

Impurities in Drug Products

.Structure Elucidation . Isolation . Synthesis
.Qualification .Storage & Shipment



Analytical Services
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Unknown impurities in the product

Impurities are unknown by-products or degradation products in APIs and finished drug products. They occur not only during the early phase of development of medicinal products but also, for example, during stability tests or when changes are made in formulations. There are many different reasons for this: e.g. other synthesis paths, interactions with excipients and packaging materials, polymorphic transitions, etc. If the concentration of a by-product and/or degradation product exceeds a specified limit value, the structure of this impurity must be determined. Structure elucidation is frequently followed by the targeted synthesis of the impurity and the analytical qualification of the impurity as a reference standard.



Genotoxic impurities

Genotoxic impurities, in particular, are at the focus of attention of the regulatory authorities (FDA, EMEA). Low limits of detection in the trace range (ppm, ppb) presuppose the existence of special analytical techniques for detecting these substances.

Highly potent substances

Highly potent substances and narcotics require special logistics, handling and sample preparation procedures.

Reference substances

Qualified reference substances are required for method validation, screening and pharmacokinetic studies. These are isolated via preparative chromatography or produced by chemical synthesis.

GMP storage

Precisely monitored premises are required for the storage of reference substances. Sampling, packaging and shipping must conform to the requirements of the medicinal product guidelines.

Time and cost controls

Customer-oriented project management, regular teleconferences and transparent transmission of information are basic prerequisites for successful services.



Services

- . Structure elucidation with state-of-the-art analytical techniques
- . Preparative isolation, synthesis and characterisation of by-products and degradation products
- . Qualification, storage and shipping of reference standards with a GMP certificate
- . Analytical methods for highly potent substances and narcotics
- . Efficient project management

Analytical methods

- . Preparative and analytical HPLC (chiral and non-chiral)
- . High-field NMR (700 MHz)
- . GC/MS and LC/MSn
- . Synthesis capacity: up to 500 grams
- . Radiochemical syntheses
- . GMP storage and monitored transports

About us

- . We are a flexible owner-run medium-sized company with short paths
- . We have been providing analytical chemical services for pharmaceutical companies worldwide for more than six years
- . Our team of scientists speaks our customers' language
- . The projects and goals of our customers are our motivation