HWI group

Laboratory Services

www.hwi-group.de

Our Services for Pharma, Biotech and Medtech

HWI group

- Method development and validation
- Purity testing of particular impurities – trace analysis including structure elucidation
- Troubleshooting (root cause analysis)
- Extractables & Leachables testing
- Batch release and stability testing
- Reference standards for quality control

Experts and Expertise

- Certification
  - GMP certificate
  - FDA approved
  - Manufacturing licence
- Our people for your success
  - 12 project leaders
  - 30 technicians
  - Administrative staff

Core Competencies

Quality control for APIs, intermediates, excipients and drug products as well as medical devices and drug-device combination products

- Small molecules
- Peptides
- Proteins
- Narcotics
- High potent APIs up to OEB 4
- Herbals

Core Competencies

Development & validation

- For assay, purity and drug release
- Chromatographic methods
- Titration testing procedures

Routine testing

- Batch release testing / quality control
- Stability studies and stability storage facilities (25°C/60%, 30°C/65%, 30°C/75%, 40°C/75%, 2-8°C)
- Photostability studies

Purity testing – trace analysis

Extractables/leachables studies

Potentially genotoxic impurities

Cleaning validation studies

Elemental impurities

Residual solvents

Troubleshooting & root cause analysis: impurities from production processes

Structure elucidation using mass spectroscopy and NMR

Modern analytical physical methods:
SEM-EDX, Raman, XMT

Consulting

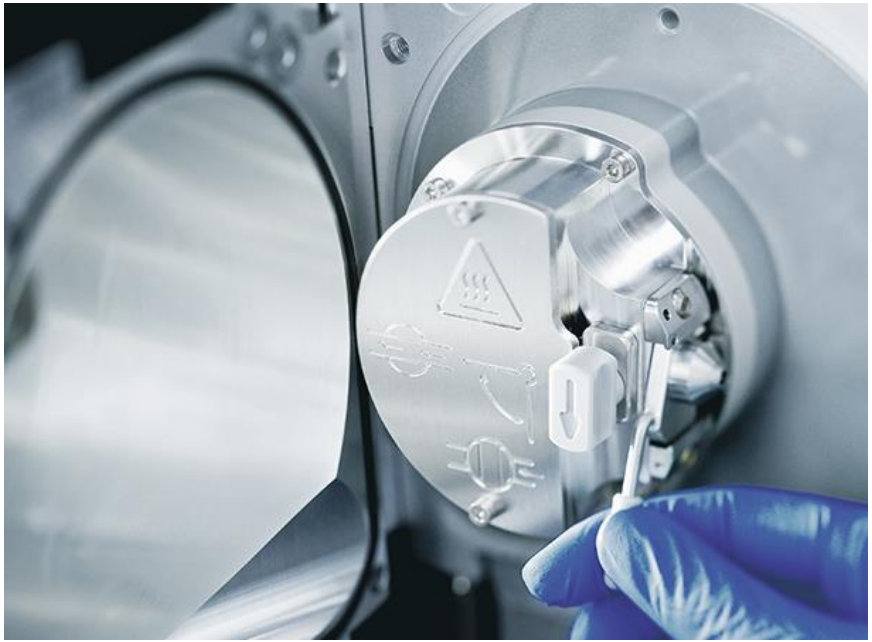
- Risk-based evaluation of product quality
- Review of specifications, analytical procedures, validation reports according to regulatory requirements
- Gap analysis of module 3 together with our experts from regulatory, drug development and manufacturing

Chromatographic Equipment: HPLC / UPLC

- 30 Waters Alliance HPLC systems equipped with
  - UV/DAD detection, fluorescence detection, refractive index detection, evaporative light scattering detection, conductivity detection, pre- or post-column derivatisation equipment
- 4 UPLC Waters Aquity systems with DAD detection
- 2 H-Class Waters systems with DAD detection, fluorescence detection
- 4 Acquity Arc Waters HPLC systems equipped with DAD detection
- Spark SPE trapping system

Chromatographic Equipment: LC-MS

- Mass spectrometry equipment
  - Triple quadrupole mass spectrometers (Quattro Micro and TQD) for routine analyses, coupled with UPLC
  - QToF (time of flight) mass spectrometer for structure elucidation via determination of exact molecular masses (high-resolution mass spectrometry), coupled with H-Class
  - New QToF system, for both the analysis of small and large molecules, e.g. peptide mapping, post-translational modifications (Q1/2022)



Chromatographic Equipment: GC and GC-MS

- 7 Agilent GC systems
  - Flame ionisation detection (FID)
  - Thermal conductivity detection (TCD)
  - Split/splitless or headspace injection
- Mass spectrometry equipment
  - 5975C XL quadrupole mass spectrometer
  - 5977A quadrupole mass spectrometer

Further Equipment

- 9 Dissolution tester
  - Paddle/basket apparatus with manual or automatic sampling (Sotax, Erweka, Varian)
- Qualitative and quantitative thin layer chromatography
- Titration equipment
  - Assay determination
  - Volumetric or coulometric Karl-Fischer titration
  - Water determination by Karl-Fischer oven
- AAS (Agilent & Perkin Elmer, flame & graphit furnace)
- UV/VIS Photometer
- Photostability testing
- Refractive index, density, pH, osmolarity, disintegration, viscosity, particle size distribution

Special Techniques for Proteins, Peptides and Oligonucleotides

- (U)HPLC: chromatographic characterisation
  - RP: assay and purity determination
  - SEC: protein homogeneity, molecular weight, oligomeric state (active and inactive portion)
  - Evaporative light scattering detection: protein purity (for example determination of free PEG in solutions of PEGylated protein)
  - Charged aerosol detection (CAD): lipids, carbohydrates, excipients
- Tecan fluorescence plate reader
  - Binding experiments (ELISA, FRET)
  - Fluorescence based enzymatic assays

Special Techniques for Proteins, Peptides and Oligonucleotides

- BioAnalyzer (Agilent)
  - determination of protein size, purity and homogeneity
- UV spectroscopy
  - UV absorption: protein quantification
  - Biuret assay: colorimetric determination of the protein concentration
  - TNBS assay: determination of primary amines (for example quantification of protein PEGylation)
- Capillary electrophoresis
  - Protein purity, charge heterogeneity, glycan analysis, small molecules

Reference Standards

- > 25 years of experience: isolation and qualification of pharmaceutical reference standards
- Assay: Primary reference standards and working standards with documentation and batch-related CoA
- Identity-purity standards
- Fullfillment of regulatory requirements in the GMP environment
- Global distribution and „just in time“ delivery
- Customised portioning
  - Primary packaging in amber glass (inert gas filling optional)
  - Secondary packaging with quality controlled leakproof aluminium bags for light & humidity protection

Qualification of Primary Reference Standard for Assay

- Dossier and batch-related CoA
- Analytical methods, validation and evaluation
- Identity: 1H-NMR, 13C-NMR, MS, UV
- Chromatographic purity: HPLC or GC
- Content: quantitative NMR
- Residual solvents (2 validated GC separation systems)
- Water content (Karl-Fischer, coulometry)
- Inorganic impurities if applicable
- Stability Data
- Date of release and retest date
- Storage conditions

Timelines

- **Contracts**
  - Templates for CDA, QAA, MSA, etc. could be provided within 2 days
  - Proposals for contracts from customer will be reviewed within a week
- **Quotations**
  - Provided within a week after all relevant information are available
- **Start of analytical work**: method development / validation / stability study within 2 – 3 weeks after final order
- **Method development**: depending on API / impurities, 2 – 4 weeks
- **Method validation**: 3 – 4 weeks including final report
- **Stability studies**: start of storage within 2 weeks after receiving samples, analytical work within 2 – 4 weeks / testing point depending on specification
- **Express services available e. g. for troubleshooting / urgent issues**

Our Services

HWI group

Laboratory Services

Vigilance & Quality

Drug Development

Regulatory Affairs

Thank you for your attention.

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