Experimental Exploration of an Industrial Pharmaceutical Crystallization Process – Facility 2

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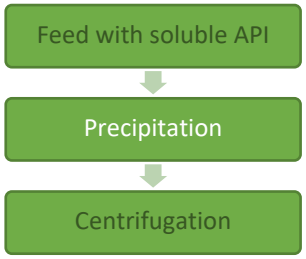
Introduction

Purpose

To gain process understanding and suggest improvements

Process



What are the issues?

Loss in centrifugation

What causes the issue?

- Particle Size Distribution
- Particle Density?

What parameters are investigated?

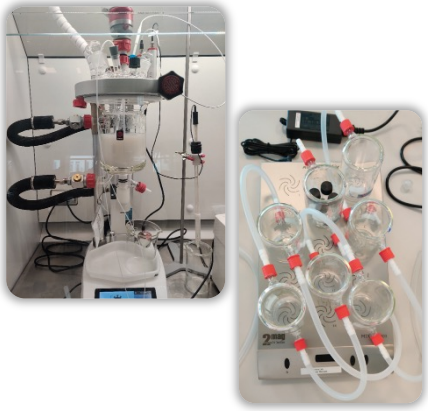
- pH
- Antisolvent (AS) concentration
- Temperature

Methods

Experiments

Performed in Helix Lab

1. Reactor
   Parameters: pH + AS
2. Solubility
   Parameters: pH + AS + Temp



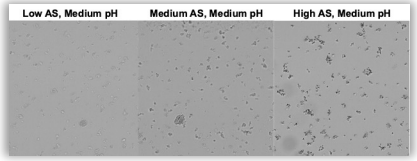
Samples

1. UPLC samples
   Analyzed by NN
2. Particle samples
   ParticleTech equipment in Helix Lab

Results

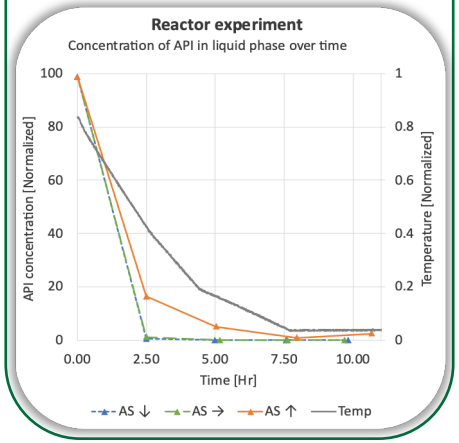
Particle samples

- Qualitative analysis
- Temperature



UPLC samples

- Higher AS conc. → better control with temp
- AS induce nucleation



Discussion

Conclusions

- Inefficient use of cooling
- Higher level of AS
  1. Particle density
  2. Cooling

Further investigations

- Solubility
  1. Temperature
  2. AS concentrations
- AS addition rate
- Cooling profile

Helix Lab

Distance from lab to company

- Easy sampling

Additional support

- Helix Staff, Fellows, company supervisors

Housing in Kalundborg

- No commuting