



## Pharmaceutical Sciences

### FACTSHEET



## Drug Substance

### Crystallization of Difficult Materials and Scale-up

Crystallization is the critical step in solid form control. We can help you define a process that ensures the solid form you manufacture is the one you want.

### Crystallization Process Development and Scale-up

We have wide-ranging experience in all areas of crystallization. We can take your compound through the stages of generating the first crystals, polymorph screening, salt or cocrystal form selection and on to the development of a robust crystallization process.

### Developing a Crystallization Process

Solubility data, scoping crystallization experiments, and metastable zone width experiments are used to determine the best initial strategy. On and off-line monitoring during the course of the crystallization provides a valuable insight into nucleation and growth of the crystals as well as the polymorphic form.

### Process Analytical Technology and Quality by Design

We welcome the FDA's Process Analytical Technology (PAT) draft guidance. Science-based decision models and quality by design have always been our preferred approach to process and product development, and we have substantial insight and expertise to offer our clients in many areas of automated analysis and control.

### Crystallization Optimization – What we offer

We can design, optimize or troubleshoot your crystallization process for product purity, recovery or solids separation and isolation. We can provide you with knowledge and understanding of your process to give rise to fewer operation problems by means of:

- Polymorph Investigations
- Control and Measurement of Impurities
- Kinetics of Nucleation and Growth

- Crystal Size Distribution Measurement and Modification
- Habit Modification
- Filtration Studies
- Drying Investigations

### Design of Experiment (DOE)

We use DOE software coupled with laboratory experiments to design and validate process steps.

### Bulk Property Design

We can design a crystallization process that gives your drug substance the bulk properties you need, reduce variability of drug substances and drug products, and achieve sameness and control in drug substance and drug product manufacturing processes. Our clients can call on us to address specific problems in process development.

### Additional Aptuit Capabilities

Aptuit offers a comprehensive suite of drug development services that range from candidate selection through to market, including consultancy services, API development and manufacture, preclinical and clinical technologies, pharmaceutical services, large and small scale manufacturing, IVRS, and clinical packaging and logistics, across a wide range of compounds, dosage forms and delivery systems.

For information about Aptuit's services, please call or email:

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**Engineering a better drug development process.**