

NON STERILE DOSAGE FORMS

Formulation development & manufacturing

EXPERTISE

- **All dosage forms: solid, semi-solid and liquid**

- **Complex drug product development**

Poor solubility, orphan drugs, controlled substances, pediatric forms, opiates, cannabinoids...

- **Innovative technologies**

Co-micronization, spray drying, automatic capsule filling
Low-shear and high-shear nanomilling
Fluid bed, high shear and dry granulation
Lyophilization
(Mini-)tableting and bilayers tablets

- **Highway To Clinic® platform**

Fast screening of wide range of formulation technologies
Analytical method development, accelerated stability assessment program (ASAP)
Drug candidate characterization
Development for PK, tox and phase I studies

- **Scale-up and facility transfers**

ROUTES



Oral

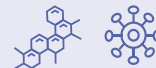


Topical



Nasal

MOLECULES



Chemicals & biochemistries / Biologicals

TOXICITY



Highly potent & cytotoxics up to OEB 5



SERVICES

Preformulation, formulation development

- Modified release dosage
- Multiparticle systems
- Self-Emulsifying Drug Delivery Systems (SEDDS, SMEDDS)
- Suspensions and nanosuspensions
- Orodispersible
- Powders and beads
- Solutions and microemulsions



Global Project Management

Analytical support (R&D, QC)

- Analytical development & method validation
- Stability studies

Non GMP and GMP small batch manufacturing

Clinical trial supply (packaging and logistics)

Regulatory dossier writing (IMPD - IND - CTD)



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CAPACITIES

Form	Batch size
Solutions, suspensions, emulsions	5 mL up to 50 L
Semi-solids	5 g up to 50 kg
Tablets	100 up to 200,000 units
Capsules	100 up to 200,000 units

FACILITIES

Formulation Development

- 4,200 m² / 45,000 ft² dedicated to development
- Cutting edge technologies
- Equipment duplicated in industrial manufacturing facility for improved technology transfer
- Multidisciplinary teams including pharmacists, chemists, bioengineers, industrial engineers, biochemists and highly skilled technicians



Non Sterile Manufacturing

- 2,200 m² / 24,000 ft² dedicated to GMP batch manufacturing
- Dedicated suites for highly potent drugs
- State-of-the-art equipment for small and medium batch production
- Wide range of primary packaging: bottles, sachets, blisters, tablets containers...
- Over encapsulation
- Blistering machine with automatic visual control



ANSES ANSM
AFMPS FAGG



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