

## 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1報)

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### Variation in Quality of Sodium Dodecyl Sulfate Used in the Dissolution Test as a Surfactant for the Poor Water Solubility Formulation (Part 1)

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#### Summary

We evaluated the quality of sodium dodecyl sulfate (SDS) used in the dissolution test as a surfactant. Dissolution tests were carried out using anetholtrithion 12.5 mg tablet, ipriflavone 200 mg tablet and cortisone acetate 25 mg tablet as samples. Three lots of commercial SDS from different manufacturers were used for these tests. It was found that the dissolution behavior of all the active ingredients differed depending upon the commercial source of the SDS used. All the SDS preparations conformed to the specifications of the Japanese Pharmacopoeia (JP) (purity, water, and total alcohol content). SDS conforming to JP standards is a mixture of sodium alkyl sulfates, consisting chiefly of SDS (C<sub>12</sub>). The homolog distributions (dodecyl (C<sub>12</sub>), tetradecyl (C<sub>14</sub>), and hexadecyl (C<sub>16</sub>)) in these commercial SDS preparations were determined by high-performance liquid chromatography, and the relative peak area for each homolog was measured.

About 25% C<sub>14</sub> and 6% C<sub>16</sub> alkyl chains were contained in one commercial SDS preparation, which gave high dissolution rates. The other two preparations contained less than one percent of C<sub>14</sub> and had no detectable amount of C<sub>16</sub> alkyl chain. It was concluded that the contents of homologs in SDS preparations are an important factor influencing the dissolution rate in the dissolution test.

The homolog distributions in other commercial SDS preparations (10 samples) were then examined. Most of these samples contained less than one percent of C<sub>14</sub> or C<sub>16</sub>. Our results indicate that the presence of small amounts of C<sub>14</sub> homolog in commercial SDS does not influence the dissolution behavior in the dissolution test.

#### Key words

Sodium dodecyl sulfate, Sodium tetradecyl sulfate, Dissolution test, Anetholtrithion tablet, Ipriflavone tablet, Cortisone acetate tablet