A Pilot Scale Continuous Manufacturing Line: Case Studies for the Process Performance Evaluation

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PROMIS Centre continuous processing pilot plant

• Flexible trials for continuous feeding, blending, roller compaction and tableting

• Piloting services with real time PAT tools and standard end product analysis
Pilot scale continuous manufacturing line

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Assembly of the equipment

- 3 powder feeders (K-Tron LIW feeder, type K-ML-D5-KT20)
- 2 continuous mixers (Hosokawa Modulomix)
- Screw conveyor (Entecon)
- Roller compactor (Hosokawa Pharmapaktor L200/30P Flake Crusher FC 200)
- Vacuum conveyor (K-Tron Powder loader P10-BV-100)
- Feeders for granules and lubricant
- Vacuum conveyor (Volkman)
- Tablet press (PTK PR-1000)
Process Control Strategy

Excipients
API

Mixing

RC

Mixing

Tabletting

Concentration (NIR)

Particle Size (EYECON)

Concentration (NIR)

Control Unit

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Case Study 1

PROCESS PHASES after start-up: TEST RUN 20kg/h ASA/MCC

- Start the feeders and mixer (0 min)
- Fill the screw conveyor (2-12 min)
- Start the roller compactor (15 min)
- Start the vacuum conveyor (18 min)
- Start the tablet press (19 min)
  -> the first tablets out (20 min)
CS 1 Process Data: Feeders

MCC

ASA

Mass Flow [kg/h]

Time [min]

Calculated Concentration [%]

Time [min]

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CS1 Process Data: Roller Compactor

![Graph of Roll Force vs. Time](image)

![Graph of Roll Speed vs. Time](image)

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CS 1 Process Data: Tablet Press
CS 1: Measured Tablet Properties

![Graphs showing measured tablet properties over time.](image)
Case Study 2

PROCESS PHASES after start-up: TEST RUN 6.6 kg/h
- Start the feeders and mixer
- Fill the feed bin
- Start the vacuum conveyor
- Start the feeders and mixer
- Fill the feed bin 2
- Start the vacuum conveyor 2
- Start the tablet press
CS 2 Process Data: Feeders (1. mixing)

Excipient 1

Mass Flow [kg/h]

Time [min]

API

Excipient 2

Mass Flow [kg/h]

Time [min]

API

Calculated Concentration [%]

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CS 2 Process Data: Feeders (2. mixing)
CS 2 Process Data: Tablet Press

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Case Study 3

PROCESS PHASES after start-up: TEST RUN 3.5 kg/h

- Start the feeders and mixer
- Fill the tablet press hopper
- Start the tablet press
CS 3 Process Data: Feeders

**Excipient 1**

- Mass Flow [kg/h]
- Time [min]
- API

**Excipient 2**

- Mass Flow [kg/h]
- Time [min]
- Lubricant

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CS 3 Process Data: Feeders (2)

API

Lubricant

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CS 3 Process Data: Tablet Press

![Graph showing compression force vs rotation](image-url)
Conclusions

• Case Study 1:
  – API concentration in the tablets was very close to the target value
  – AV was below the maximum allowed acceptance value

• Case Study 2 and 3:
  – Different flow rates can be used
  – Flow rate has no effect on the process performance

• PROMIS Centre’s pilot scale line is a fast, cost effective and flexible way to study continuous manufacturing
Thank you for your attention!

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Meet our staff at booth 511

Demos: NIR Transmission, Multipoint-NIR, Process sample port, Piloting services on continuous manufacturing