

# Pre-Formulation/Formulation Development

Pharmaceutical development services at WuXi AppTec encompass a full range of services from pre-formulation development, formulation development, supporting analytical development, and clinical trials material manufacturing through to product registration services — quickly and seamlessly moving NCE's from preclinical to NDA filings.

## Preformulation Development

Services offered for preformulation at WuXi AppTec include evaluation of intrinsic physicochemical properties of API, salt form selection, polymorphism study, powder characterization studies such as particle size and flow properties and drug excipient compatibility studies.

## Formulation Development

Formulation development services cover the development spectrum, from early safety studies to toxicity study dosage manufacturing to registration/clinical batches. Formulation stability can be evaluated at ICH or any customized storage conditions. Packaging and storage conditions are suggested based on thorough stability studies.



Glatt Powder Coater & Granulator

WuXi AppTec is a global leader in providing discovery, testing and manufacturing services for the pharmaceutical, biotechnology and medical device industries. Research-driven and customer-focused, with operations in China and the U.S., WuXi AppTec offers a broad and integrated portfolio of services designed to assist our customers with cost-effective and efficient outsourcing solutions.

WX  
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NYSE

## Instrument Highlights

Our state-of-the-art PDS preformulation laboratories are equipped with modern analytical instruments including laser diffraction particle size analyzer, DSC, TGA, DVS, XRPD and dissolution testing stations.

The PDS formulation development laboratories are equipped with state-of-the-art fluid bed and high shear granulators, dry granulator, automated tablet press, automated capsule filling machine, autocoaters, weight sorter, metal detector, automatic blister pack machine and bulk packing line. A microdozer with capability to fill from 100 micrograms to several hundred milligrams of API into capsules bottles or blisters is also available.

## Clinical Trial Materials Manufacturing

Clinical trial material manufacturing services focus on Phase I to Phase II materials manufacturing in a facility built for compliance to US-FDA and EMEA requirements. Current capabilities include solid oral (including liquid filled hard gelatin capsules) and liquid oral dosage forms.



IN-CAP Capsule Filling Machine

For more information on WuXi AppTec's services please contact:

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