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ORIGINAL ARTICLE

Accuracy of tablet splitting: Comparison study between hand splitting and tablet cutter

Walid A. Habib [a,*], Abdulaziz S. Alanizi [a,b], Magdi M. Abdelhamid [a], Fars K. Alanizi [a]

[a] Department of Pharmaceutics, College of Pharmacy, King Saud University, Riyadh, Saudi Arabia
[b] King Fahad Hospital, King Abdul-Aziz Medical City, Riyadh, Saudi Arabia

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Tablet splitter;
Half tablets

Abstract *Background:* Tablet splitting is often used in pharmacy practice to adjust the administered doses. It is also used as a method of reducing medication costs.

Objective: To investigate the accuracy of tablet splitting by comparing hand splitting vs. a tablet cutter for a low dose drug tablet.

Methods: Salbutamol tablets (4 mg) were chosen as low dose tablets. A randomly selected equal number of tablets were split by hand and a tablet cutter, and the remaining tablets were kept whole. Weight variation and drug content were analysed for salbutamol in 0.1 N HCl using a validated spectrophotometric method. The percentages by which each whole tablet's or half-tablet's drug content and weight difference from sample mean values were compared with USP specification ranges for drug content. The %RSD was also calculated in order to determine whether the drugs met USP specification for %RSD. The tablets and half tablets were scanned using electron microscopy to show any visual differences arising from splitting.

Results: 27.5% of samples differed from sample mean values by a percentage that fell outside of USP specification for weight, of which 15% from the tablet cutter and 25% from those split by hand fell outside the specifications. All whole tablets and half tablets met the USP specifications for drug content but the variation of content between the two halves reached 21.3% of total content in case of hand splitting, and 7.13% only for the tablet cutter. The %RSDs for drug content and weight met the USP specification for whole salbutamol tablets and the half tablets which were split

* Corresponding author. Address: Al-Kayyali Chair for Pharmaceutical Industry, College of Pharmacy, King Saud University, P.O. Box 2457, Riyadh 11451, Saudi Arabia. Tel.: +966 1 467 3572, mobile: +966 59 287 1604.
E-mail address: walidhbb@gmail.com (W.A. Habib).

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by tablet cutter. The halves which were split by hand fell outside the specification for %RSD (drug content = 6.43%, weight = 8.33%). The differences were visually clear in the electron microscope scans.

Conclusion: Drug content variation in half-tablets appeared to be attributable to weight variation occurring during the splitting process. This could have serious clinical consequences for medications with a narrow therapeutic-toxic range. On the basis of our results, we recommend to avoid tablet splitting whenever possible or the use of an accurate tablet splitting device when splitting cannot be avoided.

1. Introduction

Although it is most common to use the whole tablets in therapy, they can be divided into halves (Duman et al., 2000; Verrue et al., 2011). Dividing a solid dosage form offers the advantages of ease of administration to the elderly, children or patients who have difficulty in swallowing (Duman et al., 2000), to achieve doses less than the smallest available manufactured strength and it is also being advocated as a method of reducing prescription drug costs .The cost of some medication regimens can be decreased by as much as 50% (McDevitt et al., 1998).

Uneven breaking of a tablet may result in significant fluctuations in the administered dose. This may be clinically significant for drugs with a narrow therapeutic range, such as warfarin or digoxin. For many drugs, however, especially those with long half-lives and/or a wide therapeutic range, dose fluctuations are unlikely to be clinically significant.

Unless breaking tablets where dosage is not a major issue such as vitamins or analgesics, splitting tablets is not a good idea. If breaking tablets is necessary, a special tablet splitting gadget can be used. Splitting of tablets should not be prescribed for serious medical conditions, extended-release or enteric-coated tablets and tablets without a score line.

There are many different ways to split tablets in half. One way is to purchase a tablet splitter from your local pharmacy (see Fig. 1). These tablet splitters are safe and easy to use. All you need to do is to place the tablet in the proper place and then when the splitter is closed, a steel blade cuts the tablet in halves. Some tablets are scored and have a line dividing the dose in half and may be able to be snapped in half using your fingers. Other alternatives used are splitting by hands (for scored tablets) or with scissors (for unscored tablets), or with a kitchen knife (Verrue et al., 2011).

Tablets with score line allow the administration of a portion of the tablet, which can then be considered as the unit dosage of the drug. However, actual dosages of hand-split tablets may deviate by more than 20% (McDevitt et al., 1998) and it may pose a serious risk for tablet uniformity and differ in the content of the two halves resulting in high or low blood levels which may affect the cure of the disease (Duman et al., 2000; Teng et al., 2002) especially if the dose is critical in disease treatment.

Few reports compared the bioavailability and dissolution of whole vs. half of the tablets and little effort has focus on the scoring effect on the uniform tablet divisibility (Duman et al., 2000). Properly scored tablets are necessary to divide the tablets into two equal halves (Duman et al., 2000). Besides the manufacturers' decision on tablet scoring, human factors (physical and psychological) affect the final performance of the scored tablet (Duman et al., 2000). Nonetheless, a literature review concluded that the available literature was limited to adequately address the safety of this practice (McDevitt et al., 1998).

Salbutamol tablet was used as a model in this study. Salbutamol or albuterol is a short-acting β2-adrenergic receptor agonist used for the relief of bronchospasm in conditions such as asthma (one of the most common chronic diseases in Saudi Arabia), and chronic obstructive pulmonary disease.

The aim of the current study is to investigate the drug content and weight of the split half tablet by hand vs. use of tablet cutter comparing with whole tablet for Salbutamol using the drug assay analysis.

2. Materials and methods

2.1. Materials

Salbutamol 2 mg and 4 mg tablets were studied (Table 1). This drug was chosen because it is widely used in Saudi Arabia for the treatment of asthma and its low dose (4 mg) as well as the presence of whole tablet (2 mg) which will be as standard for

Figure 1 Different design of tablet splitter.