



CML'S SOLID STATE CHEMISTRY SERVICES

- **Crystallization Study** – Crystallize to obtain stable solids, for purification or isolation
- **Material Characterization** – Polymorph identification
- **Solubility Determination** – In production solvents and buffer solutions
- **Salt Selection** – Suitable form selection
- **Polymorph Study** – Behavior in production solvents
- **Crystallization Process Development** – Combine optimal synthesis conditions with optimal crystallization conditions
- **Crystal Habit Optimization** – Control of particle size and shape

Cambridge Major Laboratories (CML) has established a new Center of Excellence for Crystallization and Solid State Chemistry in our Active Pharmaceutical Ingredient (API) development facilities in the Netherlands. Significant investments have been made in equipment and personnel as part of CML's expansion into solid state services.

FormSelect™

Are you approaching candidate nomination? This is a key milestone in all drug development programs, and often directly linked to your next round of funding. Many times the HCl salt, or the free form of the molecule is taken as a default into toxicology studies. After all, this was what was generated in the medicinal chemistry phase. Unfortunately, many compounds have been rejected due to suboptimal properties, whereas the choice of a different (salt) form might have improved solubility and stability considerably. Don't let your next compound get rejected in early development due to sub-optimized form.

FormSelect is the CML approach to risk-mitigation in the early development phase. Polymorphic behavior and stability of a range of free form(s) and salts are studied in parallel, maximizing your chances of success.

By using only pharmaceutically-acceptable counter ions and solvents, and applying only scalable crystallization methods, a directed experimental program will rapidly generate information to aid in the selection of a "developable" form of your API.

CML employs state-of-the-art crystallization tools and highly experienced experts in drug substance solid state chemistry to drive your program. Make the right choice with FormSelect!

ProCryst™

ProCryst is the combination of CML's leading position in PROcess chemistry with CRYSTallization science to provide our clients the most optimal solutions ranging from polymorph studies to optimizing crystallization conditions along a synthetic pathway.

How many times have you lost yields, or extended cycle times because an intermediate is difficult to filter, or product is lost to the mother liquors? In a world where development timelines are continually squeezed, there is an opportunity to optimize the drug substance development path by having the solid state chemist work in close collaboration with the process chemist at every step of the synthesis pathway. This is the essence of CML's ProCryst approach. Careful project management allows the developmental chemistry results to feed into the program, helping to direct the best choice of solvents and conditions.

EQUIPMENT:

- **Symyx Crystallization Platform** – Well-plates
- **Crystal16™ Parallel Crystallizer** – 1 ml Scale
- **Radleys Parallel Crystallizer** – 10-250 ml Scale
- **Mettler-Toledo LabMax** – 1L Scale

ANALYTICS

- **Bruker D2 XRD**
- **TGA**
- **HPLC**
- **Ion Chromatography**
- **Optical Microscopy**
- **SEM**
- **DSC**
- **FT-IR**
- **¹H-NMR**
- **KF**
- **HSGC**