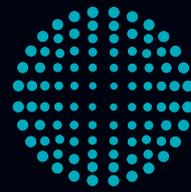


ePAT

Embedded Process Analytical
Technology for High Speed Quality
Control in Tablet Production



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ePAT, Embedded Process Analytical Technology, for Batch Tablet Production

Process Analytical Technology (PAT) is well suited for continuous processes. However, there are good reasons to also utilize it in batch production. PAT allows in-line monitoring and control of critical quality parameters during production. This can give already fast benefits as avoidance of rejection of complete batches caused by delayed detection of quality issues, which can be a step on the road to a final goal of real time release.

Fette Compacting tablet presses have one single control system performing all machine, process and quality control functions. The control system architecture consists of one high-speed embedded controller and an industrial PC for the HMI, including central recipe management and batch reporting. This simple hardware architecture, combined with 100% proprietary software from Fette Compacting, significantly reduces the system's validation requirements and results in a robust, reliable control system.

Process Analytical Technology is fully embedded in the control system:

NIR spectroscopy

- In-line product quality monitoring using embedded spectroscopic sensors, i.e. sensor spectrometers are directly connected to the machine's embedded controller
- NIR blend uniformity measurement (BU) using an active measurement head, available at various positions: tablet press infeed or inside the feed frame (Fill-O-Matic, FOM)
- NIR tablet uniformity measurement (TU) at tablet ejection on the die table allows 100% inspection of all tablets, including rejection of single out-of-spec tablets
- MVA/chemometrics running on the embedded controller; full access to all supported models of this engine via the offline model builder
- PAT method management is integrated in the central product recipe management
- Complete system, including PAT method management, is cGMP compliant
- Robust industrial execution
- MES OPC interface for partial PAT method management and retrieval of measured spectra and prediction values

BU-NIR sensor:

- Measures blend uniformity
- Fast, performs up to 10 independent measurements per second
- Flexible, can be installed in various positions
- Internal white reference
- Active measurement head: less light fibers
- Redundant light bulbs
- Robust
- Easy to handle and install

TU-NIR sensor:

- Unique development for Fette Compacting
- The only sensor measuring 100% of the tablets on the ejection
- Super-fast, measures up to 120 tablet per second
- Super-fast single rejection of the out of spec tablets based on the NIR measurement
- Internal white reference
- In-line cleaning concept
- Robust
- Easy to handle and install



Fette Compacting ePAT – Road to Real-Time-Release



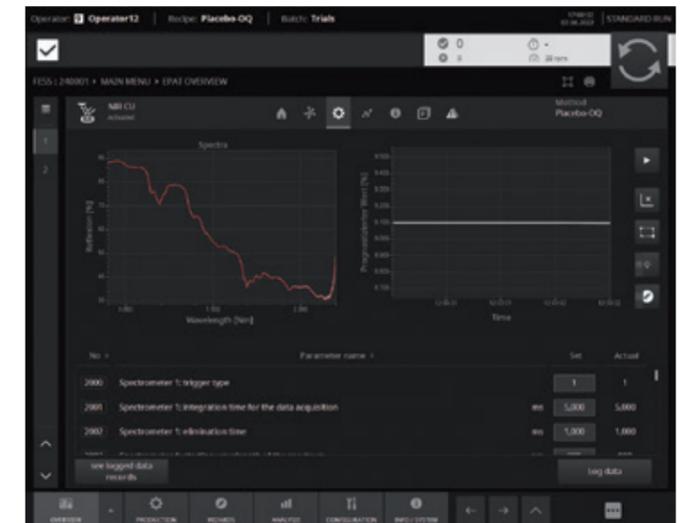
BU-NIR Sensor: High-speed blend uniformity measurement at various positions



TU-NIR sensor: High-speed 100% quality control and rejection of all tablets that do not meet specifications



Tablet press equipped with BU-NIR sensor in the FOM and TU-NIR sensor for single tablet control and rejection



ePAT spectrum and resulting API concentration embedded in the Fette Compacting software

Fette Compacting GmbH

Grabauer Strasse 24
21493 Schwarzenbek, Germany
Phone +49 4151 12-0
Fax +49 4151 3797
tablet@fette-compacting.com

Fette Compacting America, Inc.

400 Forge Way
Rockaway N.J. 07866, USA
Phone +1 973 5868722
Fax +1 973 5860450
sales@fetteamerica.com

Fette Compacting America Latina Ltda.

Av. Cambacica, 1200 módulo 10
Parque Imperador
CEP 13097-160
Campinas / SP, Brazil
Phone / Fax +55 19 37969910
contato@fette-compacting.com.br

Fette Compacting Mexico, SA de CV

Adolfo Prieto No. 1638
Colonia Del Valle Sur
03100 Mexico, DF, Mexico
Phone +52 55 40000653
tablet@fette-compacting.com

Fette Compacting (China) Co., Ltd.

No. 9 Shengtong Road,
Moling Sub-District,
Jiangning Development Zone,
211111 Nanjing
Jiangsu Province, P.R.C., China
Phone +86 25 52121818
Fax +86 25 52129951
fcn@fette-compacting.com

Fette Compacting Machinery India Private Limited

A - 406 /407, 4th floor, Atrium 215,
Next to Hotel Courtyard Marriott,
Near J. B. Nagar Metro station,
Andheri – Kurla Road, J. B. Nagar,
Andheri (East)
400 093 Mumbai, India
Phone +91 83 26750355
sales.in@fette-compacting.com

Competence Centre
Plot No S 115, Phase III B
Verna Industrial Estate
Verna, Goa 403 722, India
Phone +91 83 26750355

Fette Compacting Asia Pacific Pte Ltd.

107 Eunos Avenue 3, #01-01
Singapore 409837, Singapore
Phone +65 659 25654
Fax +65 654 71939
infoasiapacific@fette-compacting.com

Fette Compacting Ibérica SL

Avenida Labradores, 1
2ª Planta, Oficina 3
28760 Tres Cantos, Spain
Phone +34 91 8039689
Fax +34 91 3483052
fcib@fette-compacting.com

Fette Compacting France

1, Rue du Centre
93160 Noisy Le Grand, France
Phone +33 155 812121
Fax +33 155 812120
fcf@fette-compacting.com

Fette Compacting Belgium BVBA

Schaliënhoevdedreef 1b
2800 Mechelen, Belgium
Phone +32 15 684260
Fax +32 15 684269
fcbe@fette-compacting.com

EuroPharma Machinery Ltd

Unit 12 Highview
Bordon, Hampshire, GU35 0AX
United Kingdom
Phone +44 1420 473344
Fax +44 1420 488030
admin@europharma.co.uk

Fette Compacting Middle East FZE

Jebel Ali Free Zone, Jafza
Lobby 14, Office 308, Dubai
United Arab Emirates
Phone +971 4 8808226
dubai@fette-compacting.com

Fette Compacting North-West Africa

Tour d'Affaire Nord, Centre Commercial
Bab Ezzouar – Regus 4ème Etg.
16000 Algiers, Algeria
Phone +213 770 117 007
fcnwa@fette-compacting.com

www.fette-compacting.com



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