Batch Crystallization Control for Pharmaceutical Manufacturing

Project:	PH-00-04
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Partners:	Albemarle, Bruker Optics, DSM, FrieslandCampina Domo, IPCOS, MSD, Perdix Analytical Systems, TU Delft, TU Eindhoven, Zeton
Budget:	2,4 M€
Duration:	Project started October 2007 and will run up to 2013

Incentive:

Crystallization is the main purification step in the manufacturing of Active Pharmaceutical Ingredients (API's).

Batch cooling crystallization is the workhorse, but reproducibility is bad.

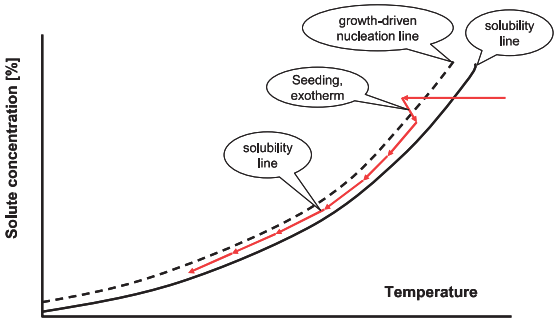

Figure 1. Cooling crystallization path

Objective:

- Seeded batch cooling crystallization
- On-line measurement techniques and control software in Pharma Manufacturing
- Demonstrate Control on crystal growth rate and on crystal size

Approach:

- Instruments in measuring skid
- Supervisory control platform (IPCOS)
- Seeding, nucleation (TU Delft, P&E)
- Instrument models, seeding control (TUE)
- Batch to batch optimizer (TU Delft, DCSC)
- Test at partner sites

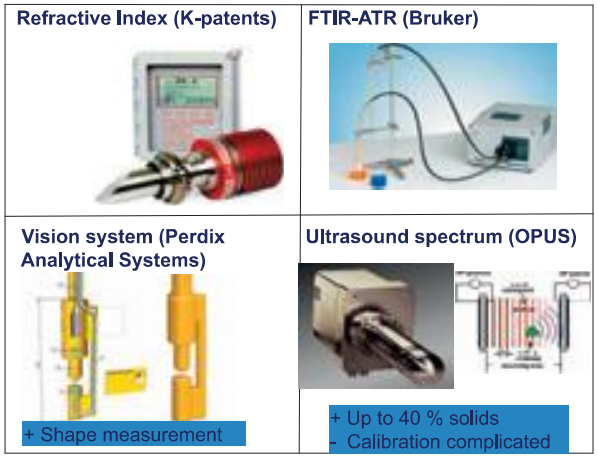

Figure 2. On-line measurement instruments

Results:

- Skid has been built by Zeton and operated at MSD, Apeldoorn in EX-environment

Figure 3. Skids at Zeton

Next Steps:

- 2011: Skid standalone testing at DSM, Geleen
- 2012: Skid tests on Ibuprofen, Albemarle
- 2012: Skid tests on DSM compound