



Experimental Study on the Kinetic Behavior of Moxifloxacin Hydrochloride

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SUMMARY. Moxifloxacin HCl is a broad spectrum fluoroquinolone antibiotic having strong activity against aerobic and gram positive bacteria. Comparison of drug release profile of different salts of fluoroquinolones antibiotic moxifloxacin hydrochloride tablets were studied according to the International Conference on Harmonization (ICH) guidelines. As per ICH guidelines accelerated stability condition 40 ± 2 °C /75% \pm 5% RH for 3 months were applied to the samples of different salts of moxifloxacin HCl. After performing all the physical and chemical quality control analysis tests the results showed that they complied the official limits provided in official monograph of tablet specifications. HPLC method was used for determination of the assay and percentage purity of the tablets, dissolution testing was performed at dissolution apparatus for 45 min, buffer solution of 0.1 N HCl at 50 rpm and disintegration was performed by the disintegration assembly. All the physical and chemical tests *i.e.* friability, hardness, weight variation, color, shape, disintegration time, and dissolution assay were performed. The results showed that all the tests were within the specified official limits and the assay were within the limits of 90-110%; no any drug salt assay was found below the limit of 90% and not exceed any salt above the limit of 110%.

RESUMEN. Moxifloxacin HCl es un antibiótico de fluoroquinolona de amplio espectro que tiene una fuerte actividad contra bacterias aerobias y gram positivas. La comparación del perfil de liberación de fármacos de diferentes sales de comprimidos de clorhidrato de moxifloxacin se estudiaron de acuerdo con las directrices de la Conferencia Internacional de Armonización (ICH). Según las pautas de ICH, se aplicaron condiciones de estabilidad acelerada de 40 ± 2 °C / 75% \pm 5% HR durante 3 meses a las muestras de diferentes sales de moxifloxacin HCl. Después de realizar todas las pruebas de análisis de control de calidad físico y químico, los resultados mostraron que cumplían con los límites oficiales establecidos en la monografía oficial de las especificaciones de la tableta. Se usó el método de HPLC para la determinación del ensayo y el porcentaje de pureza de las tabletas, la prueba de disolución se realizó en un aparato de disolución durante 45 minutos, la solución tampón de HCl 0,1 N a 50 rpm y la desintegración se realizó mediante el conjunto de desintegración. Se realizaron todas las pruebas físicas y químicas, es decir, friabilidad, dureza, variación de peso, color, forma, tiempo de desintegración y ensayo de disolución. Los resultados mostraron que todas las pruebas estaban dentro de los límites oficiales especificados y el ensayo estaba dentro de los límites de 90-110%; no se encontró ningún ensayo de sal de drogas por debajo del límite del 90% y ninguna sal excede el límite del 110%.

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