ipca | onyx scientific

www.onyxipca.com

Expert Integrated Solid Form Development services

Onyx Scientific is the CDMO division of Ipca Laboratories.
Our MHRA-licensed sites in the UK specialise in offering an integrated solid form, preformulation, crystallisation and chemical development service that facilitates manufacture of candidate APIs for clinical phases through to commercial supply.

Our dedicated teams provide full-service, independent, outsourced projects to complement or support your in-house campaigns in addition to our integrated full service approach. With a wealth of early phase development experience and success, we focus on rapid process development with a view to future GMP campaigns.

Where required, scale-up through Phase II towards commercial manufacture is retained either at Onyx or within the Group through transfer to our sister sites and colleagues in the USA and India.

Our Approach

We use solid state chemistry to mitigate risk throughout the development process by gaining an in-depth understanding of the physicochemical properties of your active pharmaceutical ingredient (API).

We take an adaptive and collaborative approach to development, flexing with your needs and working closely with you to help you meet your crucial milestones.

The combined expertise of our leadership group and our dedication to our partnership ensure that the right decisions are made to progress your product from development through to commercialization.

Our Capabilities

Early phase lead profiling screens

It is not unusual late in the Discovery Phase to be presented with more than one suitable candidate molecule. Alongside in vitro potency and ADMET predictions, solid form material characterisation and preformulation performance testing can help to differentiate which to select.

We offer a lead differentiation screen using 250-500 mg of material that can help to select the optimum structure to take forward.

Salt and Co-crystal Screening

In the early stages of your product's lifecycle, we recommend a thorough performance evaluation of your API to determine whether a salt or co-crystal version is required and developable.

As part of our preformulation activities, we perform in-depth salt screening and a risk/benefit assessment of appropriate versions. This includes identifying biorelevant dissolution and solubility characteristics to help inform your future development strategies.

Polymorphic Screening

Early in the development lifecycle, we can define the ideal polymorphic variant of your API using a robust yet pragmatic screening approach and articulating in detail its available solid state landscape.

Polymorphic screening allows us to map out the characteristics of your molecule, identify potential development challenges and therefore de-risk the transition from discovery into clinical manufacture and beyond.

Your molecule, our people - it's good chemistry

Preformulation

In the preformulation stage of your drug development journey, we analyse the characteristics and behaviours of your API to determine its optimal solid state.

We examine the chemical stability, solid state stability, shelf-life and solution behaviour of your chosen version, both in the presence and absence of excipients, enabling us to identify and troubleshoot any solubility-related issues early in the development phase.

Crystallization Development

A critical stage in your drug's development journey is the study of crystallization and the identification of a purifying recrystallization, or salt forming crystallization.

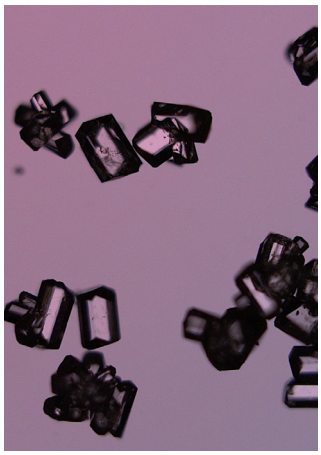
Our solid state chemistry teams work together to ensure that process-typical material is well defined and its behaviour can be contrasted with that of the pure phase.

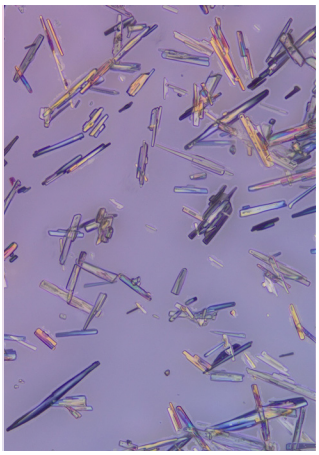
We'll successfully navigate complex solid state challenges with state of the art equipment and gain a robust understanding of the unique attributes of your molecule, allowing us to ensure that your chosen solid form can be reproduced at scale.

Chiral Resolution Screening

An extension of our solid state chemistry services, our chiral resolution screening enables us to crystallize and isolate your enantiopure API.

Conducted in parallel to screening phases, our well-established approach selects the most efficient processes to enable the straightforward isolation of your bulk enantiopure product.





Crystallography

Across all our screening activities, we endeavour to isolate candidates fit for single crystal structure determination. We also offer a bespoke crystallography service to grow single crystals of your molecule and provide a fully detailed report.

Milling for Oral Solid Dosage (OSD)

Our milling services help prepare your molecule for a range of formulation approaches, allowing you to deliver a product with an improved surface area to a defined particle size.

We can offer:

- Analytical-scaleballmillingtoaidyourpre-formulation assessments
- Ytron-QuadroFitzandComilmillingcapabilitiestoreducethe sizeofyoursolidformparticulatesandimproveblending
- MCDecJet30-scalablejetmillingtomicroniseyourmolecule, enablingarangeofformulationapproaches

All milling activities are supported by amorphous content determination and our in-house particle size distribution (PSD) method evaluation to take your molecule from early phase batch profiling to formal method development and validation.

Our Equipment

- Dedicated business unit and laboratories
- Panalytical XPert Pro XRPD
- Multiple Waters TA Discovery series thermal stations
- Malvern 3000 with Hydro MV
- Olympus microscopy bench
- MT82 HS-microscopy
- 2 X Hiden DVS
- PE Raman station
- MYA crystallisation parallel platform
- Blaze Micro probe
- Crystal 16 station
- Multiple Diehm reaction vessels
- Ytron-Quadro Comil/Fitz mill
- Retsch PM100 ball mill
- MC DecJet 30 - scalable jet milling
- Copley Tap/bulk density

Contact us

Commercial Manager

Chris.Atherton@onyxipca.com
+44 (0)7733 370 732
+44 (0)191 516 6518

Sales UK/EU

Courtnie.Wilks@onyxipca.com
+44 (0)7379 041 994

Sales US

Anthony.Harbour@onyxipca.com
+1 315-385-9666

Your molecule, our people - it's good chemistry