**COMPARATIVE TESTING OF PHYSICOCHEMICAL PROPERTIES OF REFORMULATED OPANA ER AND OXYCONTIN**

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Background/Introduction: Opana® ER (Oxymorphone HCl ER Tablets) is a formulation of oxymorphone which is designed to be crush resistant, and is intended to require a higher amount of effort, time, experience and tools to crush or manipulate, when compared to non-crush resistant formulations. OPANA ER and OxyContin® both use the excipient polyethylene oxide, which provides the extended release properties of the product and is intended to impair the ability to draw the drug into a syringe by forming a viscous hydrogel when hydrated with small amounts of water. OPANA ER and OXYCONTIN use manufacturing processes that are intended to enhance the crush resistance of the tablets.

Methods: The physicochemical characteristics of OPANA ER and OXYCONTIN were evaluated *in-vitro* by third-party laboratories to determine whether the two products behaved comparably based on their similar formulation characteristics. These studies were comprised of physicochemical tests to evaluate the potential for crushing and manipulation. Simple and advanced tools were employed to manipulate the products including spoons, hammers, pill crushers, knives, pliers, graters, and grinders. Analyses included breaking force based on the United States Pharmacopeia standard, indentation and compression using a texture analyzer, particle size analysis, and dissolution. Various sample preparation techniques were employed to evaluate the extraction of the active ingredient in water and other solvents.

Results: OPANA ER and OXYCONTIN performed comparably in tests of resistance to physical manipulation. The results of the extraction studies were similar for the two formulations.

Conclusion: Based on these results, both products provided a similar physical/chemical barrier to crushing and manipulation.