

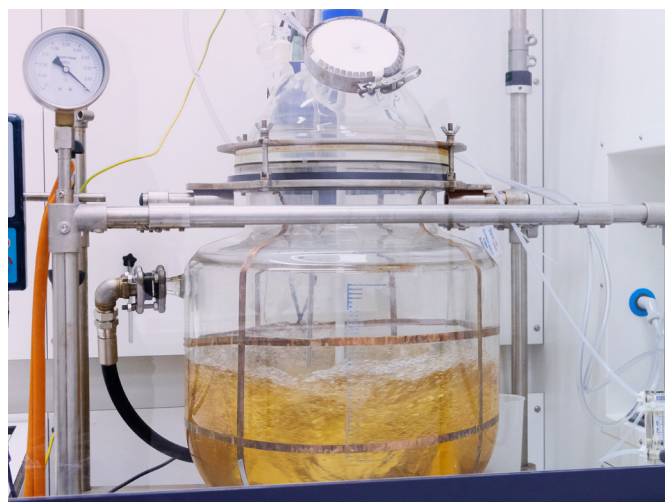
Non-GMP Large Scale Production

Onyx Scientific is the CDMO division of Ipca Laboratories. At Onyx, we perform non-GMP scale up campaigns for your small molecule API.

Our specialist production chemists scale up processes to deliver kilo quantities of materials to the highest standards, maximising efficiency and working in tandem with the development and solid state teams as part of our integrated services.

Experts in small molecule development and manufacturing

We aim to deliver reproducible quality material to the desired specifications utilising our 50L and 100L vessels and associated large scale equipment. The large-scale team is also supported by expert analytical and development staff ensuring processes run smoothly and as expected.



Kilo Lab Capabilities

Our custom-built kilo manufacturing laboratories feature 50L and 100L reaction vessels. Following process development or familiarisation, each stage of chemistry is translated to a PRS, with rigorous safety and manufacturing controls put in place. Onyx typically manufactures 3-5 kg of material per campaign (although higher volume requirements are also covered), with suitability for GLP tox studies. Certificates of Analysis and TSE statements are provided for each batch of API generated.

The synthesis of key intermediates for GMP production campaigns is also carried out in this facility, ensuring the supply of GMP starting materials is efficiently completed and is in safe hands.

Your molecule, our people - it's good chemistry

Integrated approach for maximizing efficiency and value

Throughout each campaign, the production chemists are supported by our development and analytical services. This ensures success for your compound and campaign, by putting the chemist at the centre of everything we do.

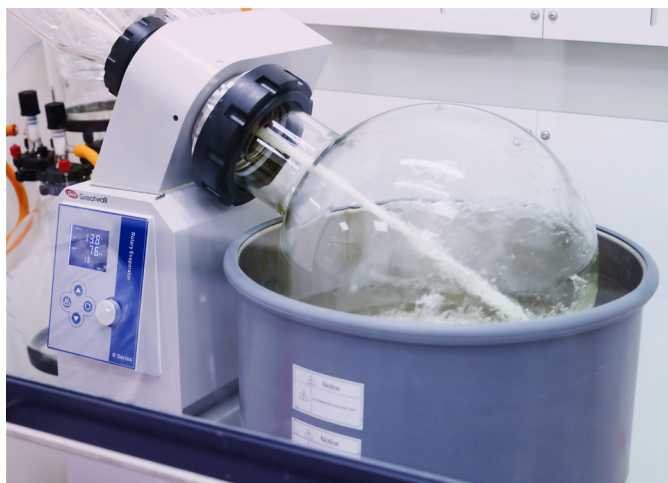
Our facilities include 4 separate laboratories, each with up to 4 x 50L or 100L vessels and a 20L rotary evaporator per laboratory. Our flexibility also allows for each suite to be modified, meaning that bench-scale chemistry or even 12kg column chromatography can be performed with ease. The facility also houses a segregated drying room for vacuum ovens and additional rotary evaporators, maximising process efficiency.

We also offer compound support services covering impurities, metabolites, and generating stable labelled compounds.

Purification

Every effort is made during development to avoid purification via column chromatography and purification via slurry or recrystallisation is normally achieved.

However, retaining column chromatography in a process is occasionally deemed pragmatic for API production for early phase. Onyx has the capability to run chromatography, utilising 12kg columns where required.



Equipment

- 50L and 100L borosilicate glass reaction vessels, each capable of maintaining an inert N₂ atmosphere for reactions and holding a vacuum of up to 0.095 MPa.
- Huber control units per vessel, allowing for precise temperature control using in-built oil jackets. This allows for TR / TJ tracking and for effective temperature ranges from -20 to 180°C
- Pressure vessels – up to 20L
- Large scale column chromatography – up to 12kg
- 20L rotary evaporators
- Dedicated lab space for small scale troubleshooting
- Dedicated oven room
- Distillation – range of columns, packing and heads
- Wiped Film Evaporator
- Milling
- HPLC for reaction monitoring
- 400MHz NMR

Contact us

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