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JANTHORN LIMPANAROM : EFFECT OF SOURCES OF COMPACTED AMOXICILLIN ON CHARACTERISTICS OF RAW MATERIALS AND THEIR CAPSULE PRODUCTS. THESIS ADVISORS : SATIT PUTTIPIPAKHACHORN, Ph.D., SONTAYA LIMMATVAPIRAT, Ph.D., 120 P. ISBN 974-664-658-3

It is known that drugs may vary in their characteristics between sources. Amoxicillin trihydrate used in this study was obtained from 6 local pharmaceutical manufacturers in Thailand. All of them were compacted granules used for capsule manufacture, which were then called compacted amoxicillin. The objective of the present study was to investigate the effect of sources of compacted amoxicillin on characteristics of raw material and their capsule products. Furthermore, the effect of particle size on dissolution behavior and stability was also studied. In this study, the properties of compacted amoxicillin obtained from various sources, such as physicochemical characteristics (i.e., appearance, powder X-ray diffraction patterns, infrared spectra, thermograms, water content), particle properties (i.e., particle size distribution, surface area, density, compressibility and flowability), dissolution behavior and stability, were assessed. The capsules containing related raw materials were analyzed for amoxicillin content per capsule, weight variation, disintegration and dissolution profiles. In addition, the compacted amoxicillin of various particle size fractions were investigated for their particle properties, particulate dissolution and stability. The results obtained from physicochemical study indicated that all compacted amoxicillins obtained from 6 sources were the same polymorphic form, trihydrate form. For particle properties, it was found that specific surface area of compacted amoxicillin was remarkably different between sources but no significant difference in the other particle properties. The sources also affected the dissolution characteristics and stability of compacted amoxicillin. A relationship between surface area and dissolution behavior of compacted amoxicillin was found to the effect that the higher surface area provided the higher dissolution rate. In addition, it was revealed that dissolution behavior of starting raw material strongly influenced the dissolution rate of amoxicillin capsules (500 mg). Furthermore, it was found that the particle size strongly affected the dissolution rate but there was no significant effect on stability of compacted amoxicillin. In summary, the overall results obtained showed that sources of compacted amoxicillin could affect important characteristics (i.e., dissolution and stability) and dissolution of their capsule products.