Design, Optimization, and Validation of Thin-Layer Chromatography–Densitometry and Chemometry-Assisted Spectrophotometry: A Comparative Study Applied on Quaternary Mixture

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Abstract

This work presents a comparative study on the development and validation of two analytical techniques applied for the simultaneous determination of hydrocortisone acetate (HCA), fusidic acid (FSA), methyl paraben (MPB), and propyl paraben (PPB) formulated as a topical cream. The first technique was thin-layer chromatography (TLC)–densitometric method, which was developed by separating the four components on silica gel 60 F254 using methylene chloride–methanol–benzene in the ratio of 10:2:5, v/v, as the developing system, followed by densitometric measurement of the bands at 240 nm. The second technique was the chemometric method using two models: principle component regression model (PCR) and partial least squares (PLS). The suggested techniques were validated in compliance with the International Conference on Harmonization (ICH) guidelines and were successfully applied for the determination of the quaternary mixtures as prepared synthetically in laboratory and in the commercial topical pharmaceutical formulation.

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