

Assays of Active Ingredient Content and Dissolution of Oral Dosage Forms Containing Amoxicillin Trihydrate and Sulbactam Pivoxil by HPLC †

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Abstract: Amoxicillin trihydrate (AMO)/sulbactam pivoxil (SP) is commercialized in solid oral forms. This combination has not been reported in any pharmacopeia. Moreover, there are no dissolution studies of AMO/SP formulations in the literature, and only one study devoted to their determination in tablets, where the AMO/SP ratio of 1:1 is analyzed. The purpose of the present work is the application of a new HPLC/UV method to perform the analytical determination of AMO and SP in oral formulations, both in assay and dissolution studies, even at the more challenging AMO/SP ratio of 7:1. The HPLC method used a reverse phase C18 column with a mobile phase consisting of acetonitrile and water (80:20 v/v) in isocratic mode. The samples analyzed were oral tablets and suspensions (AMO/SP ratio from 1:1 to 7:1). The dissolution study was carried out by testing several media of sodium lauryl sulfate, polysorbate 20, and polysorbate 80. The conditions used were: apparatus II at 75 rpm, 900mL of medium, and a temperature of 37±0.5°C. The maximum dissolved percentages achieved (99% for AMO and 91% for SP) were obtained when polysorbate 20 (0.10% w/v) was used as a medium. The HPLC method was suitable for determining AMO and SP (recovery 91.2-100%) in tablets and oral suspensions, even in formulations where the AMO/SP ratio was as high as 7:1.

Keywords: Amoxicillin trihydrate; sulbactam pivoxil; HPLC; drug content; dissolution; oral dosage forms.

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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.