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Design and Optimization of Pregabalin Conventional Release Formulations using Central Composite Design and Response Surface Methodology

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***SUMMARY*. The aim of the current investigation was to formulate a cost-effective and simple pregabalin oral tablet formulation by direct compression method. Fifteen different trial formulations were prepared using central composite design (CCD) with response surface methodology (RSM) to obtain the best optimize formulation. Three variables with five different levels (-1.73, -1, 0, +1, and +1.73) were used to develop and optimize pregabalin tablets. All formulations were evaluated utilizing micromeritic studies along with standard physicochemical tests. After initial testing, four best-selected formulations were subjected to stability studies. Results of micromeritics testing of powder blend and various physicochemical tests were found within acceptable USP limits. The drug released pattern of four best formulations was followed the first-order kinetics. Formulations tests for stability studies showed no physical and chemical changes even after storage under accelerated conditions. It is concluded that pregabalin immediate release tablets were successfully prepared by direct compression method using CCD and RSM techniques.**

RESUMEN. El objetivo de la investigación actual fue elaborar una formulación de tabletas orales de pregabalina, rentable y simple, mediante el método de compression directa. Se prepararon quince formulaciones diferentes utilizando el diseño compuesto central (CCD) con metodología de superficie de respuesta (RSM) para obtener la formulación mejor optimizada. Se utilizaron tres variables con cinco niveles diferentes (-1,73, -1, 0, 1 y 1,73) para desarrollar y optimizar las tabletas de pregabalina. Todas las formulaciones fueron evaluadas utilizando estudios micromeríticos junto con pruebas fisicoquímicas estándar. Después de la prueba inicial, cuatro formulaciones fueron seleccionadas para someterlas a estudios de estabilidad. Los resultados de la prueba micromerítica de la mezcla del polvo y de varias pruebas fisicoquímicas se encontraron dentro de límites aceptables de USP. El patrón de liberación de la droga de las cuatro mejores formulaciones siguió una cinética de primer orden. Las formulaciones probadas para estudios de estabilidad no mostraron cambios físicos y químicos incluso después del almacenamiento en condiciones aceleradas. Se concluye que las tabletas del liberación inmediata de pregabalina fueron preparadas con éxito por el método directo de compression usando técnicas del CCD y RSM.

KEY WORDS: central composite design, direct compression, formulations, pregabalin, response surface methodology.

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