

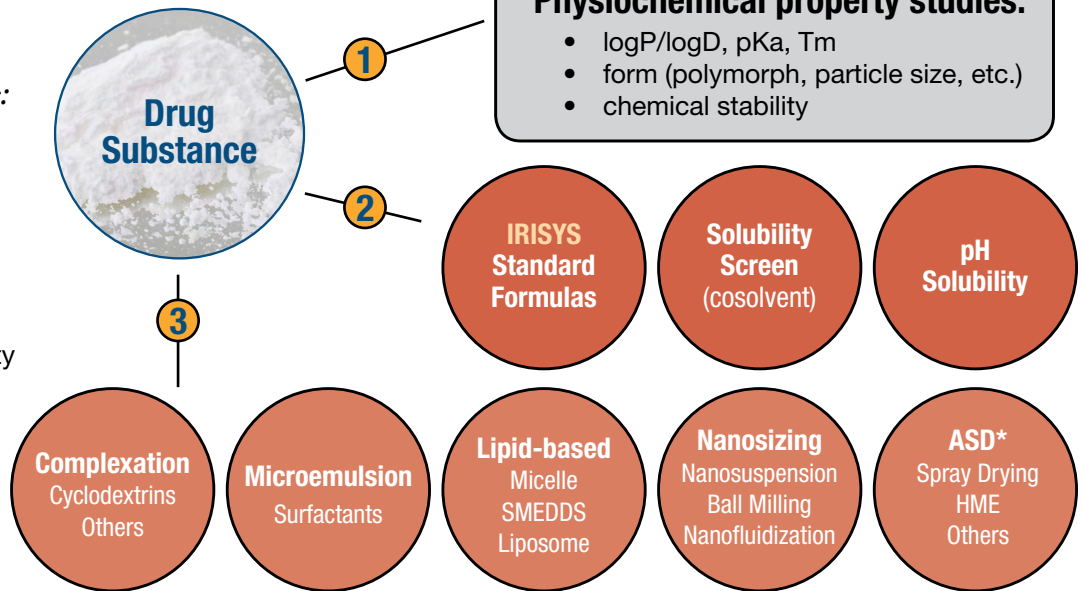
IRISYS *Delivers Phase-Appropriate Formulation Solutions*

Formulation Development Strategies from Preclinical PK, GLP Tox and Phase I, II, III Clinical Trials to Commercial GMP Manufacturing

Exploratory Formulation Suite

Special Considerations for Discovery/Pre-clinical Stages:

- Dose requirements for efficacy, PK and toxicology studies vary
- Routes: IV, PO (solution, suspension, solid), SC, IP, etc.
- Often with poor solubility and low bioavailability
- Quick turnaround time
- Limited amount of material
- Scalability for future development



Dosage Form Development

for new chemical entities, OTC products, generic products, and 505[b][2] product candidates.

- | | |
|----------------------------------|---|
| • Tablets | • Long lasting parenterals |
| • Capsules, powder-filled | • Controlled/Sustained release products |
| • Capsules, liquid-filled | • Pellets |
| • Oral solutions and suspensions | • Microspheres |
| • Creams, gels, ointments | • Lyophilized products |
| • Injectables | • Animal study materials |

Applications

- Small molecules
- Peptides
- Nucleic acids
- Proteins
- Synthetic polymers
- Inorganic compounds
- Cytotoxic and potent
- Cell therapies

Technologies

- Liquid based formulations
- Liquid-filled hard gelatin caps
- Controlled release solid dosages
- Micro and nanoparticles
- Liposomes and solubilization
- Formulations to enhance intellectual property portfolio

Other Standard Pre-Formulation/Formulation Service Packages:

- Excipient Compatibility study
- Solid state properties: particle size, state of hydration, crystal form (third party)
- Dissolution method development and testing
- Solubility in simulated gastric fluid (SGF), Simulated intestinal fluids (SIF) and simulated colon fluids (SCF) in Fasted and Fed state
- Stability studies – short-term, accelerated, forced degradation, ICH photo stability



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Examples of IRISYS Technologies Applied

IRISYS has been providing contract formulation and GMP clinical trial supplies manufacturing services to early stage development companies, governmental agencies (NCI, NCATS, NIH) and commercial pharmaceutical companies for more than 20 years. IRISYS provides these organizations with possible dosage form options including all relevant information they will need to make rational development decisions.

No.	Client	Description
1	NIH	Liquid filled capsule for bioavailability enhancement
2	NIH	IV Protein/Peptide
3	Private Client	Nano-particulate suspension for extended release (months) sub-cutaneous injection
4	Private Client	Liquid adsorbed on a solid carrier for bioavailability enhancement, solid oral tablet
5	In-house	IRI-761, liposomal drugs for accurate pH targeted release after IV injection
6	Private Client	Stable pediatric oral liquid suspension & solution
7	Private Client	Sustained release tablet
8	Private Client	Pulsatile release, mini tablets, combination product
9	Private Client	Injectable protein/small molecule complex
10	Private Client	Stable pediatric oral liquid suspension
11	Private Client	Dissolution studies in simulated biological fluids (SGF, SIF, SCF) in Fasted and Fed state; and for different polymorphic forms
12	Private Client	Immediate release tablet
13	Private Client	Sterile ophthalmic drops
14	NIH	Immediate release capsule
15	NIH	Non-aqueous sterile injectable, IV
16	Private Client	Long acting parenteral
17	Private Client	Targeted Microbiome Transplant live bio-therapeutic anhydrous ointment
18	Private Client	Subcutaneous peptide with limited bioavailability
19	Private Client	Tween stabilized gold nanoparticles (NPs) formulation
20	NIH	Powder in sachets
21	Private Client	Hydro gel filled syringe for a topical peptide
22	Private Client	Adsorption of drug solution onto a high surface area carrier for oral administration
23	Private Client	Sterile solution for inhalation
24	NIH	Sterile products for antigen-specific immunotherapy approach
25	Private Client	two syringe combination - powder filled syringe and polymer gel filled syringe

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