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A novel ion-pair RP-HPLC method for simultaneous quantification of naproxen and esomeprazole in pharmaceutical formulations

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A rapid, sensitive and stability indicating ion-pair reversed-phase high-performance liquid chromatographic method was developed for simultaneous estimation of naproxen (NPX) and esomeprazole (ESP) in pharmaceutical preparations. In our study, this new method was used to overcome the instability problem of ESP during high performance liquid chromatographic analysis in the presence of acidic drugs such as NPX. The method was validated according to ICH, FDA and USP guidelines with respect to accuracy, precision, specificity, linearity, solution stability, robustness, sensitivity and system suitability. The method was developed by using an isocratic condition of mobile phase comprising buffer [tetrabutylammonium hydroxide (0.0077 M) and n-heptane sulfonic acid–Na salt (0.002 M), pH 7.6], acetonitrile and methanol in a 60:20: 20 v/v/v ratio at a flow rate of 1.5 mL/min over a C-18 (Octadecyl-silica, 5 mm, 250 3 4.6 mm) column at ambient temperature. The recovery for both drugs was found to be > 99% which demonstrated the accuracy of this method. Intra- and inter-day precision studies of the new method were less than the maximum allowable limit [% relative standard deviation (RSD) ≤ 2.0 according to FDA]. The method showed linear response with a correlation coefficient (r^2) value of 0.999 for both drugs. More importantly, ESP was quite stable in diluting solvent and mobile phase in the presence of NPX for >3 days. Therefore, it was found to be an accurate, reproducible, sensitive and highly stability-indicating method and can be successfully applied for routine analysis of simultaneous assay of NPX and ESP in pharmaceutical dosage forms.

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Evaluation of 2, 3-epoxypropyl groups and functionalization yield in glycidyl methacrylate monoliths using gas chromatography

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Poly (glycidyl methacrylate-co-ethylene dimethacrylate) (poly (GMA-co-EDMA)) is most frequently used as parent monolith to obtain stationary phases with a variety of surface chemistries for liquid chromatography and capillary electrochromatography. Functionalization is performed by opening the accessible 2, 3-epoxypropyl groups of the monolith with a suitable reagent. The number of 2, 3-epoxypropyl groups which are accessible before and after the functionalization reaction, and the grafting yield, are important parameters required both to optimize functionalization and to interpret the chromatographic performance of functionalized monoliths. In this work, a method capable of providing this information for parent and functionalized poly (GMA-co-EDMA) monoliths prepared both in silica capillaries and in other supports is proposed. First, sulfuric acid and lithium aluminium hydride (LiAlH4) are sequentially used to release the 2, 3-epoxypropyl groups as glycerol, which is subsequently determined by GC. About 6.0 mmol of 2, 3-epoxypropyl groups per gram of monolith was found in this work for the parent monoliths prepared in silica capillaries using UV-initiation. The monoliths were also functionalized using ammonia (NH3), diethylamine (DEA) and epinephrine, and the amount of residual 2, 3-epoxypropyl groups, and hence the functionalization yield, were established by also measuring the GC peak of glycerol. The amounts of 2, 3-epoxypropyl groups and the derivatization yields were established with good RSDs. The proposed method was also applied to the characterization of poly (GMA-co-EDMA) monoliths prepared in glass vials. Significant differences with respect to those prepared in 100 µm I.D. silica capillaries were evidenced.

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