

難水溶性製剤の溶出試験に界面活性剤として使用される ポリソルベート 80 の品質に関する研究

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Effect of Variation in the Quality of Polysorbate80 Used in the Dissolution Test as a
Surfactant for Poorly Water-Soluble Drugs

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Summary

Polysorbate 80 (PS80) is a polyoxyethylene ether of anhydrous sorbitol, partially esterified with oleic acid. It is used as a surfactant to improve solubility in dissolution tests for poorly water-soluble drugs. The purpose of this study was to examine the effect of the chemical quality of PS80 on dissolution behavior.

Ten types of commercial PS80 samples were used in this study. Each PS80 sample was colorless or orange-yellow, and the pH values of their aqueous solutions (5.0 w/v %) were within the range of 5.73-6.73. All these PS80 samples conformed to the specifications of the Japanese Pharmacopoeia, sixteenth edition (acid value, saponification value, and iodine value). However, their acid values differed.

HPLC analyses of these samples were carried out using a differential refractive index detector. Multiple peaks were observed in each chromatogram. The chromatographic behaviors of these samples were classified into three types. The absorption spectra of the PS80 samples were measured by Fourier-transform infrared spectroscopy. The spectral features were not identical among the PS80 samples.

Dissolution tests were performed using nabumetone 400 mg tablet, riboflavin butyrate 40 mg tablet and allylestrenol 25 mg tablet as drug samples. Three types of commercial PS80 of different chemical quality were used for these tests. It was found that dissolution behavior of each test tablet remained the same, irrespective of the PS80 preparation used.

Key words

Polysorbate 80, Tween 80, Chemical quality, Dissolution test, pH value, Infrared absorption spectra, HPLC chromatographic pattern, Fat and fatty oils test, Nabumetone tablet, Riboflavin butyrate tablet, Allylestrenol tablet