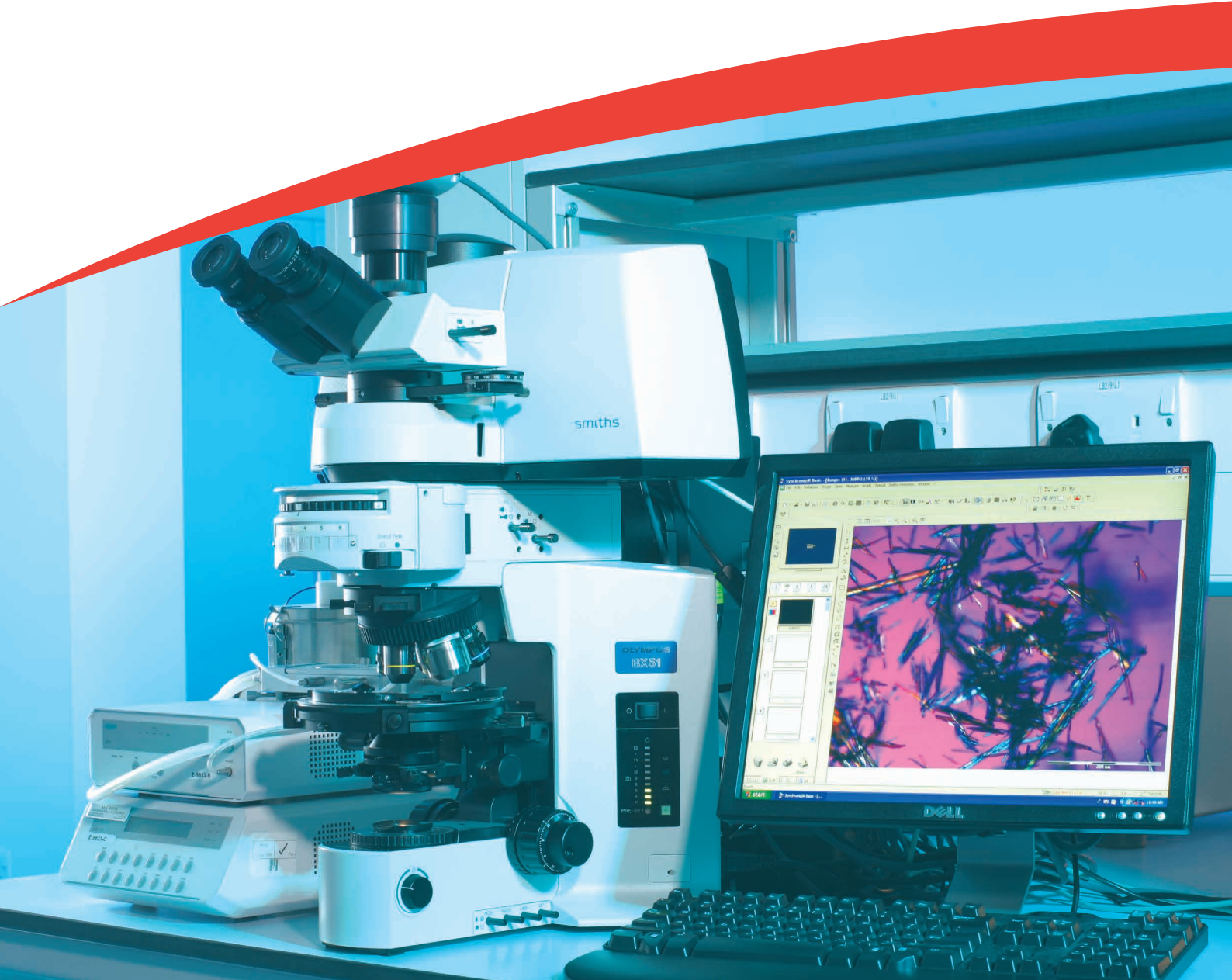




Partnering to Advance Human Health

Solid State Services

- Supporting you through the entire drug lifecycle
- Serving over 150 clients, from virtual to multinational
- Uniting process chemists, analysts & formulators in one team
- Screening services tailored to your compound
- Developing crystallisations and scaling-up under GMP
- Developing methods for release of API and drug product
- Troubleshooting issues with dissolution, physical form & particle size
- Enabling the development of your API through optimal solid form selection & appropriate early formulation strategies



Solid state services

Almac's Physical Sciences group unites chemists, analysts and formulators in one team adding value through synergy.

Identifying and consistently producing a drug in its optimal physical form is vital to any successful drug development programme. At Almac, our services are tailored to client needs and driven by science rather than robotics. Our Physical Sciences group have delivered screening, troubleshooting and analysis solutions for over 150 virtual, biotech and large Pharma clients, thus contributing to the success of many drug development programmes.

Regulatory authorities require that manufacturers demonstrate their understanding of the processes that influence the physical form and powder properties (e.g. particle size distribution) and have the means to robustly monitor and control them. We can develop and validate processes and methods to control and deliver the desired form during scale-up, troubleshoot existing problems, and provide support in intellectual property.

Our solid state support system does not end with the selection of the therapeutic physical form, our services span the entire drug lifecycle (Figure 1). By uniting experienced chemists, analysts, and formulators into one team, you will benefit from a holistic overview of each phase of development, assisting you to make the right decisions at the right time.

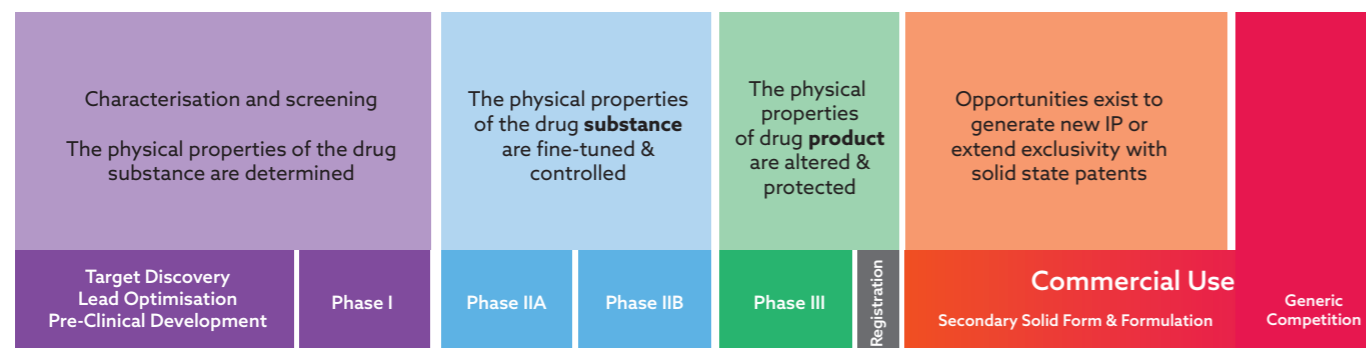


Figure 1.

Our capabilities

Expertise	Almac Approach
Preformulation	The synergy of solid state chemistry and formulation development in one team adds value and shortens the timeline of your pre-clinical project.
Polymorph Screening	A phase appropriate, manual investigation conducted by experienced specialists and tailored to client needs. Published studies show that this approach matches or exceeds the success of high throughput screening.
Salt & Cocrystal Screening	Intelligent design of screening methods and selection of co-formers. We support our clients in selection and control of the optimum form for development and intellectual property.
Amorphous Solid Dispersions	Using our formufast™ platform, we can rapidly identify the most suitable polymers at the correct concentration for further development. Prototypes are generated by various methods, characterised and their stability assessed.
Solid State Analysis	No project is too big or too small. You will benefit from the experience gained on thousands of studies that range from routine characterisation to complex method development and validation for release of marketed products utilising our extensive range of state-of-the-art equipment.
Crystallisation Development	We have expertise in generating the first crystals from a few milligrams right through to particle size and physical form control during large scale operations including support of GMP manufacturing.
Analytical support for GMP manufacture & stability studies	We undertake characterisation for batch release, in process control and analytical support for stability studies for API and drug product.
Troubleshooting	With a wealth of experience in the analysis and manufacture of drug substance and drug products, we are perfectly placed to rapidly troubleshoot any issues encountered over the entire life cycle of a drug, e.g. dissolution failures, control of polymorph and particle size.
IP & Legal Support	We provide consultancy and expert witness services for infringement and Paragraph IV cases, and technical support to overcome patent rejections and oppositions.

Case study

Integrated services for drug substance and drug product: an early phase case study

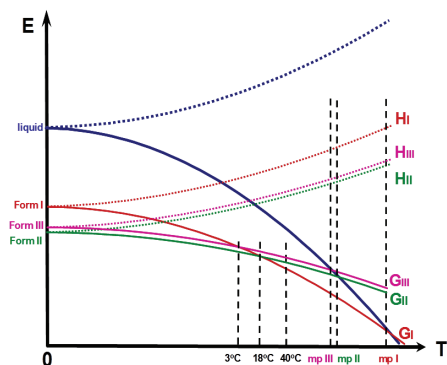


Figure 2.

- Our client in-licensed a BCS class 1 API and contracted Almac to supply powder in capsules for Phase 1.
- Our formulation team noticed differences in flow between API batches during manufacture and involved the Solid State team in troubleshooting. Analysis showed that all preclinical and Phase I batches were different, leading to a polymorph screen.
- We found a complex system of three polymorphs (Figure 2), and a hydrate, where mixtures of forms were very common. One of the forms was found to have excellent compaction properties and we supported our client through patent opposition to secure valuable Intellectual Property (IP).
- Almac helped develop a crystallisation and isolation control strategy so the API manufacturer would obtain the stable form every time.
- To date, we have completed Phase 1 capsule manufacturing, developed analytical methods to monitor physical form, performed stability studies on drug product and supplied radiolabelled materials for metabolic studies.

Get in touch

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