

平成24年度「日本薬局方の試験法等に関する研究」
研究報告

アルファー化デンプンと部分アルファー化デンプンの識別に
関する研究*²

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Study on Identification Method to Discriminate between Totally Pregelatinized Starch,
Partly Pregelatinized Starch and Starch

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Summary

The monograph on pregelatinized starch is under discussion for harmonization among the Japanese, United States and European pharmacopeias (JP, USP and EP). In the JP, two individual monographs, "Pregelatinized Starch" and "Partly Pregelatinized Starch" are listed according to the degree of gelatinization, while in the USP and EP, these two types of pregelatinized starch are listed in one monograph. As a matter of JP policy, the monographs of "Pregelatinized Starch" and "Partly Pregelatinized Starch" should be harmonized individually, because the two types of pregelatinized starch are used for different purposes, depending on their degree of gelatinization. Therefore, identification tests that can discriminate among partly pregelatinized starches, "totally" pregelatinized starches and starch are required. In this paper, we propose identification tests for this purpose: First, microscopic observation under polarized light was done. Obvious birefringence could be seen for starch granules without gelatinization, and these granules showed a distinct black cross intersecting at the hilum. Most of the partly pregelatinized starch granules also showed the birefringent feature. On the contrary, "totally" pregelatinized starch granules showed no detectable birefringence. Next, sample powder-water slurry (0.5 g in 25 mL) was centrifuged at 3500 rpm for 15 minutes, and the color reaction of the supernatant liquid was observed when iodine solution was added. Starches without gelatinization showed no apparent reaction, while both partly and "totally" pregelatinized starches gave a deep blue or reddish-violet color. Starches of the three levels of gelatinization (without, partly and totally) could be well discriminated on the basis of the combined results of microscopic observation with polarized light and the starch-iodine test of the supernatant.

Key words

Pregelatinized starch, Starch, Identification, Microscopic examination, Polarized light, Starch-iodine test