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Validation of a Rapid HPLC Method for the Simultaneous Determination of Amoxicillin Trihydrate and Sulbactam Pivoxil in Pharmaceuticals †

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Abstract: The amoxicillin trihydrate (AMO)/sulbactam pivoxil (SP) combination is used in oral antibiotic therapy in almost all Latin American countries, Korea and China. The simultaneous determination of AMO and SP presents two important challenges: firstly, both analytes have very dissimilar solubility, and they also differ considerably concerning their molar absorptivities. Furthermore, this combination has not been referenced by any pharmacopeia. This research aims to optimize and validate a simple and fast HPLC/UV method capable of simultaneously determining AMO and SP in pharmaceuticals. A reverse phase C18 column was used with a mobile phase consisting of acetonitrile and water (80:20 v/v) in isocratic mode. The retention times were found to be 2.26 min and 1.34 min for SP and AMO, respectively. No interferences were found with excipients commonly used in oral suspensions and tablets. The linearity range was evaluated over the concentration range of 2.5 and 250.0 µg mL^{-1} (correlation coefficients greater than 0.9996). The method was validated according to ICH guidelines. The optimized HPLC/UV method proved to be reliable, meeting the requirements for linearity, precision, accuracy, robustness, and system suitability in the range studied.

Keywords: amoxicillin trihydrate; sulbactam pivoxil; HPLC; method validation.

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Conflicts of Interest

The authors declare no conflict of interest. The funders had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, or in the decision to publish the results.