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Statistical Assessment of Dissolution Profile Comparison of Nimodipine 30 mg Tablets Available in Local Market of Karachi, Pakistan

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SUMMARY. **The objective of the present study was to determine the quality of six different brands of nimodipine 30 mg film coated tablets which are commercially available in the local market of Karachi, Pakistan. We performed different physico-chemical tests which were weight variation test, thickness, diameter, disintegration, hardness, dissolution and assay tests. All the brands (NimoA to NimoF) have passed all these tests and the results were within the adequate limits. Also release profiles of all brands were compared at pH 1.2, phosphate buffer pH 4.5 and pH 6.8 and in order to determine the surfactant effects on dissolution profiles, sodium dodecyl sulfate (SDS) was used in 0.3 % concentration in above mentioned dissolution media, also drug release profile was also evaluated by using acetate buffer pH 4.5 with SDS which was recommended as a official method for nimodipine film coated tablets. In the present study various statistical approaches were used for the data analysis which was recommended by FDA such as One way ANOVA, model dependent and in-dependent method. Results of the ANOVA showed that no significant variation was found within and between different brands as p-values were less than 0.05, similarly results of drug release was best fitted to Weibull model ($r^2 = 0.997$).**

RESUMEN. El objetivo del presente estudio fue determinar la calidad de seis marcas diferentes de comprimidos recubiertos de 30 mg de nimodipina que están comercialmente disponibles en el mercado local de Karachi , Pakistán. Se realizaron diferentes pruebas físico-químicas tales como variación de peso, espesor, diámetro, desintegración, dureza y disolución. Todas las marcas (NimoA a NimoF) pasaron todas las pruebas y los resultados se encontraron dentro de los límites adecuados. También se compararon los perfiles de liberación a pH 1,2, tampón fosfato pH 4,5 y pH 6,8; con el fin de determinar los efectos de agente tensioactivo sobre los perfiles de disolución se usó dodecilsulfato de sodio (SDS) en concentración de 0,3 % en los medios de disolución mencionados anteriormente; también se evaluó el perfil de liberación del fármaco mediante el uso de acetato de pH 4,5 con SDS, recomendado como método oficial para comprimidos de nimodipina. En el presente estudio se utilizaron varios métodos estadísticos para el análisis de datos recomendados por la FDA, tal como One way ANOVA, así como modelos independiente y dependiente. Los resultados del ANOVA mostraron que no hay ninguna variación significativa dentro de y entre las diferentes marcas, ya que los valores de p fueron menores que 0,05; de manera similar los resultados de liberación de fármaco mostraron modelos de Weibull y Higuchi debido a sus altos valores de r^2.

KEY WORDS: Nimodipine, Surfactant, Dissolution profile comparison, Drug release kinetics and ANOVA.

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