Core competences

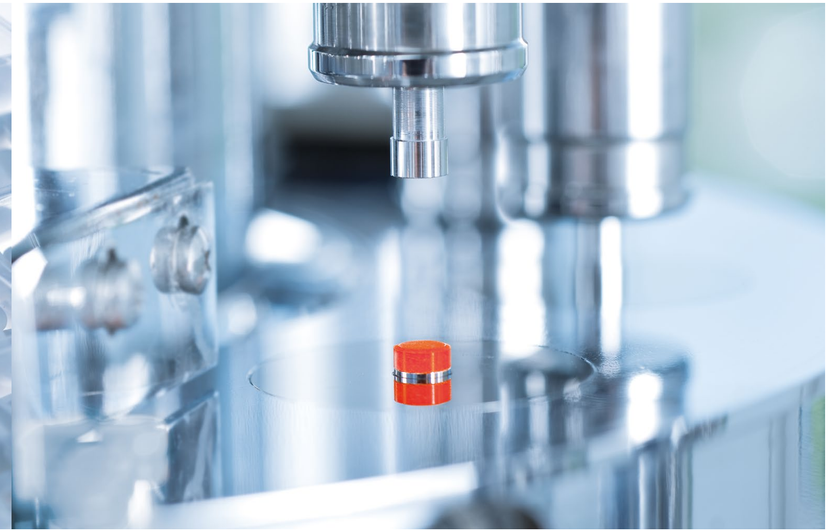
- Development of solid and liquid oral dosage forms
- Prolonged-release formulations (platform technology)
- Dry powder inhaler development and testing (platform technology)
- QbD development process
- Design of experiments (DoE) approach
- Handling of highly potent and narcotic drug substances
- GMP and non-GMP manufacturing (up to pilot batch scale)
- Manufacturing and distribution of phase I and II investigational medicinal products
- Troubleshooting (drug substances and drug products)

API Characterisation & Drug Development

Whether you wish to develop new products, improve existing ones or optimise quality, HWI development GmbH provides comprehensive support in the development of different pharmaceutical formulations.

With our highly qualified staff and the ambition to remain open to new paths, we are a successful, competent partner for all companies working in this field. We meet our clients' expectations effectively and reliably, through optimal project planning and implementation. To this end we work with tools from lean management and lean development.

We not only consistently apply the methods and processes of this streamlined, holistic management system, but also help to develop them further. Especially attractive for our clients is the energy and passion that we bring to creating marketable solutions.



Contact

For consultation or further information please contact our experts. They are looking forward to answering your questions concerning our range of services.

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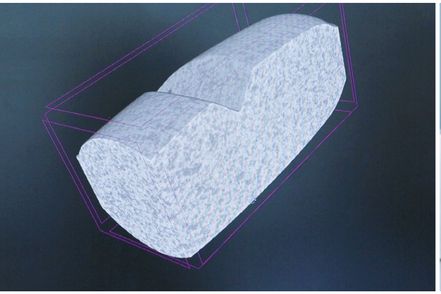
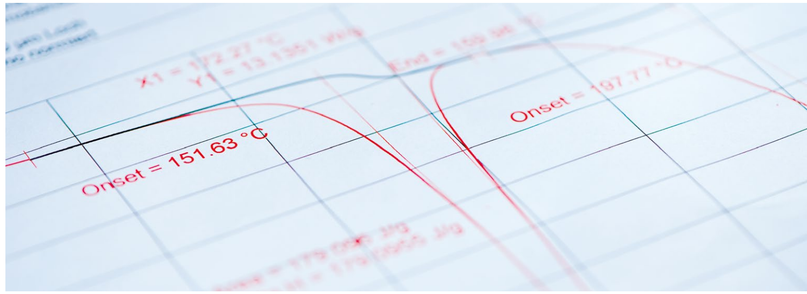
API Characterisation & Drug Development

HWI group





Drug Development

Our methodological approach to development has proven to be as successful in investigating product formulations as it has been in the processes of product manufacturing. The starting point of our development activities is always the drug substance (API).

Drug substance (API)

- Search and sourcing
- Chemical and physicochemical properties
- Evaluation of API qualities on:
  - Particle size distribution
  - Polymorphism
  - Compatibility
  - Solubility
  - Impurity profile
- Micronisation

QbD drug development approach

- Definition of Quality Target Product Profile (QTPP) with the client
- Risk analysis on product development and manufacturing process
- Feasibility studies
- Design of experiments (DoE) approach
- First scale-up of prototype batches
- Implementation of lean development tools

Product development and manufacturing

- Development of new drug products
- Product reformulation
- Manufacture, primary packaging, distribution and release of clinical batches, procurement of comparator medication
- Manufacture of GMP pilot batches and stability batches
- Drug product transfer services

Dosage Form & Equipment

In our new technical laboratory we develop and manufacture drug products according to ICH guidelines in small to medium-sized batches. We can also carry out work with hazardous substances.

Dosage forms

- Tablets, mini tablets, film-coated tablets, sugar-coated tablets
- Granules, pellets, powders
- Prolonged-release formulations (platform technology)
- Dry powder inhalers (platform technology)
- Oral liquid formulations

Technical equipment

- Mixing: high-shear mixer / rotary drum mixer
- Granulation: high-shear mixer / fluid bed granulator
- Drying: tray dryer / fluid bed dryer
- Tabletting: rotary press / eccentric tablet press
- Extrusion and compacting
- Film- and sugar-coating
- Filling of hard gelatin capsules
- Primary and secondary packaging

GMP & SHE

Handling sensitive and hazardous substances requires special protection, both for the substances themselves and for the people who deal with them. We meet this challenge by applying approved and innovative safety concepts.

We provide

- Manufacturing licence for pilot batches and clinical batches
- Established SHE management system
- Handling of drug substances up to OEB level 4
- Flex isolator technology
- GMP-certified analytical laboratory

Analytical Techniques and Services

Our analytical equipment is focused on promptly testing the key characteristics of new formulations to ensure fast progress in development projects. In addition, we use modern analytical techniques to acquire information on the internal constitution of the dosage form.

Testing of identity, purity, dissolution and particle size distribution

- Differential scanning calorimetry (DSC)
- Laser light scattering (Malvern Mastersizer®)
- Laser light scattering for DPIs (Helos/BF®)
- In vitro dissolution of solids (Ph. Eur., biologically relevant gastrointestinal media like FaSSIF and FeSSIF)
- In vitro dissolution of semi-solids (Franz Cell)
- Intrinsic dissolution
- Infrared spectroscopy
- Chromatography

Modern analytical methods for development and troubleshooting (with external partners)

- **XMT**/**XNT** (X-ray micro/nanotomography, micro-CT)
- **PXRD** (X-ray powder diffraction): crystallinity, polymorphism
- **RAMAN** microscopy and chemical imaging
- **SEM-EDX** (scanning electron microscopy in combination with X-ray fluorescence spectroscopy)
- **BET** (specific surface area and porosity testing)

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