

Facilitating clinical trial success for drug products

Ardena has extensive experience formulating drug products for early development. The breadth of our technologies enables us to provide a drug product that can be consistently prepared and accurately dosed, and that allows for mastering of potential solubility and bioavailability challenges.

A highly skilled team, actively supported by CMC experts, approaches formulation options in function of risk assessment frameworks. By navigating through a complex regulatory environment, a complete IMPD dossier is delivered on time.

Navigating you through drug development



Drug Product

Services

Formulation development
Process development & scale-up
Analytical method development & validation
ASAP and ICH stability studies
GMP-manufacturing
Packaging & labelling
Clinical logistics

Technology highlights

Oral solid dosage forms like capsules and tablets
Spray drying
High potency capabilities
Lipid-based formulations
Liquid-based formulations such as nanosuspensions, emulsions and nasal sprays
Liquid-filled capsules
Coating technologies
Fluid bed granulation
Overencapsulation

Drug Substance / Drug Product Interface

Services

Solid form screening & selection
Crystallisation process optimization
Powder flow & compaction analysis
Preformulation

Technology highlights

Single-crystal structure determination
High-throughput & high-resolution X-ray diffraction (XRPD)
Focused beam reflectance measurement (FBRM)
Real-time dissolution profiling