LATITUDE
Pharmaceuticals Inc.

Formulation Experts for Insoluble Compounds

At LATITUDE, we only do one thing, and we do it very well.

LATITUDE Pharmaceuticals Inc. has been tackling the most difficult drug formulation challenges for biotech and pharmaceutical companies since our inception in 2003. Our reputation for creative approaches, reliability, rapid turnaround and client satisfaction comes from 700+ formulation development projects for over 200 clients, large and small. We pride ourselves on our track record and experience in successfully formulating the most problematic, poorly soluble and unstable APIs.

Whether your API needs a quick PK/Tox formulation or a complete IND-ready formulation development program that covers analytical, process development, manufacturing and new IP protection, put LATITUDE to work for you.

Why choose LATITUDE?

We have many years of experience and an extensive range of analytical and manufacturing platforms to develop prototypes of nearly every kind of injectable, oral, topical, inhalation, and ophthalmic human and veterinary formulation – both simple and complex.

About LATITUDE

- Founded: 2003
- Headquarters: San Diego, CA
- Facilities: 18,650 sq ft dedicated R&D labs and pilot manufacturing facility
- Core Strengths:
  - Formulation development for insoluble and unstable drugs
  - Drug delivery systems
  - IP creation
- Over 700 CRO projects completed

LATITUDE's Service Capabilities

- Formulation development for all NCEs
  - Small molecules and biologics
- Pre-formulation
  - Solution phase compound evaluation:
    - *pH solubility profile and buffer compatibility*
    - *Solubility in pharmaceutically useful solvents*
    - *Drug solubilizer screening*
    - *Drug-excipient compatibility, screening*
  - Solid state compound evaluation:
    - *Morphology study*
    - *Hygroscopicity evaluation*
    - *Thermal characterization*
    - *Particle size and size distribution*
    - *Drug-excipient compatibility*

- Feasibility studies
- Analytical methods
  - Development through validation
- Preclinical tox formulations intended for GLP-studies
- Formulation development of all dosage forms with specialty in problematic APIs
  - Highly insoluble, unstable, high and/or bulky dose, poor absorption, vein irritating, deficient PK profile
- Formulation stability studies
- Deformulation/reverse engineering
- Intellectual property creation (to support new formulation development)
- Generics, reformulations, 505(b)(2) NDAs

LATITUDE's Dosage Forms Expertise

- **Injectable**
  - Solutions (IV, IM, & SC)
  - Emulsions (IV & SC vaccines)
  - Liposomes (Organ-targeting)
  - Suspensions (IV & IM)
  - Depots (gel & microspheres)

- **Oral**
  - Solid filled capsules (IR, SR)
  - Liquid filled capsules (bioavailability-enhancing & SR)
  - Tablets & coated tablets (IR, SR, ER, delayed release & orally disintegrating)
  - Stable amorphous powder matrices (RFAP)
  - Multi-particulate systems (IR, SR)
  - Solutions (bioavailability-enhancing)
  - Suspensions (SR)
  - Fast dissolving films

- **Ophthalmic**
  - Solutions, emulsions & suspensions

- **Topical**
  - Creams, lotions, ointments
  - Pastes
  - Foams
  - Gels
  - Patches

- **Others**
  - Vaginal tablets & gels
  - Nasal spray
  - Pulmonary inhalation

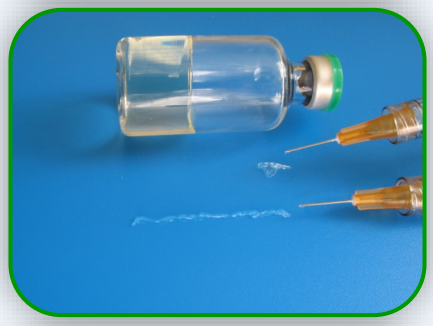
API Experience

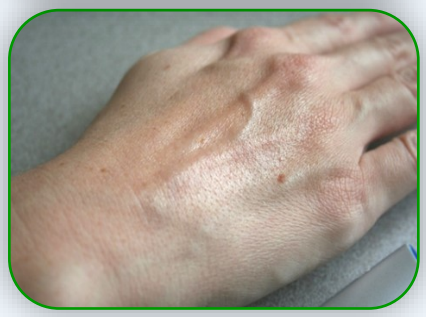
- Human and veterinary drugs
- Small organic/inorganic molecules
- Peptides *(1-25 MW)*
- Proteins *(15-150K+ MW)*
- Oligos and Plasmid DNA
- Adenovirus
- Polymers
- Drug Combinations

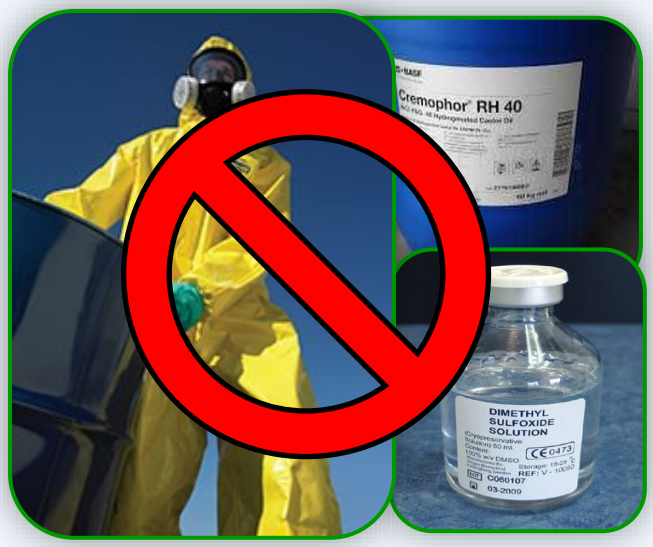
Drug Delivery Platforms

Latitude's proprietary technologies are available to our clients to solve formulation challenges presented by difficult APIs

- **Nano-E** (Nanoemulsion)
  A versatile solubility-enhancing platform for oral/injectable liquid formulations. Ideal for highly insoluble APIs
- **PG Depot** (Phospholipid Gel Depot)
  Allows a customizable release profile of a subcutaneously-administered drug over 1-7 days. Injectable through fine (up to 28 G) needles for easy subQ administration
- **ARTSS** (Aqueous Room Temperature-Stable Solutions)
  A platform for the transformation of lyophilized powders or 2-8°C solutions into RT-stable aqueous solutions.
- **RFAP** (Rapidly-Dissolving Amorphous Powders)
  Creates stable, amorphous, water-soluble powders that keep the API from reverting to the crystalline state
- **24H** (ALLDAY 24H ER Tablets)
  An oral tablet platform for increased dosage and linear,sustained release of drugs for up to 24 hrs.
- **MiniSpheres**
  Novel delivery format for high/bulky dose oral drugs and/or sustained release.
- **GelPatch**
  Novel transdermal spray/rub-on gel that dries as durable patch to provide multiday drug delivery







At LATITUDE, we set ourselves apart from other formulation companies not only with our expertise with difficult APIs, but by the fact that we do NOT use the following for our clients' formulation development:

- Allergenic detergents
- Strong solvents
- Hemolytic surfactants
- Proprietary solubilizers
- Ingredients not approved by the FDA
- Secret recipes

LATITUDE's Record of Success

- A privately-owned company with over 13 years of successful business
- Over 200 clients served with strong repeat business and word-of-mouth referrals
- Over 700 individual projects completed
- FDA-approved products
  - Example: OraVerse™, developed via the ARTSS platform
- Many client products taken from formulation development to GMP manufacture
- Multiple client products now in clinical development, including products developed via Latitude's proprietary drug delivery platforms

For more information, or to learn how LATITUDE can optimize the successful development of your drug, please contact:

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