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Bioanalytical Method Development and Validation of Gatifloxacin

Hafiz Muhammad ARSHAD [1], Muhammad H. SHOAIB [2],
Wajiha IFFAT [1] *, Muhammad Bilal AZMI [3] & Kamran ZAHEER [4]

[1] *Department of Pharmaceutics, Dow College of Pharmacy, Dow University of Health Sciences, Karachi - Sind - 75270 – Pakistan.*
[2] *Department of Pharmaceutics, Faculty of Pharmacy, University of Karachi, Karachi - Sind - 75270 – Pakistan.*
[3] *Department of Biochemistry, Dow Medical College, Dow University of Health Sciences, Karachi - Sind - 75270 – Pakistan.*
[4] *Department of Pharmaceutics, Faculty of Pharmacy, Hamdard University, Karachi - 75270 – Pakistan.*

***SUMMARY*. An HPLC isocratic pump with UV-VIS detector attached with C18 guard column and C18 column (HiChrom, 250 mm × 4.6 cm) was used. Mobile Phase consisted of 80% NaH2PO4 and 20% acetonitrile with pH adjusted to 3 with ortho-phosphoric acid. The flow rate was maintained at 1 mL/min and the wavelength was set at 293 nm having the retention time was 9-12 min. The calibration curve was derived by plotting the peak area versus concentration range of 0.039-20 μg/mL was found to be linear (r^2 = 0.9953). Limit of detection (LOD) and lower limit of quantification (LLOQ) of the method were 1.2 and 4.8 ng/mL, respectively. Absolute recovery of gatifloxacin from plasma was in the range 96.121-97.129%, The developed method being simple, rapid and reproducible can be suitably employed in pharmacokinetic and bioequivalence studies of gatifloxacin.**

RESUMEN. Se usó una bomba isocrática de HPLC con detector UV-VIS unido a una columna de protección C18 y una columna C18 (HiChrom, 250 mm × 4,6 cm). La fase móvil consistió en un 80% de NaH2PO4 y un 20% de acetonitrilo con un pH ajustado a 3 con ácido orto-fosfórico. La velocidad de flujo se mantuvo a 1 mL/min y la longitud de onda se ajustó a 293 nm con un tiempo de retención de 9 a 12 min. La curva de calibración se derivó trazando el área del pico frente al rango de concentración de 0.039-20 μg/mL que se encontró que era lineal (r^2 = 0.9953). El límite de detección (LOD) y el límite inferior de cuantificación (LLOQ) del método fueron 1.2 y 4.8 ng/mL, respectivamente. La recuperación absoluta de gatifloxacina a partir del plasma estuvo en el rango 96.121-97.129%. El método desarrollado es simple, rápido y reproducible y puede emplearse adecuadamente en estudios farmacocinéticos y de bioequivalencia de gatifloxacina.

KEY WORDS: bioanalytical method, gatifloxacin, high performance liquid chromatography, validation parameters.

* Author to whom correspondence should be addressed. *E-mail:* wajiha.iffat@duhs.edu.pk

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