



Downstream impact of crystallization process in an API purification production: Characterization and sensitivity analysis of crystallization process and subsequent freeze-drying step

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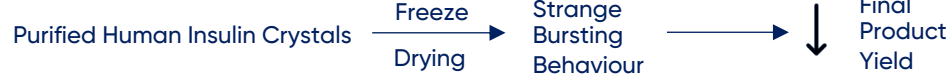
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Helix Lab

Problem



Hypothesis

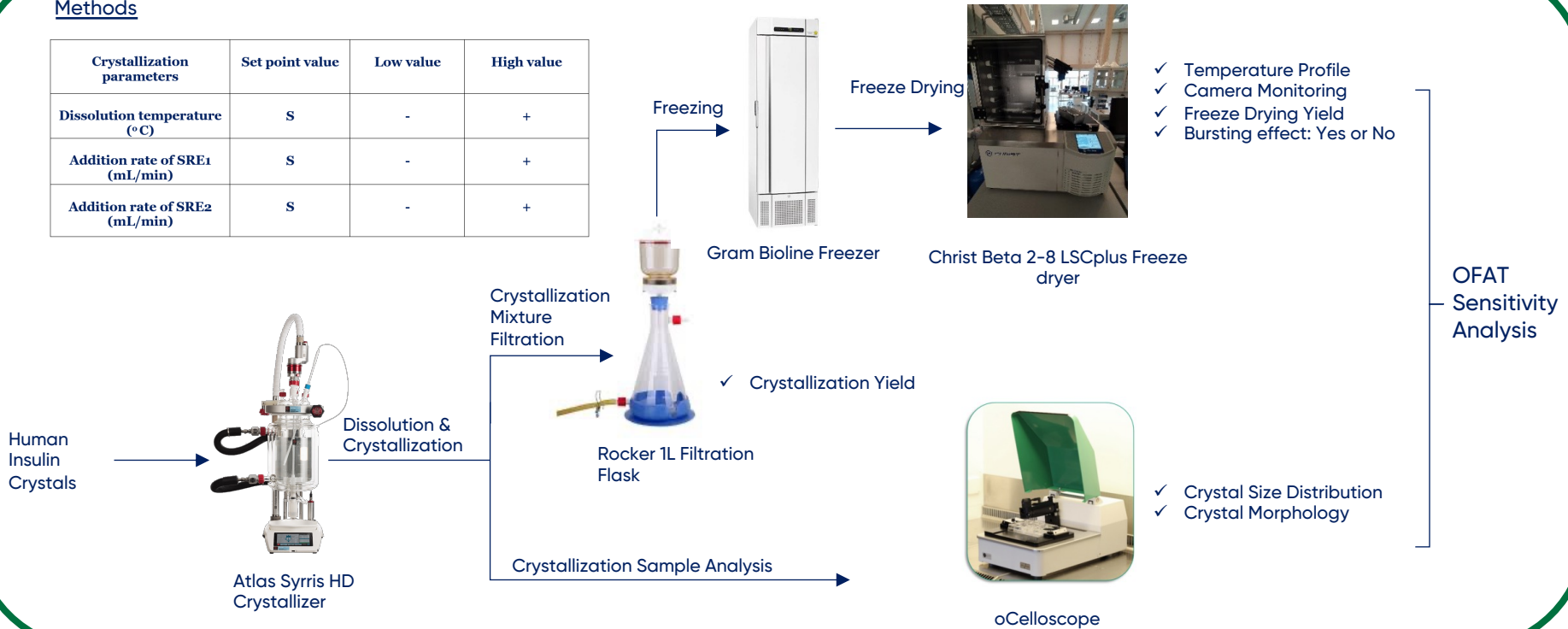
Human Insulin crystal characteristics influence bursting behaviour.

Perspectives

- Increased process understanding of final crystallization and freeze drying step.
- Increase of freeze drying step yield.
- Laboratory adaptation of industrial step.
- Insight working in a corporate team environment.
- Solving real-life problem in industry.

Methods

Crystallization parameters	Set point value	Low value	High value
Dissolution temperature (°C)	S	-	+
Addition rate of SRE1 (mL/min)	S	-	+
Addition rate of SRE2 (mL/min)	S	-	+



- ✓ Temperature Profile
- ✓ Camera Monitoring
- ✓ Freeze Drying Yield
- ✓ Bursting effect: Yes or No

✓ Crystallization Yield

- ✓ Crystal Size Distribution
- ✓ Crystal Morphology

OFAT Sensitivity Analysis