ipca | onyx scientific

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Analytical Services

Onyx Scientific is the CDMO division of Ipca Laboratories.
Our MHRA-licensed sites in the UK provide analytical services and support to all our development and manufacturing processes, from phase I through to Commercial API manufacture.

Our Capabilities

Our analytical labs are equipped with the following instrumentation, all of which are maintained and qualified to the appropriate standards:

- HPLC-UV
- LCMS
- HRGC
- Headspace GC
- IC
- vKF, cKF & KF Oven
- Residue on Ignition
- NMR
- Prep-HPLC
- Autotitrator
- FTIR
- UV Spectroscopy
- Melting Point
- Dissolution Apparatus
- Disintegration Apparatus
- Friabilator
- Tablet Tester
- Moisture Balance
- Water Activity Meter

Analytical Method Development

Analytical method development ensures that the methods used to measure purity and potency of small molecule APIs are of high quality and suitable for a cGMP synthesis. By partnering with Onyx, our customers access a highly experienced team of analytical specialists providing expert advice to ensure all the analytical needs of their projects are met. This includes methods to support raw material release, in process/intermediate testing and final product analysis. Bespoke, highly sensitive methods are also often required for PMI analysis and these are developed and proven during this phase. All of Onyx's methods are developed with cGMP quality in mind and will be suitable for validation at the appropriate phase.

Your molecule, our people - it's good chemistry

API Stability

An understanding of API stability will be obtained during the development phase of a project, with this informing the ICH stability study. Onyx recommends a formal ICH study is carried out as soon as material is available from the developed synthesis.

Our recently upgraded stability suite has capacity to house a large number of ICH compliant stability studies under the following range of conditions:

- -20 °C
- 2-8 °C
- 25 °C/60 % RH
- 30 °C/65 % RH
- 40 °C/75 % RH

We have a flexible science driven approach regarding what tests form part of stability studies and vast experience running the studies. Results are reported and documented in a timely fashion.

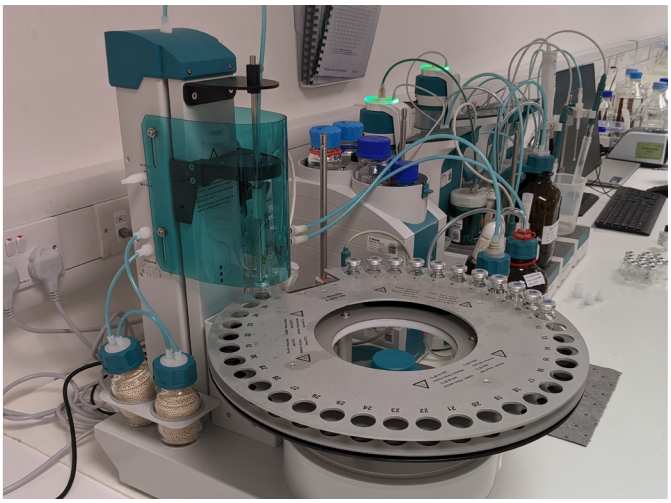
Analytical Method Validation

Our Phase I-III small molecule API analytical support includes reference standard characterisation, forced degradation and method validation.

During early phase, the main API purity methods are validated as standard. This typically includes the HPLC achiral and chiral (if appropriate) methods and GC headspace for solvents. As part of the validation activity and to understand the stability of the API, a forced degradation study is carried out which provides evidence that the method is stability indicating.

A fully characterised reference standard of the API is also produced to support HPLC assay analysis.

During late phase development, further validation is carried out on the final API methods including all specified impurities, PMIs and all methods used in the GMP stages of the synthesis.



Analytical Support

The developed and validated methods are used to support all the manufacturing which takes place at Onyx. This analysis is performed in both GMP and non-GMP environments. Our team will produce and adhere to monographs and work with our quality management system, producing non-conformance, out of specification and change controls where necessary. This documentation is key to the quality of the material we produce.

A Certificate of Analysis (CoA) always accompanies any final product which is produced at Onyx.

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

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