HWI group

Drug Development

www.hwi-group.de

Our Services for Pharma, Biotech and Medtech

HWI group

Laboratory Services

Vigilance & Quality

Drug Development

Regulatory Affairs

- Development of solid, semi-solid and liquid dosage forms for oral, topical and parenteral application
- Handling of potent and high potent APIs
- API characterisation and quality screening
- Manufacturing of small and clinical trial batches
- Primary and secondary packaging including labelling and serialisation

Experts and Expertise

- Certification
  - Manufacturing authorisation for manufacture and batch release according to section 13 (1) of the German Drug Law (AMG)
  - GMP and GDP

- Our people for your success
  - 4 QPs
  - 35 experts
  - Administrative staff

Service Overview Drug Development and Manufacturing

GMP and non-GMP

- Development of solid, semi-solid and liquid formulations for oral, topical, nasal and parenteral application
- API characterisation and quality screening
- Small batch manufacturing
- Clinical trial batch manufacturing and distribution
- Analytical method development and validation
- Stability testing according to ICH
- Primary and secondary packaging
- Serialisation

Solid Oral Dosage Forms

Formulation development and CTM manufacture

- Handling of potent and high-potent APIs
- Small scale and CTM manufacturing
- Dosage forms:
  - Tablets, coated tablets, mini-tablets
  - Hard capsules
  - Granules, pellets, powders
  - Matrix tablets for modified / sustained release
- Specialities:
  - Nanoparticulate API (via wet grinding)
  - Microprecipitated Bulk Powder (MBP)

Semi-solid and Liquid Dosage Forms

Formulation development and CTM manufacture

- For oral, topical and intranasal application
- Small molecules, peptides and proteins
- Batch sizes of up to 100 kg
- Dosage forms:
  - Solutions
  - Suspensions (micro/nano)
  - Emulsions
  - Oleo- and hydrogels
  - Lyophilisates
- Filling in vials, bottles, syringes, nasal application devices

Semi-solid and Liquid Dosage Forms

Micro- and nanosuspensions

- Netzsch Delta Vita 1 / Hettich ZentriMix:
  - Efficient tool for broad screening (40 samples)
  - Only small API amounts required
  - Predictive for larger scales
- Wet grinding (via bead mill):
  - Batch sizes of up to 10 L
  - Aseptic manufacturing (from 2022)
- Avestin Emulsiflex-C3:
  - High-pressure homogenisation (piston gap)
  - Alternative technology to wet grinding

Parenteral Applications

Sterile fill and finish and aseptic manufacturing

Today

- Formulation development of parenterals
- Sterile fill and finish with qualified partners

From 2022

- Sterile fill and finish and aseptic manufacture of
  - Solutions
  - Suspensions (micro and nano)
  - Emulsions
  - Oleo- and hydrogels
- Aseptic filling of vials and bottles with focus on small batch sizes up to 2,000 units

Containment Area

- Weighing of APIs and excipients in isolator or laminar flow (LF) areas (depending on potency)
- LF areas (ISO class 5) in clean rooms (ISO class 7) for reduced microbial load
- Use of split valve technology with HDPE containers for transport of formulations/mixtures between equipment (see video for more detail)
- WIBObarrier Containment System

Clinical Trial Supply

For IMPs

- Customized primary and secondary packaging
- Labelling and cold chain labelling
- QP-batch release
- GMP release- and stability testing
- GMP storage at various conditions
- Handling of narcotic drugs
- GDP transport to study center
- Import / export and customs clearance
- Comparator sourcing
- Patient kit labelling and assembly
- Quality management

Packaging, Labelling and Serialisation

For market products

- Flexible and individual primary and secondary packaging solutions
- Procurement of printed packaging materials (labels, folding boxes, leaflets, booklets, etc.)
- Serialisation (TraceLink)
- Safety features (e.g. tamper evident labels)

Analytical Services for APIs and Drug Products

For oral, topical and parenteral products

- Physicochemical characterisation
- Compatibility studies
- Development, verification and validation of analytical testing methods
- Development of cleaning methods and verification
- Stability studies under ICH conditions incl. stability storage
- Freeze-thaw-cycle, forced degradation and photostability studies

Special Analytical Methods

For API characterisation, drug development and root cause analysis

- Particle size distribution and zeta potential: Malvern Mastersizer 3000, Zeta Sizer Nano ZS
- Droplet size distribution of spray devices: Sympatec Helos BR Sprayer
- In-vitro dissolution (apparatus 1, 2 and 4) in biorevelant media (e.g. FaSSIF, FeSSIF)
- Differential Scanning Calorimetry (DSC)
- HPLC-MS-MS, GC-MS for trace analysis, impurity screening (also for volatile impurities)
- SDS-Page: Agilent Bioanalyzer for peptide, protein, oligonucleotide analysis
- Scanning electron microscopy with x-ray-fluorescence detector (SEM-EDX)

Special Analytical Methods

For API characterisation, drug development and root cause analysis (with partner)

- X-ray powder diffraction (XRPD) for crystallinity and polymorphism screening
- X-ray microtomography (XMT), X-ray nanotomography (XNT)
- RAMAN imaging (line scanner); microscopy and chemical imaging
- Quantitative NMR (absolute method for quantification, also for proteins, peptides)

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Thank you for your attention.

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