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Validated Stability Indicating RP-LC Assay for Determination of Gatifloxacin and Prednisolone Acetate in Ophthalmic Preparations and Biological Samples

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***SUMMARY*. A straightforward, fast and specific stability indicating RP-HPLC method was developed for the direct determination of gatifloxacin and prednisolone in ophthalmic preparation as well as in spiked human plasma and urine samples. Chromatographic separations for gatifloxacin, prednisolone as well as their degradation products (stress induced) were obtained in 16 min on BDS Hypersil C_8-5 μm (250 × 4.6 mm) as stationary phase column at 210 nm (diode array detector); mobile phase was comprised by mixture of methanol-water (60:40 v/v) and 0.1% triethylamine, flow rate 1.5 mL/min at pH 3.0 adjusted with dilute trifluoro-acetic acid. Validation studies were performed according to ICH guidelines. There was a linear function of concentrations over the range for 21-39 μg/mL for gatifloxacin and 70-130 μg/mL for prednisolone. Limit of detection and limit of quantitation for gatifloxacin were determined as 0.042 and 0.140 μg/mL, respectively, and for prednisolone were 0.110 and 0.367 μg/mL, respectively. Good separation of analytes as well as their degradation products was observed with acceptable values of resolution and tailing. After the application of all stress conditions peak purity index was ≥ 0.9999 for both analytes, indicating their complete separation from degradation products peaks.**

RESUMEN. Se desarrolló un método de RP-HPLC sencillo, rápido y específico para la determinación directa de gatifloxacina y prednisolona en una preparación oftálmica, así como en muestras de plasma y orina humanos. Las separaciones cromatográficas para gatifloxacina y prednisolona, así como sus productos de degradación (inducidos por el estrés) se obtuvieron en 16 min utilizando una columna de fase estacionaria Hypersil BDS C_8-5 μm (250 × 4,6 mm) a 210 nm (detector de matriz de diodos), usando como fase móvil una mezcla de metanol-agua (60:40 v/v) y 0,1% de trietilamina, a un caudal de 1,5 mL/min a pH 3,0 ajustado con ácido trifluoroacético diluido. Los estudios de validación se realizaron según las directrices de la ICH. Hubo una función lineal de concentraciones en el rango de 21 a 39 mg/mL para la gatifloxacina y de 70 a 130 mg/mL para prednisolona. Los límites de detección y de cuantificación para gatifloxacina fueron de 0,042 y 0,140 μg/mL, respectivamente, y para prednisolona de 0,110 y 0,367 μg/mL, respectivamente. Se observó buena separación de los analitos, así como sus productos de degradación con valores de resolución aceptables. Después de la aplicación de todas las condiciones de estrés el valor de pureza fue ≥ 0,9999 para ambos analitos, indicando su separación completa de los productos de degradación.

KEY WORDS: antibiotics, corticosteroid, serum, urine.

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