

医薬品の定量法における粉砕方法の影響について

高橋 和長^{*,#}, 長谷川 貴志^{*}, 西條 雅明^{*}, 吹譯 友秀^{*}, 浜名 正徳^{*}

(受付:平成25年8月21日, 受理:平成25年12月13日)

Effect of Tablet Powdering Method on the Assay of Drug Products

Kazunaga TAKAHASHI^{*,#}, Takashi HASEGAWA^{*}, Masaaki SAIJO^{*},
Tomohide FUKIWAKE^{*} and Masanori HAMANA^{*}

Summary

In the assays of tablets listed in monographs of the Japanese Pharmacopoeia (JP), it is often necessary for tablets to be powdered for preparing a sample solution. In the JP monographs of some tablets, powdering in an agate mortar is specified. However, in the monograph of most tablets, the method of powdering is not prescribed.

In this study, we examined the effect of different powdering methods on the assay of drugs. As tools to powder tablets, a porcelain mortar, an agate mortar and a stainless steel mill were used. Ebastine tablets, pioglitazone hydrochloride tablets and donepezil hydrochloride tablets were selected for the experiments. Assays of the selected tablets were performed according to the procedures described in the relevant monographs.

The analysis results of 20 products showed that in the case of 2 types of commercial donepezil hydrochloride tablets, the donepezil hydrochloride contents obtained when a stainless steel mill was used were significantly lower than those obtained when a porcelain mortar or an agate mortar was used. Careful analysis of powder that was released when the stainless steel mill was inverted and tapped, and powder that remained adhering to the stainless steel mill indicated that residual powder adhering to the stainless steel mill might account for the deviation of the assay value of the ingredient from the true value. These results indicated that appropriate selection of powdering method is necessary for accurate measurement of the contents of active ingredients in tablets.

Key words

Powdering method, Assay, Porcelain mortar, Agate mortar, Stainless steel mill, Ebastine, Pioglitazone hydrochloride, Donepezil hydrochloride

* 責任著者 Corresponding author