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FORMULATION DEVELOPMENT OF CHEWABLE TABLETS FOR ASTHMATIC TREATMENT

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ABSTRACT

Chewable tablets are a versatile dosage form offering several advantages including oral drug delivery without the need for water, ease of swallowing, the stability advantages of solid dosage forms, and patient-centric drug delivery. They provide a convenient means of pediatric drug delivery and the delivery of nutritional products such as chewable multivitamins. Chewable tablets have also found application in veterinary medicines. This paper reviews considerations for the formulation of chewable tablets including sensory characteristics, chewability assessment, and various parameters like weight variation, thickness, friability, drug content in-vitro drug release and stability studies. In addition, patients with asthma need fast and immediate action of drug and avoidance of water is also desirable. Further, chewable tablets are beneficial for patients having difficulty in swallowing.

INTRODUCTION

Chewable tablets disintegrate slowly when chewed or allowed to dissolve in the mouth for local action. Chewable tablets are especially useful in tablet formulations for children and commonly employed in the preparation of multiple vitamin tablets.[1]

Chewable tablets are intended to be chewed in the mouth prior to swallowing and are not intended to be swallowed intact. The purpose of the chewable tablet is to provide unit dosage form of medication which can be easily administered to infants and children or to the elderly, who may have difficulty in swallowing a tablet intact. [2]Chewable dosage forms, such as soft pills, tablets, gums and most recently chewy squares have long been part of the pharmacist armamentarium.[3]

As a dosage form, chewable tablets have the advantages of conventional tablets in terms of manufacturability, dosing accuracy, portability, and long-term stability. Additionally, chewable tablets facilitate swallowing as the product is initially broken down into particles in the oral cavity. This is a useful patient-centric advantage for populations such as pediatrics for whom swallowing of conventional tablets is a concern.[4,5] As water is not required for their administration, there is a benefit of convenience when dosing.

Techniques used in the formulation of chewable tablets[6]

- Coating by wet granulation
- Microencapsulation
- Solid dispersion
- Adsorbate formation technique
- Ion exchange
- Spray congealing and spray coating
- Formation of different salts or derivatives
- Use of amino acids and protein hydrolysates
- Inclusion complexes
- Molecular complexes

Mechanical properties and chewability

The mechanical properties of a tablet are important to ensure tablet durability and low friability after compression, during packaging, shipping, and handling. For chewable tablets, they play a further role as these dosage forms must be readily chewable. Tablets having excessively high mechanical strength may present a risk to teeth, dentures, or mandibular joints. Only a few published studies have investigated the mechanical properties of marketed chewable tablets.[7]

FDA chewable tablets guidance- critical quality consideration summary

Attribute	Recommendations
Tablet hardness	Less than 12 kp; higher hardness values may be considered if justified (e.g., tablet rapidly softens or disintegrates after brief (< 30 seconds) exposure to simulated saliva)
Disintegration	Typically the same specifications as immediate-release tabets; important to determine since some individuals may swallow tablets without chewing
Dissolution	• Typically the same specifications as immediate-release tablets. Does not apply to chewable modified-release products • In vitro dissolution testing should be conducted on intact chewable tablets since some individuals may swallow tablets without chewing
Others	• Specific to the individual product (e.g., tablets with functionally coated particles should not be adversely affected by chewing) • Tablet size, shape, thickness, friability, palatability • The chewing difficulty index is discussed in the guidance; however limits are not provided

Drug release

As for any dosage form, the drug-release characteristics of chewable tablets are critical to the bio-performance of the active ingredient. Different pharmacopeia show a large degree of variation in the disintegration and dissolution requirements for chewable tablets with some monographs not having any requirements for drug release testing.[8] Omitting these tests, however, makes it challenging to evaluate the quality of chewable tablets and fails to address the question of what happens in the case of individuals who swallow chewable tablets whole. Although rare, the gastro-intestinal impaction of (unchewed) chewable tablets in adults leading to hospitalization has been reported [9]. Despite these reports, a study by Michele et al. on the safety of chewable tablets in children two years of age and older found that these products were safe and well tolerated, with medical issues related to chewable tablet formulation being extremely rare.

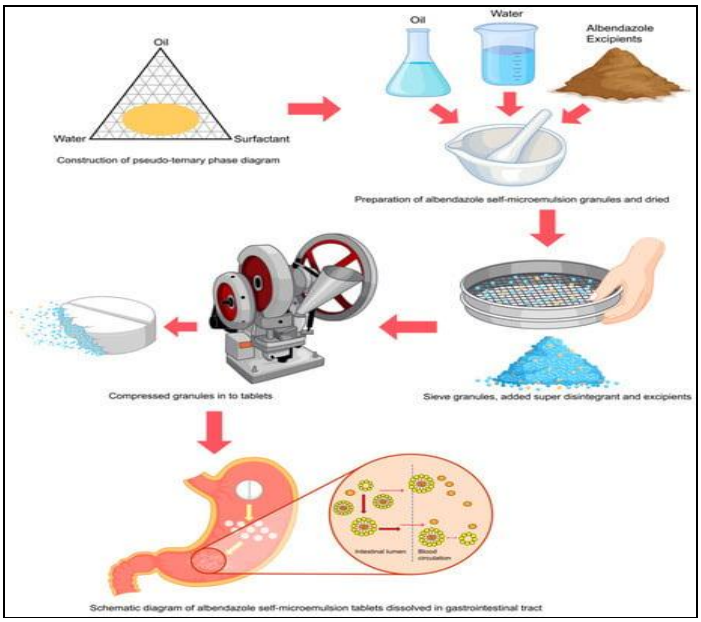

Figure Schematic diagram of the method preparation of chewable tablets with a proposed dissolution mechanism enhancing bioavailability.

Organoleptic Characteristics

The organoleptic characteristics of chewable tablets that are important to consider include taste, after-taste, odor, flavor, texture, mouthfeel, and visual aesthetics of the product. The oral processing of chewable tablets makes taste-masking a necessity for most formulations. Sweeteners are almost always used and represent the simplest means by which to address taste concerns. Combinations of bulk sweeteners (e.g., sugars or polyols) with high-intensity sweeteners (e.g., aspartame) are common. Flavors are commonly used in chewable tablets. Mint and peppermint flavors are popular in antacid tablets. Pediatric products often use fruit-based and bubblegum flavors. Dry powder forms of flavors are preferable as they avoid the loss of volatile aromatic components during drying. For the same reason, direct compression is often preferable for chewable tablet manufacturing. In cases where wet granulation is used, flavors should be added extra-granularly. Flavors can be further modified by the addition of agents such as citric acid.[10-13]

CONCLUSION

Chewable tablets are a versatile dosage form that combine the manufacturability and stability advantages of solid products while providing favorable organoleptic and administration benefits. The increased emphasis on patient-centric formulations in drug delivery presents further opportunities for the use of chewable tablets in specific populations such as pediatrics and differentiated pharmaceutical products as well as in other healthcare markets such as nutritional products, nutraceuticals, and veterinary medicines.[14,15]

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