康龙化成 PHARMARON

Formulation Development and Manufacturing

Pharmaron develops and manufactures oral dosage forms for standalone and integrated projects across all phases of clinical development. Our team delivers a broad range of formulations from extemporaneous solutions/suspensions and fit-for-purpose capsules for early phase studies to complex bioenhanced formulations and modified release products.

Drug Product Facilities

Beijing, China

- Oral development to support pre-clinical and clinical Phase I/II/III
- GMP manufacturing
- Oral dosage forms to support clinical Phase I/II
- Batch Size: Up to 30kg

Ningbo, China

- GMP manufacturing
- Oral dosage forms to support clinical Phase I/II/III through File
- Batch Size: Up to 140 kg

Hoddesdon, UK

- Oral/parenteral/inhaled development to support pre-clinical and clinical Phase I/II
- Enabling and supply for extemporaneous prep studies

Pre-formulation

- Physico-chemical characterization of APIs
- Excipient compatibility studies
- Flowability and blend uniformity assessments

Formulation and Process Development

- Extemporaneous solutions and suspensions for preparation at the clinical study site
- Fit-for-purpose capsules
- Conventional formulations – direct compression or encapsulation, roller compaction, fluid bed granulation, high shear granulation
- Bioenhanced formulations – spray drying, hot melt extrusion, wet milling
- Modified release formulations – coated multiparticulates, hydrophilic matrix tablets, enteric coated tablets
- Pediatric drug products
- Formulation and process optimization through the use of Design

Analytical Development, Quality Control and Regulatory Affairs

- Method development and validation
- QC release testing of raw materials and drug products
- ICH stability studies
- Regulatory submission authoring for FDA, EMA, TGA and NMPA
- IND filing batches
- GMP batches for Phase I/II/III clinical trials
- Packaging and labeling

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Laboratory Services

Chemistry, Manufacturing and Control

Clinical Development

Biologics & CGT

Pharmaron is a global life science service provider that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical, clinical development and commercialization process.