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粉砕調剤後の安定性の情報に関する調査・検討

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Evaluation of drug stability information after tablet crushing.

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Abstract

Objective: To pursue proper use of crushed tablet, we evaluated drug stability information after tablet crushing. We determined appropriate storage period after tablet crushing according to our evaluation standard.

Methods: We surveyed 406 drugs introduced in our hospital. To gather information about stability of crushed tablets, we surveyed literature and requested pharmaceutical companies to provide the information. We researched the examination contents including test item, conditions and period, and assessed stability based on newly established standards.

Results: Of 406 drugs, information about changes in active ingredient amounts and characteristics after tablet crushing was available in 259. Test conditions survey showed that only 80 drugs had been tested under various conditions including normal room temperature and humidity, high temperature and humidity, and light presence and absence. Stability assessment results showed that under appropriate storage conditions away from high temperature, humidity, and light, 210 drugs could be stored for greater than 4 weeks, while 14 drugs could not maintain stability for a week. However, the number of drugs deemed to be stable for more than four weeks under appropriate condition was decreased to 157 under light, and 62 under high temperature and humidity.

Conclusion: Due to lack of information, stability of many drugs after tablet crushing could not be suitably assessed. Methods and existing criteria to decide whether the drug is approved for crushing or not, vary from drug to drug. Therefore, it seemed to be very important for pharmacists to review the information strictly and provide appropriate information to patients and medical staff about tablet crushing.

Key words: tablet crushing, drug stability information, evaluation standard, approved for crushing, provision of information