

The accuracy, precision and sustainability of different techniques for tablet subdivision: Breaking by hand and the use of tablet splitters or a kitchen knife[☆]



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ABSTRACT

Introduction: Tablets are frequently subdivided to lower the dose, to facilitate swallowing by e.g. children or older people or to save costs. Splitting devices are commonly used when hand breaking is difficult or painful.

Methods: Three techniques for tablet subdivision were investigated: hand breaking, tablet splitter, kitchen knife. A best case drug (paracetamol), tablet (round, flat, uncoated, 500 mg) and operator (24-year student) were applied. Hundred tablets were subdivided by hand and by three devices of each of the following types: Fit & Healthy, Health Care Logistics, Lifetime, PillAid, PillTool, Pilomat tablet splitter; Blokker kitchen knife. The intra and inter device accuracy, precision and sustainability were investigated. The compliance to (adapted) regulatory requirements was investigated also.

Results: The accuracy and precision of hand broken tablets was 104/97% resp. 2.8/3.2% (one part per tablet considered; parts right/left side operator). The right/left accuracies of the splitting devices varied between 60 and 133%; the precisions 4.0 and 29.6%. The devices did not deteriorate over 100-fold use. Only hand broken tablets complied with all regulatory requirements.

Conclusion: Health care professionals should realize that tablet splitting may result in inaccurate dosing. Authorities should undertake appropriate measures to assure good function of tablet splitters and, where feasible, to reduce the need for their use.

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Abbreviations: EMA, European Medicines Agency; EDQM, European Directorate for the Quality of Medicines; MEB, Medicines Evaluation Board; SmPC, Summary of product characteristics; Ph. Eur., European pharmacopoeia; KNMP, Koninklijke Nederlandse Maatschappij ter bevordering der Pharmacie (Royal Dutch Society for the advancement of Pharmacy); FDA, US Food and Drug Administration.

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1. Introduction

Breaking or splitting tablets is common practice in inpatient and outpatient settings as it increases dosing flexibility, facilitates swallowing and allows cost savings for both patients and health-care providers (Dormuth et al., 2008; Ekedahl, 2013; Freeman et al., 2012b; Quinzler et al., 2006; Rodenhuis et al., 2004).

However, patients have indicated that it may be difficult and painful to break tablets by hand (Ekedahl, 2013; van Santen et al., 2002). This is especially true for patients with impaired hand function such as (school) children and older people (patient populations who often need lower doses or dose titrations) or patients suffering from rheumatic diseases (Barends et al., 2005; Ekedahl, 2013; Mehuys et al., 2012; Wilson et al., 2001). Ekedahl for example concluded that 31% of Swedish adult patients experienced

difficulties subdividing tablets, Mehuys et al. concluded that 29.7% of home dwelling older adults experienced difficulties when they had to subdivide tablets and Barends et al. concluded that older Dutch people were far less able to break tablets by hand than healthy adult volunteers. Wilson et al. reported a mean pain score of 3.2 out of 10 for generic anti-diabetic tablets when hand broken by older American citizens.

As breaking tablets by hand is often considered problematic, the use of tablet splitters is common. This is especially true for tablets that do not have a break mark. Other splitting devices such as kitchen knives or scissors may be applied as well (Ekedahl, 2013; Quinzler et al., 2009; Tahaine and Gharaibeh, 2012).

Indexed publications on the accuracy and precision of tablet splitters, kitchen knives or other devices that may be applied to subdivide tablets (all further referred to as “splitting devices”) generally show limitations as e.g. uncertainties about the type of device, operator or weight measurements applied; random selection of the device and tablet types; only small numbers of tablets/devices tested and the lack of data comparison between tablets subdivided with a splitting device and those broken by hand. Consequently, it is not yet possible to draw a firm conclusion on the suitability e.g. accuracy, precision, sustainability of splitting devices as an alternative to breaking tablets by hand.

In addition, the conclusion of Freeman’s review that tablet splitters may not subdivide tablets into equal doses and that the accuracy of tablet splitters may depend on the type of splitter, tablet or operator applied needs further consideration as the review shows methodological shortcomings such as no information on search profile, data extraction and data analysis and no quality evaluation of the included publications (Freeman et al., 2012a).

Therefore, the primary objective of this study was to evaluate the accuracy, precision and sustainability of commercially available tablet splitters and a kitchen knife as an alternative to breaking tablets by hand. The secondary objective was to evaluate if tablets subdivided with a splitting device were likely to comply with current regulatory requirements for break marked tablets (European Directorate for the Quality of Medicines (EDQM), 2013; European Union, 2001; US Department of Health and Human Services, FDA, 2011).

2. Material and methods

2.1. Study design

In this experiment three techniques for tablet subdivision were compared: hand breaking, tablet splitter, and kitchen knife. A hundred paracetamol tablets were hand broken by a single operator, by three devices of several types of tablets splitters or by three kitchen knives of the same type. The suitability of the techniques was compared by evaluation of the accuracy, precision, sustainability and regulatory compliance of the weight measurements. The experiment did not require ethical approval according to the Dutch Medical Research Involving Human Subjects Act (WMO). The study protocol was approved by the Committee on Clinical Practice of the Medicines Evaluation Board in the Netherlands.

2.2. Methodology

All data were collected between November 2012 and February 2013.

Splitting devices: Tablet splitters were included if these were available in the standard assortment of at least two community pharmacies or drug stores in Utrecht, the Netherlands. The pharmacies were identified via a list of the Dutch Society for the Advancement of Pharmacy (KNMP) whereas drug stores were identified via the Dutch Trading Register or the internet. Thirty five pharmacies and 59 drug stores were identified, selling 15 types of tablet splitters. Five tablet splitters were excluded because these were not in the pharmacy’s standard assortment and another four because these were sold in one establishment only. Six types of tablet splitters were included. The kitchen knife was purchased at a household warehouse in Utrecht (national chain) (Fig. 1).

Drug compound and tablet trade mark: Marketing authorisations for round, flat, uncoated, break marked 500 mg paracetamol tablets were identified with help of the database of the Medicines Evaluation Board in the Netherlands (MEB). The retrieved tablet authorisations were categorized in groups with authorisations for tablets sharing the same manufacturer and














	Fit&Healthy	HealthCare Logistics	LifeTime	PillAid	PillTool	Pilomat	kitchen knife
price paid (EUR)	8.99	8.54	0.99	2.67	2.25	4.95	0.59
picture device							
picture tablet holder							

Fig. 1. Characteristics splitting devices.

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