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Performance evaluation of abuse-deterrent dosage forms to mechanical manipulation

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Abstract

Abuse of prescription drugs for nonmedical purposes is a serious worldwide public health issue. Abusers have died when mechanically tampering (e.g. crushing, chewing, grating, or grinding) with medications in an attempt to quickly extract drug from the dosage form. One approach to combat this abuse is to design more resilient dosage forms, often referred to as abuse-deterrent, which need to be evaluated for their deterrence potential through in-vitro testing. Our objective was to provide a practical way to evaluate the extent of abuse by mechanical manipulation of a dosage form in its solid state. Crushing the dosage form generates particles of different size distribution, which would affect the air-flow property of the crushed particles. The larger the crushed particles are, the less favorable their flow would be. Since abusers have easy access to different household items such as low shear (spoons), or high shear (coffee grinder) mechanical tools, the size distribution of the crushed dosage form may vary. This variation can affect insufflation characteristics and alter the rate and extent of drug absorption. In general, an abuse-deterrent dosage form, if claimed as such, should have very limited flow after being crushed into particles. Flow properties of the crushed dosage form can help the manufacturer evaluate the deterrence potential of their medication. Additionally, this information may help support claims of abuse-deterrence to the FDA for product labeling purposes.

Biograpgy

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.