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Developmental challenges of a product containing both chemical and biological APIs

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Niacin and lovastatin are cholesterol lowering drugs. Niacin synthesized from tryptophan belongs to BCS class 1 with pKa 2.17 and plasma $t_{1/2}$ 20-48 min. Lovastatin naturally occurring in oyster mushrooms was isolated from *Aspergillus terreus* in 1982 and derived from red yeast rice in 1998. It is classified as BCS class 2 with pKa 13.49 and$t_{1/2}$ 4.5h. This presentation aims (1) to review lovastatin production using submerged culture vs. solid state fermentation of *Aspergillus terreus* and various chemically defined media, (2) toelucidate the fabrication ofa two-layer tablet design containing 250 mg niacin and 20 mg lovastatin, (3) to describe the formulation of a 20 mg lovastatin mini tablet in the delayed-then-extended dissolution release manner (without niacin). For aim 1, five literatures will be summarized. For aim 2, niacin heated with carnauba wax and stearic acid to blend. Once cooled, the solid mixture was tritulated with Carbomer 940 NF, Methocel K_4M Cr, sodium starch glucolate and Kollidone VA 64 to compress into a caplet. Ground mixture of lovastatin (the second drug), magnesium stearate, SDS and Avicel PH100 were added on top of niacin caplet to compress into the second layer. For aim 3, beta-cyclodextrin was complexed with lovastin (1:1 molar ratio) in hydroalcoholic solution. Once evaporated dried, this powder added with other excipients was compressed into mini tablets containing 20 mg lovastatin each. These cores were further enteric coated with a dispersion of Eudragit L 30D-55 and water (1:1 v/v). Content assay and *in vitro* release samples were quantified by HPLC.DSC confirmed no interaction between lovastatin and excipients. This project recommends that niacin (a rather acidic very water soluble small molecule) and lovastatin (an acid labile poorly water soluble macromolecule) be formulated separately.

Biography

Monica C Chuong is an Associate Professor of Pharmaceutics at the MCPHS University, Boston, MA, teaching Controlled Drug Delivery, Bioprocess Unit Operations, Pharmaceutical Technology, Introduction to Cosmetic and Personal Care Products, Pharmaceutical Particulate Science and Pharmaceutics Laboratories. She received her PhD in Pharmaceutics from University of Houston and postdoctoral training in Solid Dosage Formulation, Oregon State University. Her research interests are HPLC assay development, *in vitro* drug release, solid, percutaneous dosage forms and personal care products. She served as the chairperson of AAPS Northeast Regional Discussion Group in 2012, secretary of AAPS Chem & Bio API Manufacturing Technology Focus Group 2014-15. She is also a member of Society of Cosmetic Chemists.

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