



Drug Development



Drug Development & Manufacturing

Service Overview

- 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 – dry & liquid filling/sealing
 - Granules, pellets, powders
 - Matrix tablets for modified / sustained release
- Specialities:
 - Nanoparticulate API (via wet grinding)
 - Microprecipitated Bulk Powder (MBP)





Semi-solid & 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 & 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
- Avestin Emulsiflex-C3:
 - High-pressure homogenisation (piston gap)
 - Alternative technology to wet grinding



Semi-solid & Liquid Dosage Forms

Intranasal formulations

- Formulation development with small and large molecules (e. g. peptides and proteins), especially for high dosed and systemic applications
- Solutions, dispersions (suspensions, emulsions) and semi-solid gels
- Full analytical characterisation (e. g. U(H)PLC, PSD (Malvern Mastersizer), DSD (Sympatec Helos), z-average and zetapotential (Malvern Zetasizer), dissolution, etc.) and ASAP stability testing
- Analytical services for large molecules (e. g. UPLC-HRMS (Waters), CE-HRMS (Sciex), Bioanalyzer (Agilent), Microplate reader assays (Infinite M Nano))
- In-vitro-in-vivo correlation of prototypes
- Devices: Unidose / Bidose / Multidose : preservative and preservative free devices.
- Handling of potent and high-potent APIs (HPAPIs)
- Manufacturing and analysis and release of small and clinical trial batches
- Handling of potent and high-potent APIs (HPAPIs)
- Manufacturing and analysis and release of small and clinical trial batches





Semi-solid & Liquid Dosage Forms

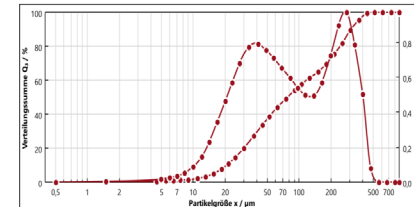
Intranasal formulations

Formulation and manufacturing services

- Formulation development and manufacture of aqueous solutions, dispersions (suspensions, emulsions) and semi-solids for i.n. administration (incl. filling into devices)

Special analytical services

- Development and validation of analytical test methods for the testing of droplet size distribution (DSD)
- HELOS/BR SPRAYER ROTOR
- Single- and multidose applicators
- Release and stability testing under GMP



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

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)

Inhouse

- 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 biorelevant 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)

Thank you for your attention.

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