

Simultaneous Determination of Aspirin, Dipyridamole and Two of Their Related Impurities in Capsules by Validated TLC-Densitometric and HPLC Methods

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Abstract

Aspirin (ASP) and dipyridamole (DIP) are widely used as a combination in pharmaceutical formulations for treatment of strokes. Many of these formulations are containing tartaric acid as an excipient (in DIP pellets formulation for sustained release), which increases the probability of formation of dipyridamole tartaric acid ester impurity (DIP-I). On the other hand, salicylic acid (SAL) is considered to be one of the synthesis impurities and a degradation product of ASP. In this work, two chromatographic methods, namely, TLC-densitometry and HPLC, have been established and validated for simultaneous determination of ASP, DIP, SAL and DIP-I. Good separation was achieved by using silica gel as stationary phase and toluene-methanol-ethyl acetate (2:3:5, by volume) as mobile phase in the case of TLC-densitometry and Zorbax ODS column with mobile phase consisting of phosphate buffer (pH 3.3)-acetonitrile-triethylamine (40:60:0.03, by volume) for HPLC. Influence of different organic solvents in mobile phase composition has been studied to optimize the separation efficiency in TLC densitometry. Moreover, factors affecting the efficiency of HPLC, like pH of the buffer used, organic solvent ratio in the mobile phase and flow rate, have been carefully studied using one variable at a time approach. Finally, the proposed methods were validated as per ICH guidelines

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