

Pharma Chemicals

Pharmaceutical Development Services

DSM offers pharmaceutical development services, analytical development services, and clinical trial material manufacturing for solid dosage forms. With numerous annual product launches and nearly four decades of experience on site, DSM's services bring added value to customers in terms of cost reduction and accelerated time to market.

The Greenville operation has a group of scientists and project managers dedicated exclusively to providing these services. Customers can therefore minimize the expense of tech transfers leading to launch and commercial supply.

Innovative Development Solutions

- :: Preformulation studies
- :: Formulation development
- :: CTM manufacturing
- :: Stability studies
- :: Evaluation of new delivery technologies
- :: Formula and process optimization through DOE

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Preformulation Services

- :: Physico-chemical characterization of drug substance
- :: Polymorphism studies
- :: Powder X-ray diffraction
- :: Qualitative and quantitative thermal analysis
- :: Solubility and partitioning studies
- :: Salt form selection
- :: Excipient compatibility studies
- :: Packaging compatibility and extractability studies
- :: Forced degradation studies

Formulation Services

- :: Tablets, capsules, liquids, suspensions and semi-solids
- :: Reformulations and line extensions
- :: Modified and controlled release tablets and capsules
- :: Controlled substance (Schedule I-III)
- :: Evaluation of packaging presentations based on formulation requirements
- :: Bottle, blister, sachet and tube packaging
- :: Clinical supply and placebo manufacture Phase I-III
- :: Review of batch documentation by Quality Assurance team

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Pharmaceutical Development Services

Analytical Research Support

- :: Method development and validation for Phase I-III
- :: Process development support and release testing
- :: Cleaning validations for manufacturing equipment
- :: Non-compendial method development and validation
- :: Dissolution studies (ICH guidelines and customer design)
- :: Validated environmental chambers
 - :: 25C/60%RH, 25C/NMT 40%RH
 - :: 30C/65%RH, 30C/75%RH
 - :: 40C/75%RH, 40C/NMT 25%RH
 - :: 5C, -20C, photostability
- :: Microbiological methods development, validation and testing
- :: Stability

Laboratory Facilities

- :: Formulation development (3,000 sq. ft.)
- :: Analytical development (27,000 sq. ft.)
- :: Process development and CTM manufacturing (30,000 sq. ft.)

Clinical Trial Material Manufacturing—Solid Dose

DSM offers pharmaceutical and biopharmaceutical companies the breadth of manufacturing support services required to take a project from clinical to commercial manufacturing. Customers work with one management team, and one point of contact.

- :: 55,000 square foot solid dose area
- :: Post discovery
- :: cGMP Phase I, II and III
- :: cGMP small batch API manufacturing
- :: Packaging services

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