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Oral Delivery of Modified Multi-layered Microstructures of Active Pharmaceutical Agent(s) by Enhanced Absorption

Patent Pending

Dual channel spray dried modified multi-layered microstructures for oral delivery

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Key Features:

- Novel dual channel (spray gun) technique for spray drier
- Enhances drug bioavailability and absorption
- Can incorporate more than one drug and produce a variety of drug delivery profiles (i.e., pulsatile release)

Field:

Pharmaceutical

Technology:

Enteric coated self emulsifying multi-layered microparticles with 1 or more drugs for oral delivery

Stage of Development:

Pre-clinical development

Status:

Seeking further research & development support and/or licensing partner.

Patent Status:

Pending

Background:

The oral drug delivery segment is the largest segment in the drug delivery market with more than a 52% market share. It is valued at roughly \$50 billion and is expected to reach \$92 billion by 2016. This increase represents an annual growth rate of 11.3%. The majority (84%) of most marketed drug products in the U.S. and Europe are oral dosage forms.

Statement of Problem:

Although oral drug delivery can potentially be problematic for certain drugs (i.e., first pass effect, poor solubility, poor absorption, degradation in the stomach, etc.), oral formulations are still less expensive to produce as they do not need to be manufactured under sterile conditions. Furthermore, many people prefer oral dosages over the pain and discomfort associated with injections. The inventors have discovered a novel spray drying process, which can incorporate more than one drug and can also be used to deliver a customized release profile tailored to a variety of systems. This invention also combines the benefits of several techniques (ex. spray drying, coating, self-emulsifying) while minimizing each technique's limitations to convey more therapeutic benefits for patients.

Potential Solution:

The present invention relates to the development of modified multi-layered microstructures of active pharmaceutical agent, which can be administered orally. Multi-layered microstructures are prepared by dual channel (spray gun) spray dryer which enables simultaneous drying of inner core or droplets embedded into outer layer or matrix of excipients to enable various combination of formulation to enhance active pharmaceutical agent's bioavailability by enhanced absorption in the gastrointestinal tract. The present invention can be applied for oral delivery of a larger group of active pharmaceutical agents (i.e., small molecules, proteins, peptides), enabling the delivery of more than one active pharmaceutical agent with enhanced absorption of the active pharmaceutical agents in the gastrointestinal tract. Furthermore, this method has applicability to enteric-coated self-emulsifying microstructures and can be used to produce specific drug release profiles (i.e., pulsatile, controlled release, immediate release). The inventors claim that their present invention (Enteric coated self emulsifying multi-layered microparticles) by spray drying may have applications in treating a variety of cancers by improved oral delivery.

Commercialization Status:

This technology is currently in the pre-clinical development stage, and R&D was funded at FAMU by the Florida Government for James & Esther King Biomedical Research Program "Technology Transfer Feasibility (TTF) Grants. Already, the development of the DIM-P (novel anti-cancer agent) was formulated in enteric coated self-emulsified micro-particles as Spray BIO-Max DIM-P and was evaluated for in-vitro performance, pharmacokinetics in rats as well as dogs, toxicology on normal mice and anti-cancer therapeutic potential in different lung tumor models. We are seeking collaborative partners or licensees in the Biotechnology and/or Pharmaceutical Industries to take these developments into commercialization.