

VISIT ENAVAIL BOOTH #2055 AT THE AAPS MEETING, D.C., OCT. 23-27

Enavail Expands Drug Formulation and Manufacturing Capabilities with Hot Melt Extrusion Technology

AUSTIN and ABILENE, TX -- October 18, 2011-- Enavail, a specialty pharmaceutical company focused on generating unique dosage forms and solving challenging formulation issues, announced today that the company has expanded its pharmaceutical manufacturing capabilities for hot-melt extrusion (HME). The addition of HME technology enhances Enavail's quality by design approach to provide specialized manufacturing expertise for pharmaceutical, biotech, and nutraceutical companies. The technology also strongly leverages Enavail's existing capabilities including working with cytotoxic, high potency and DEA scheduled compounds. Enavail will be exhibiting at the annual meeting of the American Association of Pharmaceutical Scientists (AAPS) in Washington, D.C., October 23-27.

HME is emerging as a preferred manufacturing methodology for dosage forms. The high cost and limited availability of raw materials during the development phase has resulted in the need to process small amounts of active pharmaceutical ingredients (API's) and excipients via extrusion to determine process viability.

Brian Windsor, President of Enavail, said, "Enavail's goal is to provide our clients with the most cost-effective and time-saving processes that solve their formulation and delivery needs. HME expands our capabilities to develop innovative formulation solutions, particularly for poorly soluble drugs."

While many pharmaceutical companies can manufacture a highly soluble compound into a simple tablet or capsule, Envail's forté is in developing formulation solutions for poorly-water soluble and/or marginally bioavailable APIs, with complex or prolonged (up to weeks) release profiles, extended stability requirements, difficult delivery routes, and unusual dosage forms.

Enavail's broad areas of expertise include oral, inhalation, topical and parenteral formulations.

R&D to Commercial Scale

Enavail can accept projects for volumes of API or batch sizes of finished dosage forms ranging from a few milligrams to kilos to millions of discrete units (films, rings, patches). With its cGMP facility in Abilene, TX, Enavail can produce material for clinical batches up to commercial scale release.

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High Potency/Cytotoxic Compounds

The company has 800 sq. ft. of dedicated facilities specifically for handling high potency and cytotoxic compounds in both their research facility in Austin, TX, and their cGMP facility in Abilene, TX. These facilities have dedicated equipment trains, security and safety measures and SOP protocols for Enavail personnel working with these compounds.

DEA Controlled Substances

Enavail is registered with the Drug Enforcement Agency (DEA) for Analytical work on Schedule I compounds and expects registration to be complete for manufacturing work with Schedule II compounds by the end of 2011.

About Enavail

Enavail is a specialty pharmaceutical company focused on generating unique dosage forms and solving challenging formulation issues. With state-of-the-art research and cGMP manufacturing facilities located in Austin and Abilene, Texas, Enavail uses a quality by design approach to provide specialized manufacturing expertise for pharmaceutical, biotech, and nutraceutical companies, with capabilities including working with cytotoxic, high potency and DEA scheduled compounds. Areas of expertise include oral, inhalation, topical and parenteral formulations using standard pharmaceutical techniques as well as specialized technologies such as hot melt extrusion (HME) and proprietary particle engineering for poorly water-soluble compounds.

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