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Development and Validation of an HPLC-UV Method for Determination of Sertraline Hydrochloride and Application to Study Dissolution of Tablets

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***SUMMARY*. Sertraline hydrochloride, an antidepressant drug, belongs to the selective serotonin reuptake inhibitors. An HPLC-UV method suitable for studying the drug dissolution from different dosage strengths (25-100 mg) was developed and validated according to the Food and Drug Administration agency (FDA) reviewer guidance on validation of chromatographic methods and the recommendations of International Conference of Harmonization (ICH). Chromatographic separation was performed on a Shimadzu-10AV system using a Hpersil GOLD C18 column (4.6 × 150 mm, 5 μm) for the separation and a mobile phase consisting of methanol and phosphate buffer (0.2 mol/L, pH 7.40) mixture (80:20 V/V). Results indicated that the method was selective, linear in the range 10-300 μg/mL (R^2 > 0.9996), accurate (88.47-103.31) and precise (CV%: 1.35-4.7). Stock solutions and the prepared samples exhibited satisfactory stability at room temperature. The method was robust to small changes in composition, pH of the mobile phase, and in flow rate. It was applied successfully to study dissolution from 50 mg Zoloft® tablet (Pfizer).**

RESUMEN. El hidrocloruro de sertralina, un fármaco antidepresivo, pertenece a los inhibidores selectivos de la recaptación de serotonina. Se desarrolló y validó un método de HPLC-UV adecuado para estudiar la disolución del fármaco a partir de diferentes concentraciones de dosificación (25-100 mg) de acuerdo con la guía de validación del método cromatográfico (FDA) y las recomendaciones de ICH. La separación cromatográfica se realizó en un sistema Shimadzu-10AV usando una columna Hpersil GOLD C18 (4,6 × 150 mm, 5 μm) para la separación y una fase móvil consistente en una mezcla de metanol y tampón fosfato 0,2 mol/L de pH 7,40 (80:20 V/V). Los resultados indicaron que el método era selectivo, lineal en el rango de 10-300 μg/mL (R^2 > 0,9996), seguro (88,47-103,31) y preciso (CV%: 1,35-4,7). Las soluciones madre y las muestras preparadas mostraron una estabilidad satisfactoria a temperatura ambiente. El método es robusto a pequeños cambios en la composición, pH de la fase móvil y caudal. Se aplicó con éxito para estudiar la disolución de comprimidos de 50 mg Zoloft® (Pfizer).

KEY WORDS: dissolution testing, HPLC-UV, method development and validation, sertraline hydrochloride.

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