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Chromatographic Stability Indicating Quantification of Ramipril in Bulk and Dosage Forms

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***SUMMARY*. A reversed phase high-performance liquid chromatographic (RP-HPLC) method was adopted and validated as a stability indicating method for the determination of ramipril (RMP) in presence of its degradation products. The degradation process was performed under acidic, basic, oxidative and thermal conditions, as recommended by the International Conference on Harmonization (ICH)-guidelines. Also, the stability of the tablet form was studied under the storage conditions indicated by the ICH-guidelines (temperature of 40 °C and relative humidity of 75%, for 6 months). The cited method was validated according to the guidelines of ICH-Q2B. The method was conducted on Hypersil™ ODS C_{18} column (150 × 4.6 mm, 5 μm) as a stationary phase. The mobile phase was optimized to be 0.05 M potassium dihydrogen phosphate buffer (adjusted to pH 5 using *ortho*phosphoric acid): acetonitrile (15:85, *v/v*), pumped using an isocratic pump. The method was found to be suitable for the analysis of RMP in bulk and dosage forms.**

RESUMEN. Se adoptó y validó un método de cromatografía líquida de alta resolución de fase inversa (RP-HPLC) como método de indicación de la estabilidad para la determinación de ramipril (RMP) en presencia de sus productos de degradación. El proceso de degradación se realizó bajo condiciones ácidas, básicas, oxidativas y térmicas, según lo recomendado por la Conferencia Internacional sobre Armonización (ICH). Además, se estudió la estabilidad de la forma de tableta en las condiciones de almacenamiento indicadas por las directrices ICH (temperatura de 40 °C y humedad relativa del 75%, durante 6 meses). El método citado fue validado de acuerdo con las directrices de ICH-Q2B. El método se realizó en una columna Hypersil™ ODS C_{18} (150 × 4,6 mm, 5 μm) como fase estacionaria. La fase móvil se optimizó con tampón de dihidrógeno fosfato de potasio 0,05 M (ajustado a pH 5 usando ácido *orto*fosfórico):acetonitrilo (15:85, *v/v*), usando una bomba isocrática. Se encontró que el método era adecuado para el análisis de RMP en masa y dosificado.

KEY WORDS: HPLC, ramipril, stability indicating, storage conditions.

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