HWI group

Laboratory Services

Experts and Expertise

Certification

- EU-GMP certificate
- FDA approved
- Manufacturing license

Our people for your success

- 8 project leaders
- 23 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
- Oligos
- Narcotics
- High-potent APIs up to OEB 5
- 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 in 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

HPLC / UPLC

Chromatographic Equipment

- HPLC systems equipped with
  - UV/PDA detection
  - Fluorescence detection
  - Pre- or post-column derivatisation equipment
  - Refractive index detection,
  - ELSD
  - Conductivity detection
- UPLC systems with
  - PDA detection
  - CAD detection
- (U)HPLC systems with up to 6 colums, integrated column ovens, for rapid analytical method development

LC-MS

Chromatographic Equipment

- UPLC systems with MS equipment
  - QToF (time of flight) mass spectrometer for structure elucidation via determination of exact molecular masses (high-resolution mass spectrometry)
  - ZenoToF system, for both the analysis of small and large molecules, e.g. peptide mapping, post-translational protein modifications

GC and GC-MS

Chromatographic Equipment

- GC systems
  - Flame ionisation detection (FID)
  - Split/splitless or headspace injection
- Mass spectrometry equipment
  - 5977A quadrupole mass spectrometer

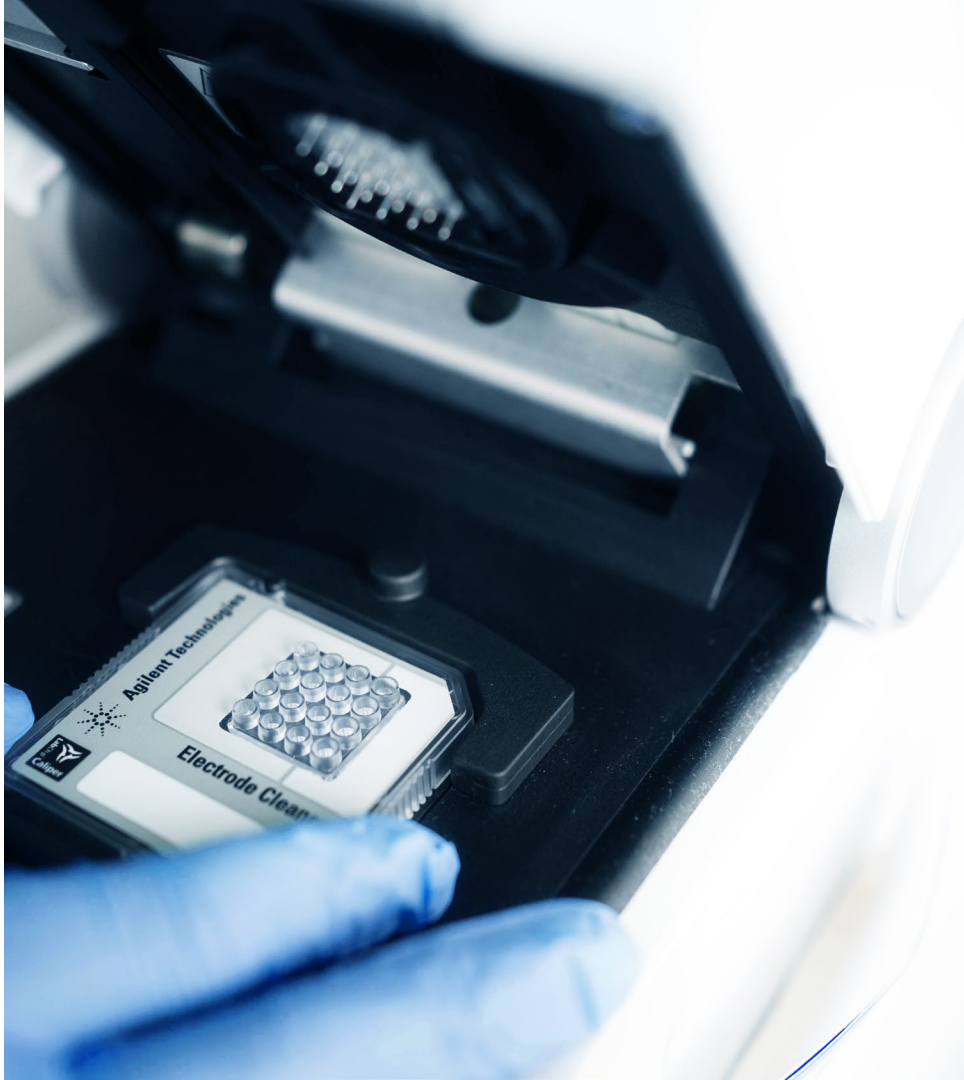
Further Equipment

- Dissolution tester
- Paddle/basket/flow through cell apparatus with manual or automatic sampling
  (Sotax, Erweka, Varian)
- Qualitative and quantitative thin layer chromatography (TLC)
- Titration equipment
- Assay determination
- Volumetric or coulometric Karl-Fischer titration

- Water determination by Karl-Fischer oven
- AAS (flame & graphit furnace)
- UV/VIS Photometer
- Photostability testing
- Refractive index, density, pH, osmolarity, disintegration, viscosity, particle determination (visible, sub-visible particles)

Proteins, Peptides and Oligonucleotides

- Capillary electrophoresis
  - Protein purity, charge heterogeneity, glycan analysis, small molecules
- SDS-Page: Agilent Bioanalyzer for peptide, protein, oligonucleotide analysis
  - 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)



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
- Fluorescence plate reader
  - Binding experiments (ELISA, FRET)
  - Fluorescence based enzymatic assays

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
- Fulfillment of regulatory requirements in the GMP environment
- Global distribution and „just in time“ delivery
- Customized portioning
  - Primary packaging in amber glass (inert gas filling optional)
  - Secondary packaging with quality controlled leakproof aluminum 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. to 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

Thank you for your attention.

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