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QbD Based Optimization of Saxagliptin and Dapagliflozin Simultaneously in Pharmaceutical Dosage Form by Spectroscopic and Chromatographic Methods

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SUMMARY. The concurrent determination of dapagliflozin (DPZ) and saxagliptin (SGT) in bulk and tablet dosage forms has been made attainable by developing a modest, consistent, and accurate UV absorbance ratio, HPLC and HPTLC approach. The UV absorbance ratio method enumerates the absorption at 276 and 290 nm, which is the isosbestic point and wavelength maximum of dapagliflozin respectively. A 20 cm × 20 cm HPTLC glass plate coated with silica gel 60 F_{254} was operated for the HPTLC separation process using a mixture of ethyl acetate: toluene: glacial acetic acid: water (12:4:2:2) as the mobile phase. For HPLC analysis, the acetonitrile and phosphate buffer a 75:25 ratio were used as the mobile phase in an isocratic C_{18} column. HPTLC-densitometry and HPLC scanning were effectuated by UV detection at 276 nm. A unique chromatogram and spectra for DPZ and SGT were able to be envisioned by developed methods, which are analogous to the sample results. The developed techniques were verified in terms of precision, accuracy (recovery) and linearity. The developed methodology can be used to estimate pharmaceutical formulations without the immersion of additional diluents or excipients. The outcomes were verified using the QbD methodology and ICH recommendations and found to be reliable for the routine examination of drugs in therapeutic formulations.

RESUMEN. La determinación simultánea de dapagliflozina (DPZ) y saxagliptina (SGT) en presentaciones farmacéuticas a granel y en comprimidos se ha logrado mediante el desarrollo de un método de HPLC y HPTLC de razón de absorbancia UV modesto, consistente y preciso. El método de razón de absorbancia UV enumera la absorción a 276 y 290 nm, que son el punto isosbéstico y la longitud de onda máxima de dapagliflozina, respectivamente. Se utilizó una placa de vidrio de HPTLC de 20 cm × 20 cm recubierta con gel de sílice 60 F254 para el proceso de separación HPTLC utilizando una mezcla de acetato de etilo: tolueno: ácido acético glacial: agua (12:4:2:2) como fase móvil. Para el análisis HPLC, se utilizó acetonitrilo y tampón de fosfato en una proporción 75:25 como fase móvil en una columna C18 isocrática. La densitometría por HPTLC y el barrido HPLC se efectuaron mediante detección UV a 276 nm. Se logró visualizar un cromatograma y espectros únicos para DPZ y SGT mediante métodos desarrollados, análogos a los resultados de las muestras. Las técnicas desarrolladas se verificaron en términos de precisión, exactitud (recuperación) y linealidad. La metodología desarrollada permite estimar formulaciones farmacéuticas sin la adición de diluyentes o excipientes adicionales. Los resultados se verificaron utilizando la metodología QbD y las recomendaciones de la ICH, y se demostró su fiabilidad para el análisis rutinario de fármacos en formulaciones terapéuticas.

KEYWORDS: dapagliflozin, HPLC, HPTLC, saxagliptin, UV absorbance ratio,

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