

# Survey on the Usage of Active Pharmaceutical Ingredients by Modern Pharmaceutical Manufacturers

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## ABSTRACT

In the initial stage of promoting the implementation of GMP for modern pharmaceutical products in Taiwan, for the purpose of encouraging manufactures to comply with the GMP standards and improving the research and development in domestic medicine, the importation of raw materials for private use was open to solve the dilemma of the difficulty to gain franchise agreement from manufactures of certain less-use materials in other countries. This measure really did enhance the growth of the pharmaceutical industry in Taiwan.

In view of rampant situation of counterfeit and inferior drugs recently, the Executive Yuan convened the 25<sup>th</sup> session of “Strength on cracking down on the counterfeit/inferior drugs and illegal radio stations” on 29 September, 2010 and passed a resolution of “Block Source and Ban Illegality”. In order to block the source of counterfeit and inferior drugs, inspection on raw materials used by modern pharmaceutical manufacturers will be reinforced to prevent the raw materials from being used illegally. This report is a research about the inspection on raw materials usage of modern pharmaceutical manufacturers.

Since November 2010, in order to cooperate with the follow-up GMP inspection of modern pharmaceutical manufacturers, the inspections of using raw materials by modern pharmaceutical manufacturers during 1 to 4 seasons in 2010 were conducted at the same time. Until April, 2011, 148 items in a total of 757 items of 25 inspected manufacturers were found to have deficiencies. It indicated that raw materials should be managed with more attention, at the present stage, by developing the feedback system on the application and usage of raw materials, reinforcing the management of agents, implementing the high standard PIC/S GMP in the future, implementing GMP on raw materials and amending Pharmaceutical Affairs Act, to protect the safety of public drug usage.

Key words: GMP, PIC/S GMP, modern pharmaceutical manufactures