WuXi AppTec

Move Fast.
Move Forward.

Site Spotlight

San Diego

Let's Accelerate Your Early-Phase Clinical Development

Supporting all synthetic modalities, our San Diego site provides fully integrated CMC services: from API process development and manufacturing, preformulation, and TOX studies, to analytical services, drug product manufacturing, and clinical supply.

API
- Process R&D
- Manufacturing
- Technologies: Hydrogenation, Milling, Prep-HPLC

Formulation
- Preformulation
- Solid State Development
- Drug-in-Capsule and Powder-in-Capsule Manufacturing

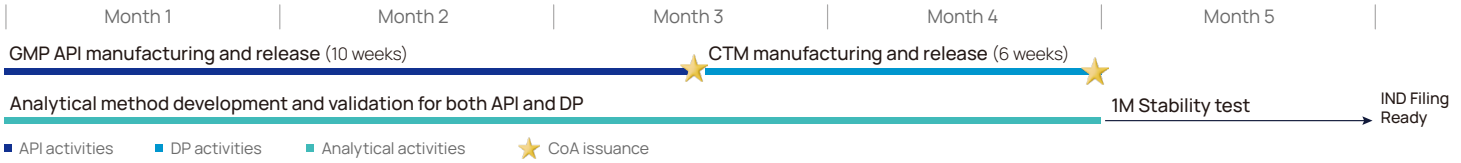
Analytical
- Method Development & Validation
- Reference Standard Qualification
- Release Testing
- Structure Elucidation
- Stability Study

Clinical Supply
- 15°C-25°C Depot & Storage
- Distribution

[Case Study] Integrated API and DP Manufacturing for Phase I in 5 months

Background

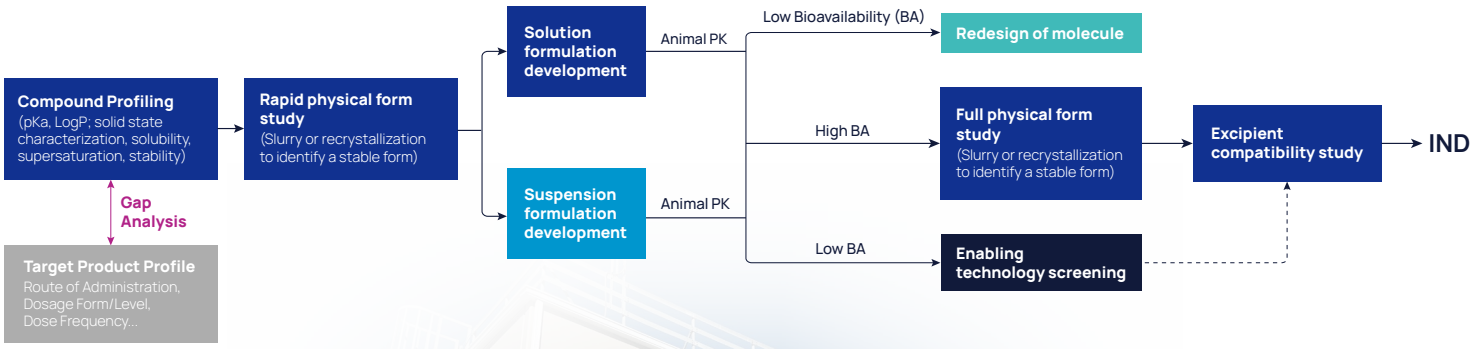
- Produced 2.7 kg of GMP API within 6 weeks
- Delivered 7,000 capsules in two dosage strengths as clinical trial materials (CTMs) within 4 months
- IND-submission ready in 5 months



WuXi STA Solution: IND-Enabling Preformulation Package (IEPP) to Accelerate Drug Candidates into Clinical Phase

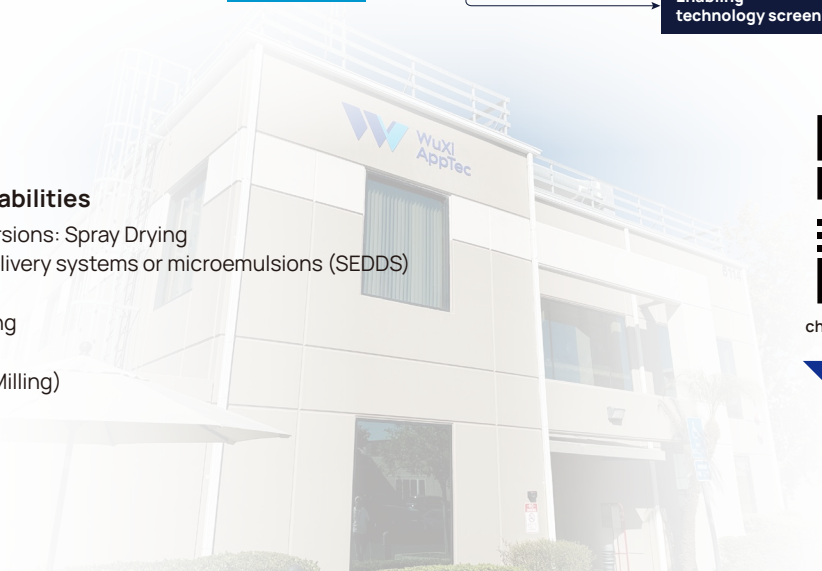
8-12 weeks for IND-ready formulation

- Parallel screening with bioavailability enhancing technologies
- Integrated PK/PD & Tox studies for clinical candidates
- Local in-silico, in-vitro & in-vivo compound profiling service



Pre-formulation Capabilities

- Amorphous solid dispersions: Spray Drying
- Self-emulsified drug delivery systems or microemulsions (SEDDS)
- Cyclodextrins
- API Polymorph Screening
- Salt Screening
- API Micronization (Jet Milling)



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