

# OFFICE OF TECHNOLOGY TRANSFER

# AUBURN UNIVERSITY

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Reference: Stable Drug Particles

## Inventors

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## Reference

"Simultaneous Microparticle Formation and Mixing in Supercritical CO<sub>2</sub>. Fast-Release Navirapine Drug Formulation." *AICHE 2009 Abstract* ([link](#))

## Licensing Opportunities

- This technology is available for exclusive or non-exclusive licensing
- Joint development opportunities include funded research or testing of a target drug

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## Production of Stable Mixture of Drug and Excipient Particles

### Overview

Auburn University is seeking a licensee or development partner for a process to produce fine drug particles that do not aggregate after production. Using a modification of a well-established process, drug particles are formed in the presence of excipient (filler) particles. This works to keep drug particle size small, and therefore drug quality high. Additionally, two process steps (particle formation and mixing) are combined into one. This has potential application in the formulation of hydrophobic drugs for oral and pulmonary delivery.

### Advantages

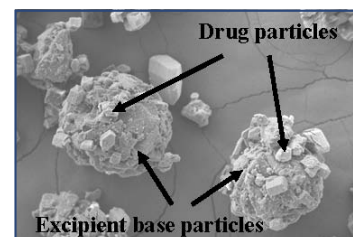
- Drug particle size remains small, offering high solubility and bioavailability, high quality control (homogeneity), and desired shelf-life
- Particle formation and excipient mixing steps are combined, saving on processing costs
- Highly flowable mixtures can be direct compressed, simplifying downstream processing
- Process uses low temperature and benign solvents, suggesting potential wide application, including peptide- and protein-based drugs
- Highly potent drug micro/nano particles are immediately diluted, thereby minimizing potential toxicity during handling of materials
- Compatible with any existing supercritical antisolvent drug particle production process

### Description

Some potentially promising drugs have difficulty in real-world use due to poor solubility in water, and thus low bioavailability in the patient. Producing small micro- or nano-sized drug particles can help solve this problem by increasing the surface area of the drug, which in turn increases dissolution rate and bioavailability. In addition, small particles are also ideal for pulmonary-based delivery through aerosol and inhalation.

Unfortunately, these small drug particles tend to aggregate — or agglomerate — after formation, which increases their average size and minimizes these advantages. Additionally, such agglomeration can adversely affect quality control by making the formulation less consistent and by limiting the drug's shelf life. Traditional mixing methods cannot overcome this problem, either due to a lack of efficiency or because the high energies required risk altering the drug's crystal structure.

Supercritical carbon dioxide (SCCO<sub>2</sub>) is used commercially in the pharmaceutical and food industries in such processes as drug particle production and decaffeination of coffee. In the Auburn process, dissolved drug is injected into a tank containing SCCO<sub>2</sub> in which excipient particles are already suspended. This produces drug particles of a desired size that are simultaneously mixed with excipient particles. The excipient particles interact with the drug particles, limiting the formation of drug-drug particles, and therefore limiting agglomeration. The simultaneous mixing of drug and excipient particles is inherent in the process. Very fine drug particles can actually be deposited on the surface of excipient particles (see picture).



### Status

- A patent application has been filed
- This has been demonstrated in the lab with an antiretroviral drug and a pair of excipients, yielding significantly faster drug release than formulations made via physical mixing
- Currently performing demonstration of method with a number of additional drugs