Backgroud Survey on the Quality of Active Pharmaceutical Ingredients from Pharmaceutical Plants in Taiwan

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ABSTRACT

In order to survey the quality of active pharmaceutical ingredients in Taiwan, 21 samples were collected from the pharmaceutical manufacturers by local health authorities in Taiwan from June to July in 2011.

These samples of active pharmaceutical ingredients belonging to acetaminophen, amoxicillin and dipyridamole were analyzed by the method referred to the respective monographs as described in the USP 32, and the results showed that all fulfilled the requirements of USP 32 monographs specification. In addition, we also analyzed the residual solvents in all samples according to USP Guide to General Chapters (467 Residual Solvents), and the results revealed that 5 samples failed to meet the general specification of methylene chloride.

Key words: active pharmaceutical ingredient, acetaminophen, amoxicillin, dipyridamole, quality survey