

18th ANNUAL PHARMA MIDDLE EAST CONGRESS

November 05-07, 2018 Abu Dhabi, UAE

Recent developments in abuse-deterrent and tamper-resistant opioid formulations and its changing regulatory requirements

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In recent year's number of opioids prescribed to patients for treating acute and chronic pain has significantly increased in United States. Steady rise in use of prescription opioids lead to an escalating misuse of these opioids which resulted in serious health consequences for the abusers. The opioids abuse epidemic has reached to a stage where it's affecting entire communities resulting in to a staggering financial burden due to the monetary costs associated with its nonmedical use, including reduced productivity and increased healthcare utilization. The problem of this magnitude requires a comprehensive approach which includes partnership of the regulatory agencies and industry. To confront the staggering human and economic toll created by opioid abuse and addiction, employing novel abuse deterrent technologies is one part of a comprehensive intervention strategy that can deter abuse of prescription opioid analgesics without creating barriers to the safe use of prescription opioids. Abuse deterrent and abuse resistant are the type of formulations where the opioid abuse can be prevented by using a physical barrier that makes manipulation of dosage form more difficult or using a combination of a substance making it less rewarding for abusers. Some significant technological advances are made by researchers and institutions to develop the formulation which can achieve the tamperproof formulation while maintaining the desired pharmacokinetic profile for the opioids. Current discussion includes review of the epidemiology of the crisis as background for the development of abuse deterrent technologies and provides a comprehensive overview of most recent technologies that are currently employed or are under study for incorporation into abuse deterrent technologies. These technologies can be mainly divided in 5 different classes' physical barrier, chemical barrier, antagonists, aversive agents and prodrug approach. The discussion also includes the updated regulatory requirements to generate data sufficient for a description of a product's abuse-deterrent properties.

Biography

Alap Choudhari is working in pharmaceutical industry as a research scientist for more than 15 years. His primary area of research work is focused on the development of solid oral, liquids and transdermal formulations. In his current assignment he is responsible to develop difficult to develop and complex generic formulations. Dr. Choudhari and his team has developed generic formulation for 6-8 abuse deterrent formulations and filled them with regulatory agencies. Due to his constant interactions with the regulatory agencies, he has knowledge of most updated requirements which the agencies are trying to enforce to make these formulations more difficult to abuse and safe for the patients. He is also involved in the development of in-house abuse deterrent formulation platform which is being used for various opioid formulations.

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