

トラネキサム酸カプセルにおける溶出挙動の経時変化に関する検討

川口 正美^{*1, #}, 梶村 計志^{*1}, 田口 修三^{*1}

(受付：平成 23 年 3 月 30 日, 受理：平成 23 年 7 月 29 日)

Changes in Dissolution Behavior of Tranexamic Acid Capsules during Storage

Masami KAWAGUCHI^{*1, #}, Keiji KAJIMURA^{*1} and Shuzo TAGUCHI^{*1}**Summary**

Many drugs have recently been recalled from the market because of decreased dissolution rate after storage. So, we investigated changes in the dissolution behavior of tranexamic acid (TA) capsules during storage.

Four products from different manufacturers were stored under 3 conditions (25°C/60% RH, 40°C/75% RH, and 25°C/75% RH), and then dissolution tests were performed after 0, 1, 4, 6 and 10 months using 4 types of dissolution medium (pH 1.2, pH 4.0, pH 6.8, and water). Dissolution curves were prepared according to the Orange Book (Japanese Edition). After storage at 25°C/60% RH and 25°C/75% RH, no time-course changes in dissolution behavior were observed in any of the products. After storage at 40°C/75% RH, marked changes were observed in three out of four products, and the most marked differences among the products were observed when water was used as the dissolution medium.

We then investigated the cause of these variations. When dissolution tests were performed using the capsule contents only, there was no delay or reduction of dissolution after storage. Thus, dissolution tests under the same conditions were performed, using samples prepared by exchanging the capsular shells and contents with those of other products.

Based on these study results, we concluded that the changes in the dissolution behavior of TA capsules after storage at 40°C/75% RH were mainly due to alterations in the capsular film.

Key words

Tranexamic Acid, Hard capsule, Dissolution behavior, Time-course changes, Storage test, Accelerated storage condition, Quality reevaluation, Japan edition of Orange Book