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Deterrence capacity of abuse-deterrent dosage forms to ethanol

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Due largely to the misuse of opioid pain medications, prescription drug abuse has rapidly reached epidemic proportions in America. Of particular concern is the non-medical use of products having opioids in highly potent long-acting formulations. Certain products of this type became known to rapidly release their drug load in the presence of alcohol. Since co-ingestion of alcohol with prescription drugs is a common form of abuse, novel abuse-deterrent formulations should be insensitive to the effects of ethanol as well as other tampering methods. In evaluating a products' resistance to ethanol extraction, in-vitro testing is preferred over clinical studies as less risk to human subjects is involved. The tests performed should replicate or directly simulate what the product may encounter by abusers. With chewing and crushing being common forms of abuse and accidental misuse, effects of ethanol both on intact and crushed product should be determined. Different ethanol-containing beverages such as beer, wines, spirits or aqueous solutions containing varied amounts of ethanol (range 4-40% v/v%) should be used in such studies. Several oral abuse-deterrent delivery systems form a viscous mass when dissolved in aqueous liquids. This creates a substance too thick to abuse by snorting or injecting. Most of the aqueous thickening agents used in these abuse-deterrent dosage forms are very hydrophilic, and hence display alcohol-sensitive rheology. In this study we used a cone-and-plate viscometer with an accurate temperature-controlled heating system to evaluate rheology of extract solution of polymeric excipients in different alcoholic solutions.

Biography

David Mastropietro received his B.S. in Pharmacy from Massachusetts College of Pharmacy in 1999. He is completing his Ph.D. in Pharmaceutics at Nova Southeastern University (NSU) with dissertation work focused on abuse-deterrent dosage-forms.

Srinath Muppalaneni earned a B.S. in Pharmacy from Andhra University (2008) and a M.S. in Pharmaceutical Sciences from Campbell University (2010). Srinath is currently a second year Ph.D. student at NSU in Pharmaceutics.

Hossein Omidian has a M.Sc. in Chemical Engineering and a Ph.D. in Polymer Science. He is currently an Associate Professor at NSU where David and Srinath are both part of his research group.

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