

Quality of a Commonly Manipulated Oral Dosage Form Given to Children

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Manipulation of dosage forms is done due to a lack of commercially available child friendly formulations and required doses. The quality of the manipulated oral dosage form will affect the safety of the child. Hence, this study focused to assess the quality of a commonly manipulated oral dosage form. A detailed literature search was carried out to identify the commonly manipulated medicines, their available dosage forms and the methods used to manipulate them. All brands of the selected medicine currently available in Colombo district were collected and split by hand, knife, and tablet cutter. The whole dosage forms and the fragments were tested for their uniformity of weight, disintegration time, friability (BP 2012), assay (BP 2002) and dissolution (USP 42). Thickness, hardness and diameter were tested only for whole tablets. Tablet splitting was found to be the most common manipulation method. Carbamazepine tablets were selected for the study. The weight variation tests for all the fragments of the three tested brands did not comply with the BP specifications. No significant difference was seen in half tablets ($P=0.666$) and quarter tablets ($P=0.18$) split by tablet cutter and knife. All assay tests failed for hand split tablet fragments. When considering tablet halves, only 50% of fragments split by knife and 33.33% of fragments split by cutter passed the assay test. Only 16.66% of quarter tablets split by knife and tablet cutter passed the assay test and none of the one eighth fragments split by all the splitting methods passed the assay test. Except for the half tablets of one brand all others failed the friability test. The mean disintegration times of the fragments were less than the whole tablets. The correlation coefficient between the weight of the fragment and the percentage of drug release was 0.4168. The quality of the manipulated dosage form was not satisfactory. The quality of fragments split by a kitchen knife was better than fragments obtained from hand splitting and a tablet cutter.

Keywords: Manipulation, Split tablets, Tablet cutter, Dosage forms, Quality, Oral dosage form, Children