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Analytical Optimization of Auranofin, Oxaceprol and Tofacitinib in Pharmaceutical Dosage Form by Response Surface Methodology: A Qbd Approach

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SUMMARY. An analytical method was developed for the newer rheumatoid arthritis medications Auranofin, Oxaceprol and Tofacitinib by chromatography (HPLC and HPTLC) and ultra violet (UV) spectroscopy. The Cary 5000 double-beam spectrophotometer was used to detect the UV absorbance. Chromatographic separation was performed in Agilent C_{18} column with a mobile phase consisting of different concentrations of methanol and phosphate buffer and HPTLC determination using Camag Linomet with densitometric scanner. Variables of the methods was optimized by response surface methodology via the Box-Behnken design using Digital expert Stat-Ease-360 software. The methods were verified by ICH requirements, the stability of the drugs was considered under forced stress environment and observed a transitional degradation pattern. The drugs exhibit chromatographic peak with reliable retention periods with a clear and distinct peak for Auranofin, Oxaceprol and Tofacitinib detected at wavelength maximums of 232, 212, and 295, respectively. The three medications have a percentage recovery ranging from 97% to 100% w/w in its oral formulations by parallel determination with relative standard deviation less than 2. By ICH regulations, the procedures were confirmed and a transitional deterioration pattern was perceived while taking into account the medications' stability in a forced stress environment. The developed method was found to be consistent and appropriate for routine screening of selected anti rheumatic drugs in bulk dosage form as well as in pharmaceutical formulation without any intrusions.

RESUMEN. Se desarrolló un método analítico para los nuevos medicamentos para la artritis reumatoide, Auranofin, Oxaceprol y Tofacitinib, mediante cromatografía (HPLC y HPTLC) y espectroscopía ultravioleta (UV). Se utilizó el espectrofotómetro de doble haz Cary 5000 para determinar la absorbancia UV. La separación cromatográfica se realizó en una columna Agilent C18 con una fase móvil compuesta por diferentes concentraciones de metanol y tampón fosfato, y la determinación por HPTLC se realizó con Camag Linomet y escáner densitométrico. Las variables de los métodos se optimizaron mediante la metodología de superficie de respuesta mediante el diseño Box-Behnken con el software Digital Expert Stat-Ease-360. Los métodos se verificaron según los requisitos de la ICH, se consideró la estabilidad de los fármacos en un entorno de estrés forzado y se observó un patrón de degradación transicional. Los fármacos presentan un pico cromatográfico con períodos de retención fiables, con un pico claro y distintivo para auranofina, oxaceprol y tofacitinib detectado a longitudes de onda máximas de 232, 212 y 295, respectivamente. Los tres medicamentos presentan un porcentaje de recuperación que oscila entre el 97 % y el 100 % p/p en sus formulaciones orales mediante determinación paralela, con una desviación estándar relativa inferior a 2. Según las normas de la ICH, se confirmaron los procedimientos y se observó un patrón de deterioro transitorio, considerando la estabilidad de los medicamentos en un entorno de estrés forzado. El método desarrollado resultó ser consistente y adecuado para el cribado rutinario de fármacos antirreumáticos seleccionados, tanto en forma de dosificación a granel como en formulación farmacéutica, sin intrusiones.

KEYWORDS: Auranofin, Box Behnken, HPLC, Oxaceprol, Tofacitinib, UV.

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