



Development and Validation of a New Spectrophotometric Method for the Determination of Regorafenib in Pure and Tablet Dosage Form

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SUMMARY. Regorafenib is an oral multikinase inhibitor indicated for metastatic colorectal cancer and gastrointestinal stromal tumour. Simple, sensitive, rapid, accurate, precise and economical new spectrophotometric methods were developed and validated for the estimation of regorafenib in pure and its dosage form according to ICH guidelines. Regorafenib exhibited maximum absorbance at 261 nm. The calibration curve was found to be linear over the concentration range from 0.5 to 25 µg/mL with the correlation coefficient value (r) of 0.999. Limit of detection (LOD) and limit of quantification (LOQ) were 0.11 and 0.29 µg/mL, respectively. The proposed method does not require expensive solvents, extraction, derivatization and time consuming steps. The developed method was found to be simple, sensitive, accurate, cheap, rapid and precise and was applicable in routine analysis and quality control laboratories of pharmaceutical industries for the determination of regorafenib in pure form and pharmaceutical formulations.

RESUMEN. Regorafenib es un inhibidor oral de la multiquinasa indicado para el cáncer colorrectal metastásico y el tumor del estroma gastrointestinal. Se desarrollaron y validaron nuevos métodos espectrofotométricos simples, sensibles, rápidos, precisos, seguros y económicos para la estimación de regorafenib en forma pura y su forma de dosificación de acuerdo con las directrices de ICH. Regorafenib exhibió una concentración absorbancia máxima a 261 nm. Se encontró que la curva de calibración era lineal en el rango de de 0.5 a 25 µg/mL con un valor del coeficiente de correlación (r) de 0.999. El límite de detección (LOD) y el límite de cuantificación (LOQ) fueron 0,11 y 0,29 µg/mL, respectivamente. El método propuesto no requiere costosos solventes, extracción, derivatización y pasos que requieren mucho tiempo. Se comprobó que el método desarrollado era simple, sensible, preciso, económico, rápido y preciso y era aplicable en análisis rutinarios y laboratorios de control de calidad de industrias farmacéuticas para la determinación de regorafenib en forma pura y formulaciones farmacéuticas.

KEY WORDS: regorafenib, tablet dosage form, UV-spectrophotometric method, validation.

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