REVIEW ARTICLE

ORODISPERSIBLE TABLETS – A NOVEL APPROACH

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ABSTRACT

Pharmaceutical technologists have developed a novel oral dosage forms known as orally disintegrating tablets or fast disintegrating tablets or mouth melting tablets or mouth dissolving tablets which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water. The performance of ODTs depends on the technology used in their manufacture. The orally disintegrating property of these tablets is attributable to the quick ingress of water into the tablet matrix, which creates porous structure and results in rapid disintegration. Hence, the basic approaches to develop ODTs include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent and using highly water-soluble excipients in the formulation. Fast disintegrating tablets have better patient acceptance, compliance and possibly will tender enhanced biopharmaceutical properties, superior efficacy, and enhanced safety compared to conventional oral dosage forms. The perspective for such dosage forms is promising because of the accessibility of new technologies combined with strong market/patient acceptance.

KEYWORDS: Deglutition; Compliance; Tablets; Patients.

This article may be cited as: Bakhsh S. Orodispersible tablets – a novel approach. Gomal J Med Sci 2016; 14:175-7.

INTRODUCTION

Pharmaceutical technologists have developed a novel oral dosage form known as orally disintegrating (ODTs) or mouth dissolving tablets which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to take water.[1-7] The performance of ODTs depends on the technology used in their manufacture.[8,9] The orally disintegrating property of these tablets is attributable to the quick ingress of water into the tablet matrix, incorporating the appropriate disintegrating agent and using highly water-soluble excipients in the formulation.[10] A fast dissolving drug delivery system, in most cases, is a tablet that displays a fast and spontaneous de-aggregation in the mouth soon after contact with saliva, therefore, can be handled or extracted from the package without alteration.[7] The active agent can thus rapidly dissolve in the saliva and be absorbed through whatever membrane it encounters, during deglutition, unless it is protected from pre-gastric absorption.

ODTs have a number of immense beneficial features over other conventional dosage forms. It has been reported that dysphagia[11] is common among all age groups and especially pediatric and geriatric population along with institutionalized patients and patients with nausea, vomiting, and motion sickness complications.[12] A detailed survey revealed that 26 percent of patients mentioned problems in swallowing tablets.[8] A prominent complaint was the size and taste of the tablets. Twice as many women as men experienced swallowing problems. Elderly patients (>70 years) had less difficulty than younger patients in swallowing tablets. Pediatric and geriatric patients in particular experienced the greatest difficulty in swallowing tablets as well as people who were ill and supine in bed and those patients who were busy traveling without having access to water.[14,15]

ODTs with good taste and flavor increase the acceptability of bitter drugs in various groups of population. Recent advances in Novel Drug Delivery System (NDDS) aims to enhance safety and efficacy of already in use drug molecules by formulating a convenient dosage form for administration and to achieve better patient compliance.[13]

A drug cannot show its quick pharmacologic action until its serum concentration has to reach optimum level within a short period of time.[15] Apart from these, ODTs also offer easily measured dosing[16], consequently accurateness of dosage can be obtained.[17] The system gives swift commencement of action, and increase in bioavailability. The increased bioavailability of some orodispersible tablets compared to conventional tablets could be due to the

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Date Submitted 31-10-2016
Date Revised 20-11-2016
Date Accepted 15-12-2016

dispersion in saliva and pre-gastric absorption. This pre-gastric absorption avoids first pass metabolism and can be an immense advantage in drugs that go through a great deal of hepatic metabolism. Although chewable tablets have been on the market for some time, they are not the same as the new ODTs. Patients for whom chewing is difficult or painful can use these new tablets easily. ODTs can be used easily in children who have lost their primary teeth but do not have full use of their permanent teeth.[17,18]

DISCUSSION

Recent market studies indicate that more than half of the patient population prefers ODTs to other dosage forms[10] and most consumers would ask their doctors for ODTs (70%), purchase ODTs (70%), or prefer ODTs to regular tablets or liquids (>80%).[19]

Many drugs can be incorporated in ODT especially unpalatable drugs. Several factors must be considered when selecting drug for delivery as ODT dosage forms. In general, an ODT is formulated as a bioequivalent line extension of an existing oral dosage form. Under this circumstance, it is assumed that the absorption of a drug molecule from the ODT occurs in the post-gastric GIT segments, similar to the conventional oral dosage form[20] but this scenario may not always be the case. An ODT may have varying degrees of pre-gastric absorption and therefore, the pharmacokinetic profiles will vary. Therefore, the ODT will not be bioequivalent to the conventional oral dosage form. For instance, ODT formulations of some of the drugs like buspirone has significantly different pharmacokinetic profiles as compared to the same dose administered in a conventional dosage form[20,21] and the possibility for these differences may be due to the drug molecule, formulation, or a combination of both. If considerably elevated plasma levels have been observed, pre-gastric absorption leading to the avoidance of first-pass metabolism may play an important role. This situation may have implications for drug safety and efficacy, which may need to be addressed and assessed in a marketing application for an ODT.[21] For instance, safety profiles may be enhanced for drugs that produce a significant amount of toxic metabolites mediated by first pass liver metabolism and gastric metabolism and for drugs that have a sizeable portion of absorption in the oral cavity and segments of the pre-gastric GIT. Drugs having ability to diffuse and partition into the epithelium of the upper GIT (log P > 1, or preferable > 2); and those able to permeate oral mucosal tissue are considered ideal for ODT formulations. Patients who concurrently take anticholinergic medications may not be the best candidates for these drugs. Similarly, patients with Sjogren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.[21,22] Drugs with a short half-life and frequent dosing, drugs which are very bitter or otherwise of unacceptable taste because taste masking cannot be achieved or those which require controlled or sustained release are unsuitable candidates of rapidly dissolving oral dosage forms. Researchers have formulated ODT for various categories of drugs used for therapy in which rapid peak plasma concentration is required to achieve the desired pharmacological response.[22] These include neuroleptics, cardiovascular agents, analgesics, antiallergic, anti-epileptics, anxiolytics, sedatives, hypnotics, diuretics, anti-parkinsonism agents, anti-bacterial agents and drugs used for erectile dysfunction.[23-25] The research is still going on. More products need to be commercialized to use this technology properly. Thus ODT may be developed for most of the available drugs in near future.[22]

CONCLUSION

Fast disintegrating tablets have better patient acceptance, compliance and possibly will tender enhanced biopharmaceutical properties, superior efficacy, and enhanced safety compared to conventional oral dosage forms. The perspective for such dosage forms is promising because of the accessibility of new technologies combined with strong market/patient acceptance.

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CONFLICT OF INTEREST
Authors declare no conflict of interest.
GRANT SUPPORT AND FINANCIAL DISCLOSURE
None declared.

AUTHORS' CONTRIBUTION

Conception and Design:	SBA
Data collection, analysis & interpretation:	SBA
Manuscript writing:	SBA