

Quality Survey of Antibiotic Preparations in Taiwan between 2004 and 2011

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ABSTRACT

In order to investigate the quality of antibiotics used in Taiwan, series of post-marketing surveillance have been performed for eight years. All samples were collected from hospitals, clinics, manufacturers and importers in various counties from 2004-2011 by local health authorities. Totally, 35 different antibiotics with nine testing items have been examined during eight years. The 1,567 test samples, which contained 1,364 domestic samples (87%) and 203 (13%) imported samples, were evaluated according to the analytical methods described in the Chinese Pharmacopoeia, the US Pharmacopoeia and the original manufactures' documents. The results showed 59 samples (3.8%) did not meet the requirements. Among them, quinolones antibiotic (10.2%) and oral preparation (11.0%) were the highest proportions in nine categories of antibiotics and nine different preparations that we have investigated, respectively. In addition, we found the common uncertified items were the dissolution test (4.4%) and moisture (0.9%) which involved the drug absorption and stability. The follow-up treatments and improvement of antibiotic products and manufacturers have been continuously monitored and tracked by health authorities.

Key words: antibiotic, quality control, post marketing surveillance