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Development, Validation and Pharmacokinetic Application of a Simple and Robust RP-HPLC Method for Quantitation of Raloxifene in Rat Plasma

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***SUMMARY*. A simple and sensitive HPLC method has been developed and validated for the quantification of raloxifene in rat plasma. Liquid- liquid extraction procedure was employed for extracting raloxifene from rat plasma sample. Separation of raloxifene was achieved through a RP- C18 column with a mobile phase consisted of phosphate buffer and acetonitrile (66:34 %, v/v). The method was validated for specificity, selectivity, sensitivity, linearity, accuracy, precision, recovery and stability parameters. A linear response (R2 value 0.9991) was found over the calibration range of 50 to 500 ng/mL. The accuracy for intra and inter day run varied between 86.73 to 102.30 % and 91.11 to 95.56%, respectively. The corresponding precision (% CV) were within 0.82 to 9.43% and 6.23 to 8.33%. The method was also found to be specific and stable. The applicability of the method was established through a single dose oral pharmacokinetic study of raloxifene in rat.**

RESUMEN. Se ha desarrollado y validado un método de HPLC simple y sensible para la cuantificación de raloxifeno en plasma de rata. Se empleó un procedimiento de extracción líquido-líquido para extraer raloxifeno de la muestra de plasma de rata. La separación xifeno se consiguió a través de una columna RP-C18 con una fase móvil constituida por tampón fosfato y acetonitrilo (66:34%, v/v). El método fue validado para los parámetros de especificidad, selectividad, sensibilidad, linealidad, precisión, seguidad, recuperación y estabilidad. Se encontró una respuesta lineal (valor R2 = 0,9991) en el intervalo de calibración de 50 a 500 ng/mL. La exactitud para intra- e inter día varió entre 86.73 a 102.30% y 91.11 a 95.56%, respectivamente. La precisión correspondiente (% CV) fue de 0,82 a 9,43% y de 6,23 a 8,33%. También se encontró que el método era específico y estable. Se estableció la aplicabilidad del método mediante un estudio farmacocinético de dosis única oral de raloxifeno en ratas.

KEY WORDS: bioanalytical method development; pharmacokinetic application; raloxifene hydrochloride; rat plasma; validation.

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