Targeted Protein Degraders

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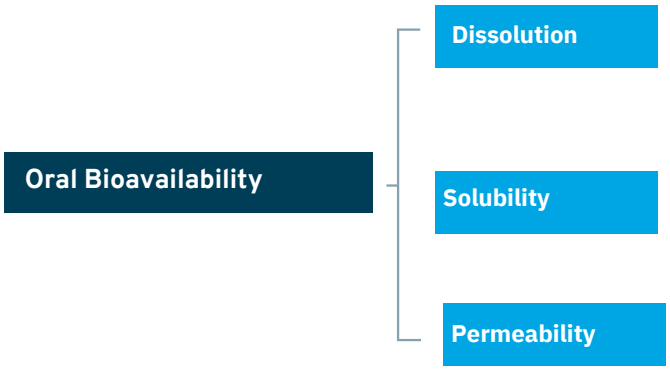
There's a Science to Success™

Protein degrades have shown promising clinical outcomes utilizing a novel degradation-based mechanism. However, adequate oral bioavailability remains a significant challenge for these large complex molecules due to low solubility and permeability. Serán's expertise formulating complex molecules has resulted in a track record of success for clients with these challenging molecules. By using science-based formulation approaches, a large number of tools, including ASD, permeation enhancers, and other state of the art technologies.



SOLUBILITY AND BIOAVAILABILITY ENHANCEMENT

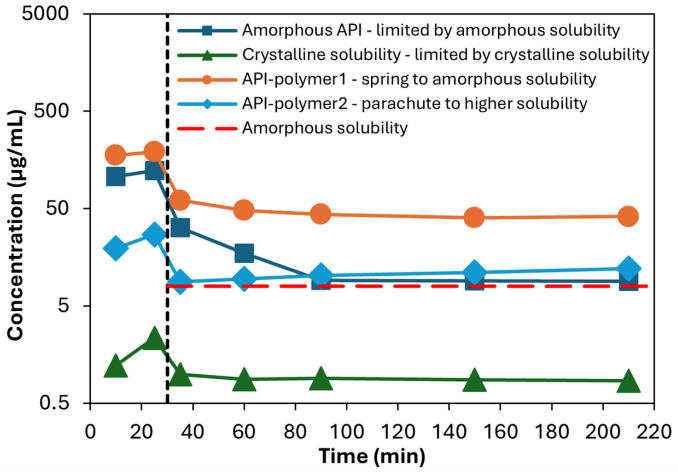
- Bifunctional protein degraders typically have high Tm/Tg, and a low propensity to crystallize. The amorphous solubility can significantly enhancement bioavailability.
- Colloidal species formed in the GI tract by proper selection of Drug polymer ASD formulations can promote further enhancements of BA
- The increased rates of diffusion for these colloidal nano-species and fast re-dissolution rates can exhibit a major advantage compared to crystalline formulations

POLYMER DOES MUCH MORE THAN SOLUBILIZATION

Many protein degraders are produced as amorphous material in the early phase. However, ASD formulations comprised of drug and polymer are often advantageous compared to the amorphous API in many aspects:

- Formation of drug-polymer colloids enhances supersaturation
- Improved stability to derisk crystallization
- Improved down-stream manufacturability by enabling powder flowability and compressibility for tablets
- Enabling rapid dissolution
- Mitigating p

Example 2-Stage Dissolution of ASDs



Advanced Tools for Targeted Protein Degradation

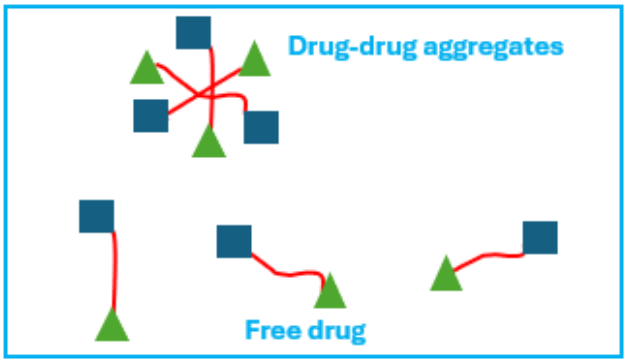
FUNDAMENTALS OF SPECIATION & PERMEABILITY

One unique attribute of protein degraders compared to other small molecules is their flexibility in conformation. The change in conformation can be impactful in two aspects:

- Formation of drug-drug aggregates
- Unique permeation mechanism

We employ:

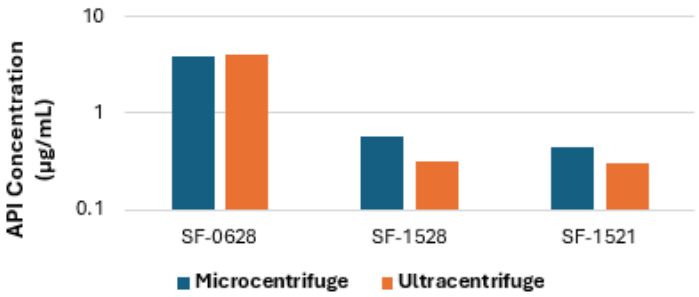
- Dynamic light scattering, nanoparticle counting to assess formation of the drug-drug aggregates
- Discriminating centrifuge assays to deconvolute multiple species
- MicroFLUX analysis to assess permeability



PERMEABILITY ENHANCEMENT

For protein degraders with limited permeability, we have technologies to incorporate permeation enhancers, surfactants, and lipids into tablet formulation to further enhance absorption.

Speciation of Drug-Drug Aggregates for 3 Protein Degraders



The difference between micro- and ultracentrifuge assays is the concentration of drug-drug aggregates. The potential to form such aggregates can vary significantly between different protein degraders.

ORAL SOLID DOSAGE FORMS

Serán has a demonstrated a track record of developing robust clinical dosage forms that enable our clients to deliver their medicines for clinical studies. Our strategy is to develop a formulation that is advanceable through the entirety of clinical trials from FIH to registration and commercial.

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Connect & Learn More

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Serán is a world leader in drug development and manufacturing. Utilizing a foundation of physical and chemical science, Serán designs robust formulations and engineering solutions to some of the industry's toughest drug product problems.