Our outsourcing services

For companies developing their own reference materials LGC Standards can also be a strong partner: LGC Standards provides a broad range of modular services which enable you to outsource single process steps.

This delivers great flexibility, efficiency and cost savings, allowing you to focus on your core competences.

Our services:

- Sourcing of candidate material
- Quality control of the candidate material
- Packaging of material
- Characterisation according to ISO 17025
- Certification
- Temperature controlled storage of reference materials
- Distribution according to your needs

Materials science

Furthermore, we provide intellectual input and experience to help solve pharmaceutical problems within materials science and other analytical disciplines. We draw upon an intimate knowledge of drug delivery from early discovery and research support to late stage manufacturing, licensing and development troubleshooting to provide novel solutions using cutting edge technology, ensuring that your project is fully supported to a successful conclusion.

Extractables and leachables

LGC also has great experience and knowledge of the regulations around extractables and leachables for the medical device and pharmaceutical industry. We provide a comprehensive service from the initial assessment of all materials used, particularly elastomeric, rubber and plastic components, through to the development and validation of methods for routine analysis. Our extensive capability in the characterisation of unknowns combined with custom synthesis expertise also enables us to cope with issues that may arise in the most cost effective manner.

LGC Standards

Excellence through measurement

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LGC Standards

Excellence through measurement

Pharmaceutical services and products

About LGC Standards

LGC Standards is the global leader in the production and distribution of pharmaceutical reference materials. Our extensive range of impurities and active pharmaceutical ingredients (API) reference materials as well as custom-made research materials enable superior accuracy in measurement science, and compliance with international regulations. LGC's production facilities in Europe have an unparalleled depth of capabilities from sourcing and synthesis through to characterisation and certification. Our wealth of experience is sure to add value to your business.

In addition to our in-house services, LGC Standards also offers a comprehensive catalogue of materials from the world's Pharmacopoeia, and third party materials relevant to the pharmaceutical industry.

LGC Standards is a part of the LGC Group, which serves as National Measurement Institute for chemical and biochemical measurement in the UK, a role equivalent to NIST in the US.

Pharmaceutical impurities

Impurities are always present in a drug substance and can significantly alter a drug's effects and side effects. Limit and threshold values are required by official bodies such as FDA, MHRA and BfArM, as well as legislation like European Commission Directive 2003/63/EC, Annex 1. To detect, identify, quantify and qualify impurities in accordance with the International Conference on Harmonisation (ICH) Guidelines LGC Standards has a catalogue of over 2,800 impurity reference substances developed over 15 years serving the pharmaceutical industry. Our impurity standards are of the highest purity, and come with the most extensive certificate of analysis on the market, affording you greater analytical certainty. Our impurity standards allow for exact identification and characterisation for correct results, and can eliminate the need for expensive ICH characterisation studies.

Custom synthesised impurities and their reference standards

LGC Standards custom synthesis is a special service to customers who need a specific impurity standard which is not available in our catalogue range as it is a unique product. All kinds of impurity standards are possible – from ordinary pharmacopoeial impurities to deuterated substances – with the desired purity and characterisation, in batch scales from milligramme to kilogramme.

Furthermore, LGC Standards offers custom-made primary reference standards, traceable secondary standards and working standards for quantitative and qualitative purposes.

APIs can be synthesised as well, but strictly for analytical purposes.

Pharmaceutical primary standards

Pharmaceutical primary standards are set up to facilitate the accurate measurement of APIs.

LGC Standards can produce these materials on a custom basis when no official standards from the pharmacopoeias are available for the given purpose.

This helps save time and cost for a pharmaceutical producer, allowing you to focus on core analytical activities. All primary standards from LGC Standards come with a detailed certificate of analysis, including explicit identity information and purity data, made to your specification.

Pharmaceutical secondary standards

Secondary standards are often set up against primary standards whenever a substance is used in daily routine analysis and where using a primary material would be un-necessarily expensive. This approach is widely acknowledged, by both regulatory authorities and the pharmacopoeias. In order to save you time-consuming set-up processes LGC Standards offers custom-made secondary reference standards which are compared to USP, Ph. Eur. or BP and accompanied with an advanced certificate of analysis.

We also have extensive experience of setting up secondary standards based on custom primary standards which we have provided. Furthermore, they are accepted by regulators and pharmacopoeia commissions worldwide and produced under GLP/GMP or ISO 17025 compliance.