



Formulation of Pregabalin Controlled-Release Tablets: Influence of Some Lipid-Based Matrix Systems on the Release Rate

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SUMMARY. The aim of the current investigation was to evaluate the different types and concentration of newly used lipid-based matrix polymers, including cetyl alcohol (CA), carnauba wax (CW), cetostearyl alcohol (CSA), emulsifying wax (EW), and stearyl alcohol (SA) for the formulation of controlled-release tablets containing 150 mg pregabalin. The formulations were prepared by hot-melt granulation method. The prepared formulations were evaluated for the release of the drug over a period of 12 h in the different dissolution medium. All formulations were showed good mechanical strength. CA and CSA containing formulations were showed high retarding efficiency in pregabalin release along with good stability and reproducibility in their released pattern after 6 months stability studied of prepared formulations. The *in vitro* drug dissolution data of CA and CSA containing tablets were followed zero-order kinetics and Korsmeyer-Peppas model respectively. It has been concluded that the *in vitro* dissolution profile and the kinetic models indicate that CA and CSA are good candidates as a polymer for controlled release pregabalin tablet formulations.

RESUMEN. El objetivo de la investigación actual fue evaluar los diferentes tipos y concentración de polímeros de matriz basados en nuevos lípidos, incluyendo alcohol cetílico (CA), cera carnauba (CW), alcohol cetostearílico (CSA), cera emulsionante (EW) y alcohol estearílico (SA) para la formulación de comprimidos de liberación controlada que contienen 150 mg de pregabalina. Las formulaciones fueron preparadas por método de la granulación en caliente. Las formulaciones preparadas fueron evaluadas para el lanzamiento de la droga durante un período de 12 h en el diverso medio de la disolución. Todas las formulaciones demostraron buena fuerza mecánica. El CA y CSA que contenían formulaciones demostraron alta eficacia de retraso en la liberación de la pregabalina junto con buena estabilidad y reproducibilidad o después de 6 meses de estabilidad. Los datos *in vitro* de la disolución de la droga del CA y de las tabletas que contenían CSA mostraron una cinética de orden cero y modelo de Korsmeyer-Peppas, respectivamente. Se ha concluido que el perfil de disolución *in vitro* y los modelos cinéticos indican que CA y CSA son buenos candidatos como polímeros para formulaciones de tabletas de pregabalina de liberación controlada.

KEY WORDS: cetostearyl alcohol, cetyl alcohol, controlled release, hot melt granulation, pregabalin.

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