HIGH QUALITY
HWI REFERENCE STANDARDS
LOW COSTS

Reference Standard Services

Contact

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HWI group

Our reference standard concept offers every pharmaceutical company the required high-quality reference standard for the intended use at an attractive price/performance ratio.

Reference Standard Services

Benefit from our more than 25 years of experience in producing, purifying, qualifying and supplying pharmaceutical reference standards. With our expertise we are your perfect partner in the complete management of your standards. We provide a comprehensive variety of reference standards for R&D and QC:

Primary reference standard (assay)

› Identity: ^{1}H-NMR, ^{13}C-NMR, MS, UV spectrum
› Chromatographic purity (validated HPLC/GC separation systems)
› Assay: quantitative ^{1}H-NMR
› Residual solvents (validated GC separation systems)
› Water content (Karl Fischer)
› Batch-related certificate of analysis (CoA)
› Retest date, storage conditions
› Full documentation of methods, validation data, spectra, chromatograms

Working standard (assay)

› Intercalibrated against comprehensively qualified primary reference standard assay
› Batch-related certificate of analysis (CoA)
› Reference to used batch of primary reference standard for intercalibration
› Intercalibration method
› Retest date, storage conditions
› Full documentation of primary reference standard used for intercalibration available for 10 years

Ident purity standard

› Identity: MS, UV spectrum, HPLC/GC retention time
› Chromatographic purity (HPLC/GC)
› Batch-related certificate of analysis (CoA)
› Retest date, storage conditions

Your benefits

› Tailor-made reference standard concept according to client's needs
› No initial investments
› Linear cost allocation during the contract period (fixed costs per month)
› Fixed rate without fluctuations
› No additional effort in storage, retesting and quality assurance
› Reduction of administration and invoicing

Our Service Package

Easy-to-handle standards

The reference standards show good flowability and crystallinity, which enables perfect handling.

Portioning

All reference standards are bottled, optionally under inert gas, in amber glass bottles with a secure twist cap and wide bottle opening or in amber glass ampoules. The portions can be filled for individual needs. Our standards are ready to use for your analysis.

Packaging

Our reference standards are packaged in leakproof aluminium bags as secondary packaging. This packaging offers optimal protection from external influences over a very long storage period under extreme storage conditions.

Transport and distribution

We take over the global just-in-time delivery of the reference standards in substance-specific packaging, thus ensuring safe delivery of the reference standards.

Storage

All reference standards are stored under controlled climatic conditions in accordance with GMP requirements. We supply portions or analysis as required according to the just-in-time policy.

Retests

As part of our stability programme we frequently perform retests of our reference standards with specifically developed and validated testing methods. Consequently no expenses are incurred for you for transferring and establishing testing methods.

GMP

All HWI reference standards are processed and tested in our GMP-certified laboratories. The standards are of a defined quality and fully comply with the statutory and regulatory requirements. HWI reference standards are extensively verified according to the latest scientific and technical research for their intended use.

HWI group

HWI group provides a wide range of individual and specialised services for the pharmaceutical, medtech and biotech industries, in particular for drug substances, drug products and medical devices. Over the last 25 years, our company group has gained a wealth of regulatory as well as scientific knowledge and long-term experience to support our clients. Our services are divided into five business units – Laboratory Services & Quality Control, Reference Standard Services, Vigilance & Quality Services, API Characterisation & Drug Development and Regulatory Affairs Services & Life Cycle Management.

your success is our success