With 25 years' experience we are your partner for pharmaceutical analysis and quality control. Next to development and validation of analytical methods, batch release testing, stability testing and structure elucidation, the risk-based and solution-oriented consultation of our clients is one of our core competencies.

With our long-term experience in trace analysis we offer the complete management and laboratory services for extractables & leachables studies, cleaning validation studies and the investigation on genotoxic impurities.

Our project leaders with years of experience in the CMC field together with more than 40 employees in our analytical laboratories implement our clients' requirements, target-oriented and efficiently, supported by lean-management tools.

Contact

For any questions concerning our services, please contact us!
We are looking forward to assist you!

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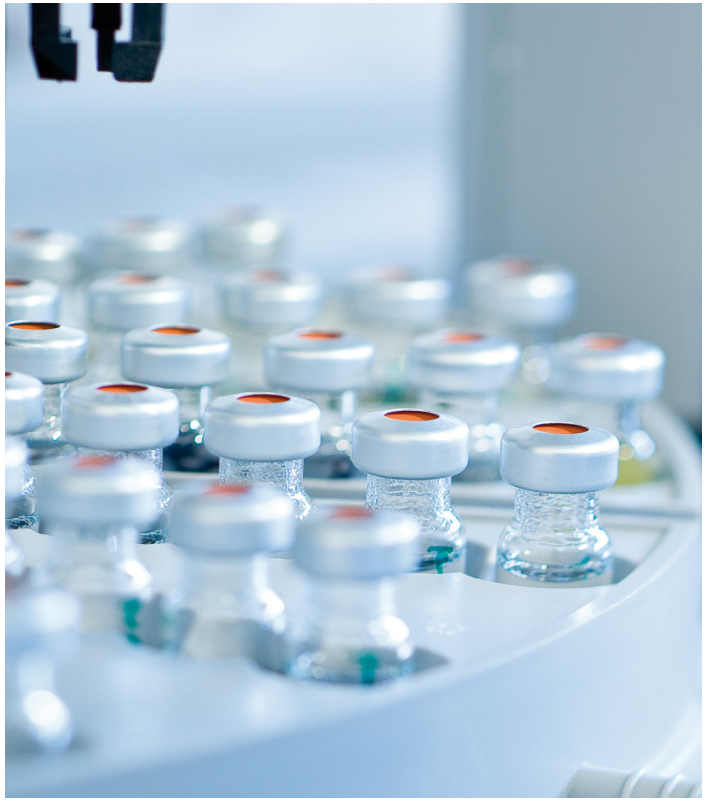
HWI group



Impurities

HWI group – your experts in purity testing of particular impurities and trace analysis

HWI group

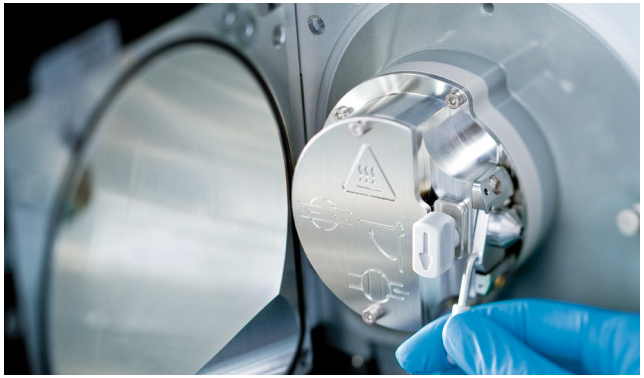
Impurities from API synthesis and degradation products

- Development and validation of chromatographic testing procedures for purity testing of APIs and finished products as well as medical devices and drug-device combination products
- Development of stability indicating methods including stress testing according to ICH Q3A & Q3B
- Identification of impurities and related substances using mass spectrometry (GC-MS/LC-HRMS) and NMR
- Isolation of impurities using (semi-)preparative LC
- Qualification and distribution of purity reference standards
- Consulting for setting up specifications & toxicological evaluation of impurities

Nitrosamines

HOT TOPIC

- Supporting the preparation of product specific risk assessment
- Development and validation of analytical methods
- Batch release testing/stability sample testing (APIs, excipients, drug products) for NDMA and NDEA, as well as for NMBA, DIPNA and EIPNA based on FDA methods



Extractables & leachables: investigation of packaging materials

- Individual set-up of extractable studies based on packaging material and product composition
- Identification of extractables using in-house LC-HRMS and GC-MS methods
- Toxicological evaluation of extractables and potential leachables
- Development and validation of leachables method based on results of extractable studies
- Migration studies within stability testing for investigation of leachables

Potentially genotoxic impurities

- Development of control strategies according to ICH M7
- Review of synthesis pathways
- Trace analysis and ultra-trace analysis including analytical method development and validation for potentially genotoxic impurities (PGIs)
- Setting up specifications according to TTC approach

Troubleshooting in production issues

- Express services for investigation of production issues including root cause analysis
- Structure elucidation of organic impurities using in-house screening methods with LC-HRMS and GC-MS
- Investigation of inorganic impurities using SEM-EDX and ICP-OES/MS techniques
- Determination of particles using x-ray micro/nano tomography, micro-CT and RAMAN microscopy/ chemical imaging
- Particle size distribution using Malvern Mastersizer & Helos

Residual solvents

- Product-specific validation for residual solvents according to Ph. Eur. 2.4.24 and ICH Q3C
- In-house method for high-price samples using very low sample amounts
- Identification of unknown residual solvents using GC-MS and NIST database