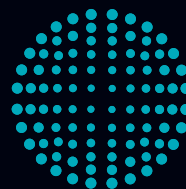


# ePAT

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



**FETTE**  
**COMPACTING**  
be efficient



# ePAT, Embedded Process Analytical Technology, for Batch Tablet Production

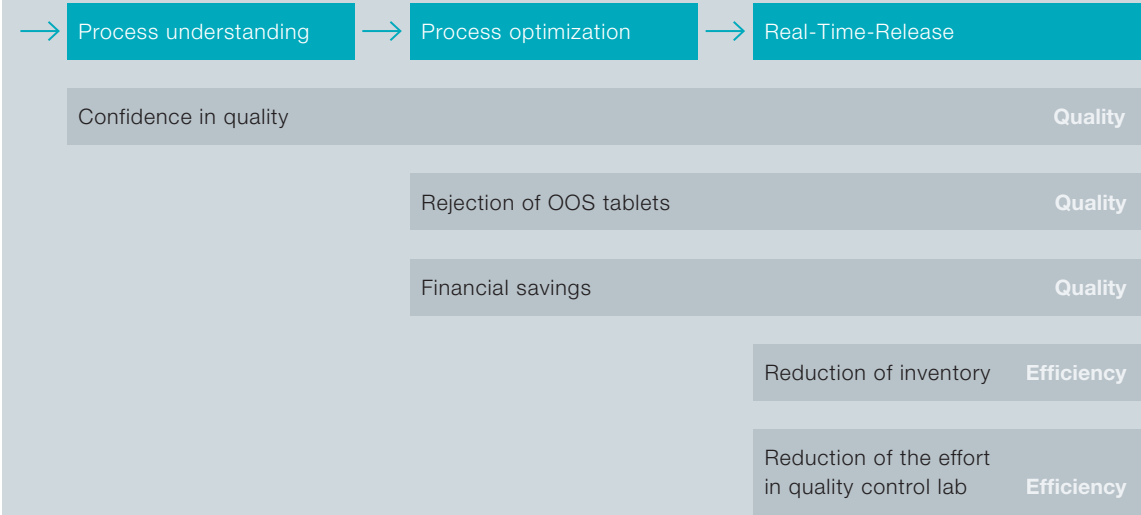
Process Analytical Technology (PAT) is well suited for continuous processes. However, there are good reasons to also utilize it in batch production. PAT allows in-line monitoring and control of critical quality parameters during production. This can give already fast benefits as avoidance of rejection 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



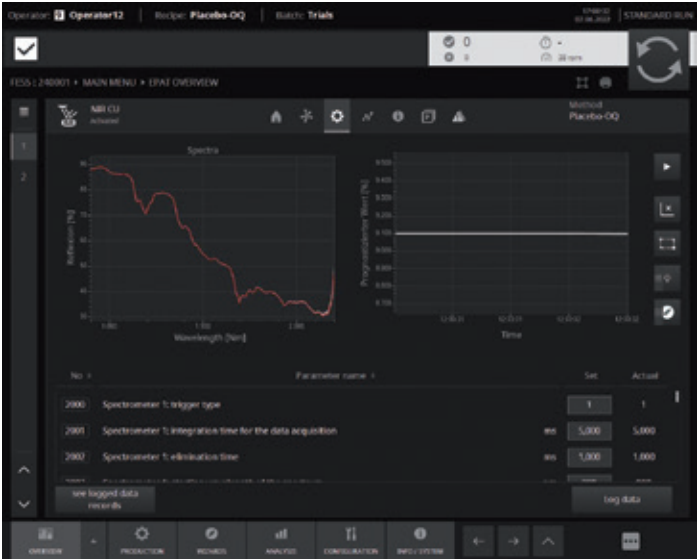
BU-NIR Sensor: High-speed blend uniformity measurement at various positions



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**

Schaliënhoevedreef 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

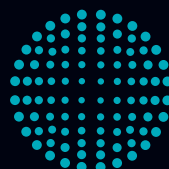
**Fette Compacting Middle East FZE**

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](http://www.fette-compacting.com)



**FETTE  
COMPACTING**  
be efficient