**DETERMINATION OF PHYSICOCHEMICAL PROPERTIES OF REFORMULATED OPANA ER AND A GENERIC OXYMORPHONE HCL ER FORMULATION**

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Background/Introduction: In 2012, Endo Pharmaceuticals introduced to the market reformulated Opana® ER (oxymorphone HCl ER tablets) which is designed to be crush resistant (CR). OPANA ER uses the excipient polyethylene oxide, which forms a viscous hydrogel when hydrated with small amounts of water and a manufacturing process that is intended to enhance the crush resistance of the tablets. Recently, generic oxymorphone HCl ER tablets have been approved by FDA. This study evaluates the physicochemical properties of a generic formulation and compares the results to those of similar testing performed previously on OPANA ER.

Methods: *In-vitro* tests were conducted by third party laboratories. These tests were comprised of physicochemical testing to evaluate the potential for crushing and manipulation of the generic formulation. Various sample preparation techniques were also employed to evaluate the extraction of the active ingredient in water.

Results: The generic oxymorphone HCl ER tablets were easily crushed between two spoons. In contrast, when tested using various tools including spoons, hammers, and pill crushers, OPANA ER could not be crushed although a coffee grinder was able to manipulate OPANA ER tablets. Additionally, the active ingredient from the crushed generic oxymorphone HCl ER tablets was solubilized and readily extracted from the excipients yielding a high percentage of oxymorphone . The polyethylene oxide in OPANA ER formed a viscous hydrogel in small amounts of water thereby limiting the amount of active ingredient which could be extracted.

Conclusion: *In-vitro* studies demonstrated that reformulated OPANA ER possesses physicochemical barriers to crushing and manipulation. In contrast, generic oxymorphone HCl ER , which does not possess these physicochemical barriers, was shown to be non-crush resistant and easily manipulated.