

Nonconfidential Summary Disclosure



UM 1520 - Bioadhesive Film Technology And Drug Delivery Systems

THE TECHNOLOGY

The current research continues on the development of a relatively new technology – hot-melt extrusion (HME) for pharmaceutical applications. The hot-melt extrusion technique is a viable method to prepare numerous drug delivery systems. For pharmaceutical applications, HME offers many advantages over traditional processing techniques, including (1) a more environmentally friendly technique (2) a potential continuous process; and (3) a lower production cost.

The bioavailability of drug substances also improves when dispersed at the molecular level in HME dosage forms.

Natural product compounds and other poorly soluble drugs that show a low bioavailability due to solubility issues are prime candidates for this technology.

Immunization and the oral mucosa: The Hot-melt Extruded Bioadhesive Laminated Platform (iHELP™) technology may be used as a delivery system for peptides and proteins, which may include vaccines. The iHELP™ technology entails a bioerodable film matrix for transmucosal drug and vaccine delivery. The system has demonstrated adhesiveness to the wet mucosal surface for up to 16 hours. Protein/peptides and vaccines can be pre- or post-loaded into the laminated matrix without hindering adherence time to the mucosa.

Transmucosal drug delivery system: The intra-oral transmucosal buccal or labial route of drug administration has some unique benefits, including avoiding the first pass effect, easy accessibility and enhanced patient compliance. The other advantages include high cellular turn over rate contributing to rapid cellular recovery and ability to withstand environmental extremes.



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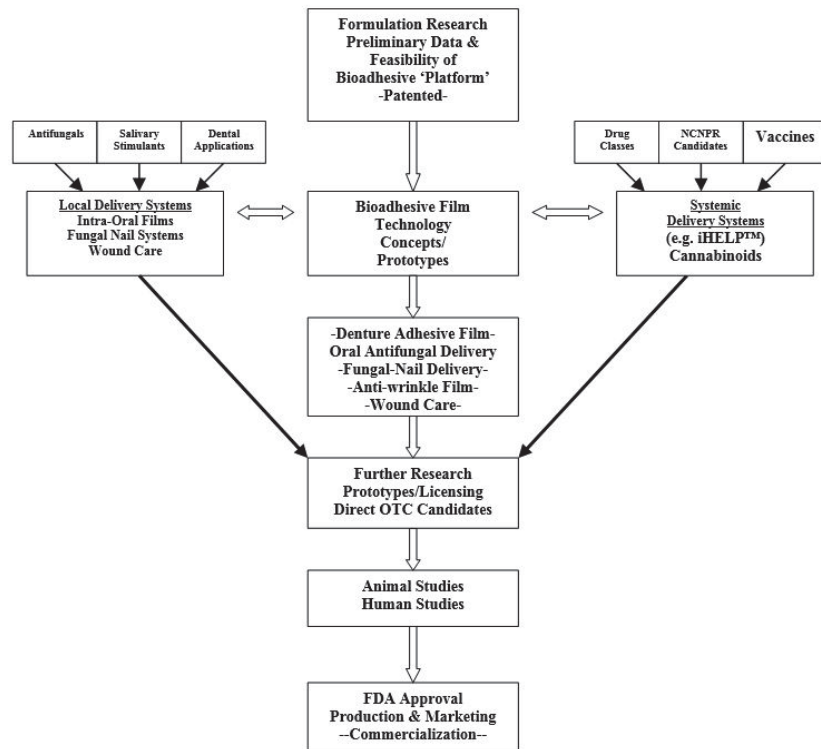
COMPETITIVE ADVANTAGE

Fungal Nail Treatment: The current platform technology has been demonstrated to be applicable for topical treatment modalities for the recalcitrant disease process, onychomycosis (fungal nail). Novel bioadhesion techniques have been developed to determine the peak adhesive force, the elongation at adhesive failure and the work of adhesion of polymeric film systems applied onto nail samples.

Skin Care: Wrinkles and Aging spots may be treated with Alpha-hydroxy Film Strips. With the option of containing Vitamins E and/or C, these Strips are wetted and applied at night to areas of concern. The transparent film comfortably works throughout the night to remove those unwanted wrinkles.

DEVELOPMENT POTENTIAL

OTC product development platform
 Rx product development platform



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