Dina S. El-Kafrawy et al, Pharmaceut Reg Affairs 2017, 6:1(Suppl)
DOI: 10.4172/2167-7689-C1-025

Validated stability-indicating HPLC-DAD method for simultaneous determination of sertaconazole nitrate, Sorbic acid and Methylparaben in cream dosage form

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This study deals with the development and validation of a comprehensive stability-indicating high performance liquid chromatography with diode array detection (HPLC-DAD) method for simultaneous determination of sertaconazole nitrate (SN), sorbic acid (SA) and methylparaben (MP). To the best of our knowledge, no published methods could be found in the scientific literature for analysis of this ternary mixture. Effective chromatographic separation was achieved using Venusil XBP CN column (4.6 × 250 mm) with gradient elution of the mobile phase composed of mixed phosphate buffer pH 2.5 and acetonitrile. The quantification of SN was based on measuring its peak areas at 225 nm, while the quantification of MP and SA was based on measuring their peak areas at 259 nm. SA, MP and SN peaks eluted at retention times of 4.76, 6.77 and 11.28 min, respectively. Analytical performance of the proposed HPLC procedure was thoroughly validated with respect to system suitability, linearity, ranges, precision, accuracy, specificity, robustness, detection and quantification limits. The linearity ranges for SN, MP and SA were 1–200, 1–250 and 0.5–100 μg mL−1, respectively, with correlation coefficients >0.9999. The analytes were subjected to forced-degradation conditions of neutral, acidic and alkaline hydrolysis, oxidation, photo and thermal degradation. The proposed method proved to be stability-indicating by resolution of the analytes from their forced-degradation products. Moreover, specificity of the method was verified by resolution of the analytes from more than 15 pharmaceutical compounds of various medicinal categories. The validated HPLC method was successfully applied to the analysis of the cited compounds in their combined cream dosage form. The proposed method made use of DAD as a tool for peak identity and purity confirmation.

Biography

Dina S. El-Kafrawy is graduated 2003 from faculty of pharmacy, Alexandria university. She has her expertise in development and validation of new analytical methods for the determination of various drugs in their pure form and different dosage forms, also development of stability indicating analytical methods for many drugs and their simultaneous determination with their degradation products and related substances. She has got her master in pharmaceutical sciences 2007 and her PhD 2012.

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