WuXi TIDES

Preformulation for Oligonucleotides and Peptides



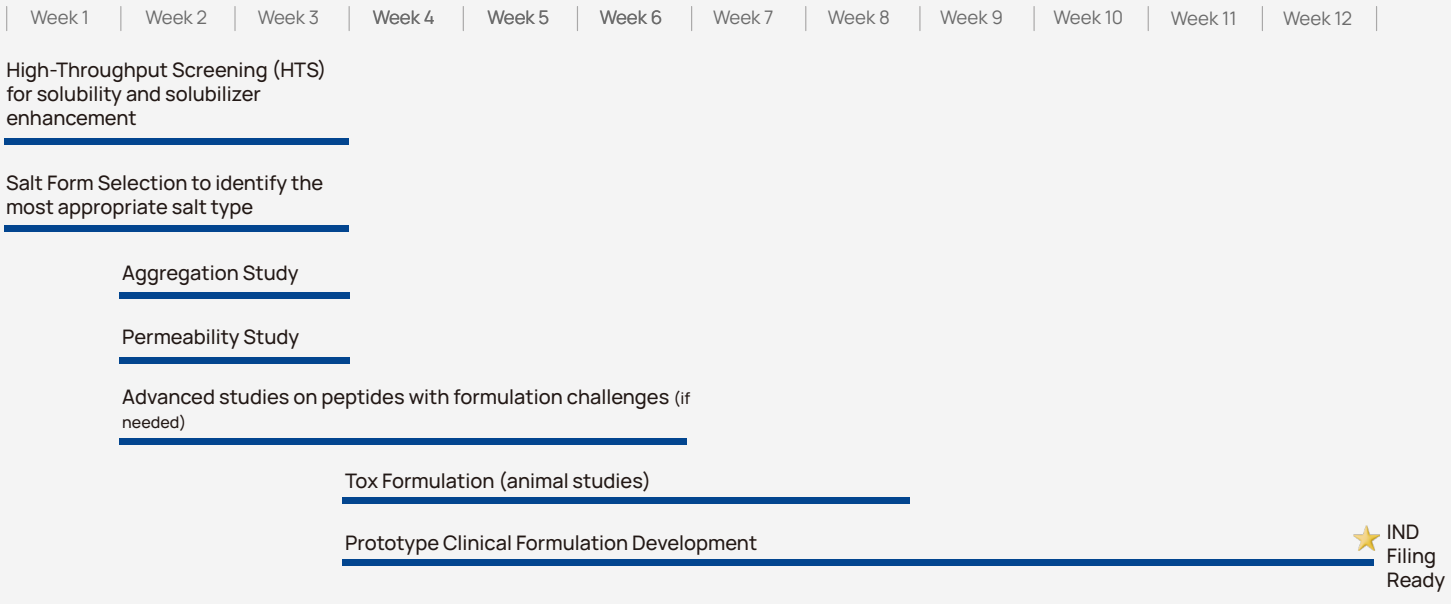
IND-Enabling Preformulation Package (IEPP)

IEPP is an integrated service for new chemical entities (NCEs) designed to rapidly assess developability, identify the best drug candidate, and develop the optimal human formulation for IND filing.

A Fast, Cost-Effective Path to IND

- Data-Driven Candidate Selection
- Animal PK Studies
- Tailored Formulation Solutions
- Risk & Cost Mitigation
- Integrated CMC Support
- Bioavailability Enhancement Technologies

Preformulation and Formulation Strategies for Peptides



API Requirements at Each Stage

20 mg	100 mg	1–2 g	5 g
PK Formulation	**Risk Assessment**	**Preclinical Formulation**	**Clinical Formulation**
• Solubility • Dilution & Stability • PK Formulation • Permeability Study	• Chemical/Physical Stability • Salt Form Selection • Aggregation Study • Formulation for PK/PD	• PK/PD/Tox Formulation • Viscosity Reduction • Absorption Reduction • Long-Acting Injections (e.g., in situ gels, liposomes)	• Compound Profiling • Excipient Compatibility • Tox Formulation • Clinical Formulation • Storage Condition and Shelf-Life Predictions

Preformulation and Formulation Strategies for Oligonucleotides

- Rapid Tox Batch Supply: Available within 1-2 weeks
- Optimized Formulation Development: Lock formulations within 4-8 weeks
- High-Quality Preclinical Formulations: Low endotoxin levels (< 3 EU/ml) in R&D batches
- Advanced Delivery Systems: Expertise in lipid nanoparticles (LNP) and other innovative approaches

20mg API

PK Formulation

- Solubility confirmation
- Stability test
- Formulation for PK

1-2g API

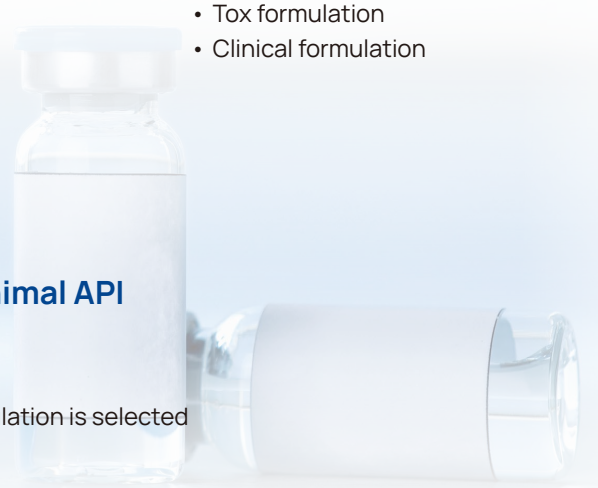
Preclinical Formulation

- Visible particle identification and trouble shooting
- High concentration
- Viscosity reduction
- Lipid nanoparticles (LNP)

5g API

Clinical Formulation

- Compound profiling
- Excipient compatibility
- Tox formulation
- Clinical formulation



Comprehensive Complex Formulation Screening using Minimal API

- Requires only 1–2 g of API per formulation type
- Parallel formulation development and PK studies completed in 6–8 weeks
- Clinical formulation development can be done in 8-12 weeks once the lead formulation is selected
- Overall DP CMC timeline for IND-filing readiness is ~ 8 months

Conventional Formulations

Solution

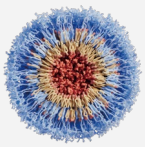
- Vial
- Pre-filled syringe
- Cartridge in auto-injection pen

Lyophilization

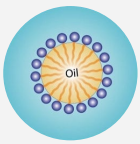


Complex Formulations

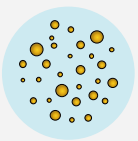
Liposome/LNP



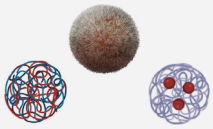
Emulsion



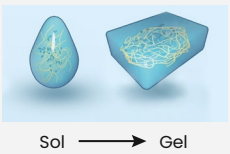
Nanosuspension



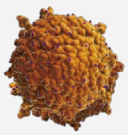
PLGA nanoparticles and microspheres



In Situ Gel



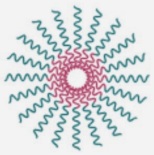
Albumin nanoparticles



Microsuspension



Micelles



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Looking for a fast and cost-effective way to bring your peptide or oligonucleotide to IND?

Get in Touch to Accelerate Your IND Filing!