SYNTEGON
PROCESSING & PACKAGING

Automated Process Development (APD).

A SOPHISTICATED APPROACH TO LAB AUTOMATION

Automated process development (APD) is a unique and sophisticated approach for establishing the porcess for new tablet and capsule formulations, and the process optimization of existing products. APD combines a systematic planning method (DoE = Design of Experiments) with a patented, automated execution setup on a capsule filling (GKF) or tablet compression (TPR) machine. The result is an outstanding and unmatched methodology, which enables a higher number of experiments in less time with reduced product consumption.

APD allows the customer to efficiently perform a broad process screening to quickly identify interactions between critical material and quality attributes with critical process parameters. APD also optimizes output, quality and robustness of the process and helps to reduce time to market for new formulations, with increased data quality. The Syntegon APD – Automated Process Development approach can be offered as a service within our OSD Customer Center in Waiblingen, Germany by our Pharma Services team.

APD PHASES



APD APPLICATION EXAMPLES

- Increase in output
- Increase in dosage accuracy
- Adjustment to target weight (e.g., in case of overfilling or input material variability)
- Reduction in product losses/increase in yield
- Avoid/reduce OSD form defects
- Transfer process settings for scale-up amd batch variability
- Compare different product batches/formulations with each other
- Obtain a general understanding of the process (as required by regulatory agencies)

Benefits

- Rapid screening of machine settings and products by means of statistical experimental design and data analysis.
- Efficient analysis of the interaction between critical product attributes, critical quality attributes and critical process parameters.
- Process robustness achieved through systematical optimization of process parameters.
- In-depth process understanding leading to higher final product quality, with easier troubleshooting in case of input material variability.
- Automated customization and monitoring reduces process development time and material consumption for broad parameter screening.



Save time
Automated customization and monitoring guarantees less time effort and material consumption for a broad parameter screening. It reduces costs and supports your faster time to market.



Improved process quality
Automated execution with adjustment of machine parameters reduces operator intervention and human failure during predefined test runs of a DoE.



Reduced product consumption
Combining statistical trial planning with automated process development optimizes trial number and reduces product consumption throughout the trial phase, while increasing yield.



APD module on GKF 720 capsule filling machine.



APD feeder on TPR 200 Plus tablet press.

APD FOR ENCAPSULATION PROCESSES

The combination of Design of Experiments (DoE) with an automated test set-up on a GKF capsule filling machine is a unique and patented technology. Up to 50 trial runs can be performed in less than two hours. The APD application on a tamping pin powder dosing station on a GKF 720 contains the following:

- Five individual controlled tamping pin blocks with servo drive to adjust the tamping pin immersion depth into the dosing disc with a pneumatic cylinder adjusting the tamping force
- Transfer station with slug transfer force monitoring
- Unit to monitor and control the powder bed level within the dosing station
- Software interface to upload a trial plan to the machine
- Operation of APD function to convert the trial plan information into machine motion for trial execution

Tamping force
Powder bed height
Tamping pin profile
Machine speed
Tamping immersion

APD FOR TABLETTING PROCESSES

The APD technology application for tablet compression machines can be used to determine the optimal manufacturing parameters for a specific compression blend to ensure tablet quality and minimize material loss. The APD feeder technology offers an automated systematic approach to find the most suitable tablet compression parameters.

Two paddle feeder
Three paddle feeder
Paddle design
Feeder speed
Distribution feeder wheels, rotation direction
Main and pre compression force

As a pure R&D application, these parameters can then be transferred to the standard production machine by mechanically replacing components such as the 2 or 3 paddle feeders and the paddle themselves. The use of APD proves that the influence of feed frame geometry and paddle configuration is essential for achieving a reproducible process and ultimately tablet quality.

APD as a service

Automated process development is an investment that offers a leaner development and major advantages in subsequent commercial production. However, you can also improve existing production processes. Our Engineering Pharmaceutical Services team is at your disposal with over 50 years of experience, offering the following:

- Unique combination of statistical trial planning (DoE) and process automation
- Automated adjustment and testing of process parameters with direct and digital measurement of critical quality attributes
- Evaluation of trial results and identification of critical process parameters and interactions
- Efficient process optimization and formulation development
- Real machine tests warranty “real quality by design”

Our team can also support you with the development of new machine features for specific product needs.

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