

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 ラウリル硫酸ナトリウムの品質に関する研究 (第2報[†])

梶村 計志^{*1, #}, 川口 正美^{*1}, 四方田 千佳子^{*2}

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Variation in Quality of Sodium Dodecyl Sulfate Used as a Surfactant in the Dissolution Test for Poorly Water-Soluble Drugs (Part 2)

Keiji KAJIMURA^{*1, #}, Masami KAWAGUCHI^{*1} and Chikako YOMOTA^{*2}

Summary

The quality of sodium dodecylsulfate (SDS) reagents used in the dissolution test for poorly water-soluble drugs was investigated. We examined the effect of the pH value of the aqueous test medium containing SDS on the dissolution behavior in this study.

The pH values of aqueous solutions prepared with several commercial SDS reagents (20 samples; 1.0 w/v%) were measured. Three kinds of SDS reagents whose aqueous solutions showed different pH values were selected for further studies. The pH values of aqueous solutions (1.0 w/v%) prepared with these SDS reagents were 5.61, 6.98 and 8.32, respectively. All these SDS reagents conformed to the specification of "Sodium Lauryl Sulfate" prescribed in the Japanese Pharmacopoeia sixteenth edition (purity, water and total alcohol content). The pH-buffering abilities of the dissolution test media except for water were unaffected by the difference of SDS reagents. Dissolution test was carried out using piromidic acid 250 mg tablet, teprenone 50 mg tablet and mefenamic acid 250 mg capsule as test samples, with water as the test medium. It was found that all the above formulations showed different dissolution behaviors dependent on the SDS reagents used. In particular, the dissolution behavior of mefenamic acid capsule was dependent on the pH value of the test medium.

Our findings show that aqueous test media prepared with commercial SDS reagents have different pH values, which may influence the dissolution behavior of the active ingredient..

Key words

Sodium dodecyl sulfate, pH value, Dissolution test, Piromidic acid tablet, Teprenone capsule, Mefenamic acid capsule