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A Comparative Study on the Dissolution Profiles of Commercial Aminophylline Tablets

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ABSTRACT

Dissolution profiles (DPs) of "U-L" aminophylline tablet, supplied by U-Liang Chem. & Pharm. Co., Ltd. Taiwan, used as the reference formulation in this study, were compared with those of ten commercial tablets. Dissolution tests were performed by employing USP XXIV apparatus-II (Paddle type) at 50 rpm. Pure water, 0.1N HCl and pH7.4 buffer were used as the dissolution media. The releasing percentages of the active ingredients were measured at 5, 10, 20, 30, 45, 60 and 90 minutes, respectively. The factor f_2 of the FDA SUPAC Guide was applied to the qualitative determination on the similarity of "U-L" aminophylline tablets dissolution profiles, and those of each investigated formulations. The results indicated that none had similar DPs comparing to those of controlled samples in all three media. 2 out of the 10 tested samples were of similar DDS (20%) to those of "U-L" aminophylline tablets in both water and pH 7.4 buffer solution. One tested formulation showed similar in-vitro release profile to that of controlled tablets in water (10%), yet was different in both of the other two media. In summary, the number of tested samples showing similar DPs as "U-L" aminophylline tablets in individual media were as follows: 3 in water (30%); 2 in pH 7.4 buffer solution (20%); and none in 0.1N HCl.

Key words : aminophylline, dissolution profile, f_2 factor