Quotient Sciences

Molecule to cure. Fast.™

Information sheet

Spray drying

Overcoming poor drug solubility and bioavailability challenges

Drug solubility has a significant impact on bioavailability. 70% of new chemical entities (NCEs) suffer from low aqueous solubility that can result in failure during clinical testing due to poor bioavailability. Selecting an appropriate drug formulation is imperative to the success of the program.

At Quotient Sciences we use a broad range of formulation approaches to address complex solubility and bioavailability challenges, ensuring technology selection is driven by molecule need. Within our technology portfolio, spray drying is an established capability. Our experts tailor formulation strategies based on the unique physical, chemical and biopharmaceutics properties of each drug, working within state-of-the-art facilities capable of handling high potent compounds.

Spray Dried Dispersions (SDDs)

Spray drying is a bioavailability enhancing drug delivery technique, producing homogeneous solid mixtures of drug and solubilizing polymers from organic or aqueous solutions. SDDs effect several critical changes in a drug relative to its parent crystalline form.

- The molecule is converted to an amorphous, high-energy physical form which, in the presence of the polymer, promotes enhanced aqueous solubility resulting in a faster dissolution rate and up to ten times the saturated solubility of crystalline drug.
- The polymer can inhibit precipitation of the dissolved drug, resulting in sustained solubility.
- The polymer stabilizes the drug in a glassy state, improving the long-term physical stability at a variety of temperature and humidity conditions.

What can Quotient's formulation development do for me?

- Identify and address critical formulation issues quickly
- Optimize the performance of your formulation
- Support your formulation development from preclinical to clinical evaluation

Spray drying

Quotient's formulation development and GMP spray drying capabilities enable rapid screening of solid dispersions at a suitable scale with subsequent clinical production of a range of batch sizes, from 100 mg to 3 kg using either ProCepT or GEA Niro Mobile Minor™ equipment. We can screen several drug and polymer combinations to achieve an optimum drug: polymer ratio with preferred physicochemical properties (i.e. dissolution performance, amorphous state and stability).

In addition to the development and clinical production of SDDs, we have expertise in their downstream formulation into a variety of drug product formats depending on clinical and long term development requirements. Formulations can be manufactured as reconstituted suspensions for initial First-In-Human (FIH) trials or alternatively as dispersible granules, capsule or tablet dosage forms for Phase Ib/IIa studies and beyond.

Our approach

- **Assess** the physicochemical and biopharmaceutics properties of the drug
- **Define** the critical product attributes of the intended final dosage form
- **Select** best-fit SDD components and process for the intended final dosage form (solvent selection, API loading, polymer selection, spray parameters)
- **Make** small-scale batches (milligrams to grams) of prototype SDDs for in vitro assessment
- **Develop and test** the dosage form containing the SDD including the generation of an appropriate stability package
- **Develop and validate** appropriate test methods for the SDD and final dosage form
- **Manufacture** GMP supplies of lead SDDs and dosage forms
- **Select the clinically proven** SDD dosage form using emerging human PK data
- **Provide** ongoing drug product supply for POC / Phase II studies

Clinical testing options

SDD products manufactured at Quotient can be dosed in our clinical pharmacology unit, for use in initial First-In-Human (FIH) studies, and to manage transitions between dosage forms demonstrating improved bioavailability. These integrated studies deliver time and cost benefits via our Translational Pharmaceutics® platform, and provide maximum flexibility to adjust formulation compositions within the study by manufacturing all drug products in real time. Alternatively formulations can be manufactured, packaged and labelled and distributed to global clinical sites for dosing.

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