air drawn 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 the drum pressure slightly negative relative to the room in order to provide a completely isolated process atmosphere for the operator.

Tablet coating equipment may include spray guns, coating pan, polishing pans, solution tanks, blenders and mixers, homogenisers, mills, peristaltic pumps, fans, steam jackets, exhaust and heating pipes, scales and filters. Tablet coating processes may include sugar coating (any mixtures of purified water, cellulose derivatives, polyvinyl, gums and sugar) or film coating (purified water, cellulose derivatives).

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

- Batch identification and recipe selection (film or sugar coating)
- Loading/Dispensing (accurate dosing of all required raw materials)
- Warming
- Spraying (application and rolling are carried out simultaneously)
- Drying
- Cooling
- Unloading

A control system must therefore provide flexibility in the way in which accurate and repeatable control of the coating environment is achieved and will include the following features:

- Precise loop control with setpoint profile programming
- Recipe Management System for easy parameterisation
- Sequential control for complex control strategies
- Secure collection of on-line data from the coating system for analysis and evidence
- Local operator display with clear graphics and controlled access to parameters

Eurotherm Eycon™ Visual Supervisor

The Eurotherm visual supervisor is ideal for autoclave applications because it combines all these key features into a single compact unit:

- **Powerful loop and sequence control**
- **Flexible graphics**
- **Setpoint programmer**
- **Batch control and reporting**
- **Audit trail**
- **XGA touchscreen display to IP65**
- **Secure data logging and trending**
- **Recipe management**
- **Alarm management**
- **Access control and electronic signatures**

21 CFR Part 11 - 'Ready to use!'

Tablet coating machines are used in industries likely to require validation to the requirements of the FDA, EMEA or other applicable regulatory body. The visual supervisor has been widely used in validated processes including freeze dryers, autoclaves, reactors, fermenters, purified water systems, tablet coating machines, etc.

The Auditor feature on the visual supervisor has been specifically designed to meet the requirement of the FDA's 21 CFR Part 11 including:

- Controlled user access
- Secure data logging in tamper resistant format
- Audit trail recording user actions and changes to process parameters
- Electronic signature

21 CFR Part 11
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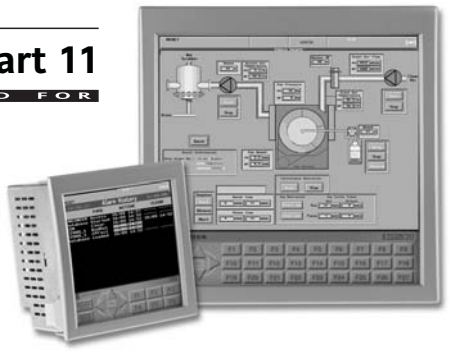

With the Auditor feature, Electronic signature is configurable for all actions which may be performed from the visual supervisor display including the customised display and standard features such as batch, recipe changes, access control changes, etc.

Scalable architecture

A complete system can be created in combination with T2550 DIN rail I/O bases. Connection is via ELIN and I/O is scalable by adding 4. 8 or 16 slot bases as required. A range of I/O modules caters for the various interfaces required:

Analogue inputs	Temperatures (inlet and outlet air), air flow, differential pressure (Pan), pressure (atomising air), RPM, level, etc.
Analogue outputs	Control valves, air flow/pressure regulators, fans and pumps speeds
Digital inputs	Coating solution low level switch, fans and pumps statuses, etc.
Digital outputs	Valve control solenoids, pump control etc.

System building blocks:

- Single coating unit (single Eycon)
- Multiple units with supervisory workstation(s)

Eurotherm: International sales and service

Understanding and providing local support is a key part of Eurotherm's business. Complementing worldwide Eurotherm offices are a whole range of partners and a comprehensive technical support team... to ensure you get a service you will want to go back to.

AUSTRALIA *Sydney*
Eurotherm Pty. Ltd.
T (+61 2) 9838 0099
F (+61 2) 9838 9288
E *info.au@eurotherm.com*

AUSTRIA *Vienna*
Eurotherm GmbH
T (+43 1) 7987601
F (+43 1) 7987605
E *info.at@eurotherm.com*

BELGIUM & LUXEMBURG *Moha*
Eurotherm S.A/N.V.
T (+32) 85 274080
F (+32) 85 274081
E *info.be@eurotherm.com*

BRAZIL *Campinas-SP*
Eurotherm Ltda.
T (+5519) 3707 5333
F (+5519) 3707 5345
E *info.br@eurotherm.com*

DENMARK *Copenhagen*
Eurotherm Danmark AS
T (+45 70) 234670
F (+45 70) 234660
E *info.dk@eurotherm.com*

FINLAND *Abo*
Eurotherm Finland
T (+358) 22506030
F (+358) 22503201
E *info.fi@eurotherm.com*

FRANCE *Lyon*
Eurotherm Automation SA
T (+33 478) 664500
F (+33 478) 352490
E info.*fr@eurotherm.com*

GERMANY *Limburg*
Eurotherm Deutschland GmbH
T (+49 6431) 2980
F (+49 6431) 298119
E *info.de@eurotherm.com*

HONG KONG & CHINA
Eurotherm Limited *North Point*
T (+85 2) 28733826
F (+85 2) 28700148
E *info.hk@eurotherm.com*

Guangzhou Office
T (+86 20) 8755 5099
F (+86 20) 8755 5831
E *info.cn@eurotherm.com*

Beijing Office
T (+86 10) 6567 8506
F (+86 10) 6567 8509
E *info.cn@eurotherm.com*

Shanghai Office
T (+86 21) 6145 1188
F (+86 21) 6145 1187
E *info.cn@eurotherm.com*

INDIA *Chennai*
Eurotherm India Limited
T (+91 44) 24961129
F (+91 44) 24961831
E *info.in@eurotherm.com*

IRELAND *Dublin*
Eurotherm Ireland Limited
T (+353 1) 4691800
F (+353 1) 4691300
E *info.ie@eurotherm.com*

ITALY *Como*
Eurotherm S.r.l
T (+39 31) 975111
F (+39 31) 977512
E *info.it@eurotherm.com*

KOREA *Seoul*
Eurotherm Korea Limited
T (+82 31) 2738507
F (+82 31) 2738508
E *info.kr@eurotherm.com*

NETHERLANDS *Alphen a/d Rijn*
Eurotherm B.V.
T (+31 172) 411752
F (+31 172) 417260
E *info.nl@eurotherm.com*

NORWAY *Oslo*
Eurotherm A/S
T (+47 67) 592170
F (+47 67) 118301
E *info.no@eurotherm.com*

POLAND *Katowice*
Invensys Eurotherm Sp z o.o.
T (+48 32) 2185100
F (+48 32) 2177171
E *info.pl@eurotherm.com*

SPAIN *Madrid*
Eurotherm España SA
T (+34 91) 6616001
F (+34 91) 6619093
E *info.es@eurotherm.com*

SWEDEN *Malmo*
Eurotherm AB
T (+46 40) 384500
F (+46 40) 384545
E *info.se@eurotherm.com*

SWITZERLAND *Wollerau*
Eurotherm Produkte (Schweiz) AG
T (+41 44) 7871040
F (+41 44) 7871044
E *info.ch@eurotherm.com*

UNITED KINGDOM *Worthing*
Eurotherm Limited
T (+44 1903) 268500
F (+44 1903) 265982
E *info.uk@eurotherm.com*
www.eurotherm.co.uk

U.S.A. *Leesburg VA*
Eurotherm Inc.
T (+1 703) 443 0000
F (+1 703) 669 1300
E *info.us@eurotherm.com*
www.eurotherm.com

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