

A Review on Formulation and Evaluation of Orally Disintegrating Tinospora Cordifolia Tablet

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Abstract: Oral route is the most preferred and convenient method of drug administration, with tablets and capsules being the most widely used dosage forms. Among these, Oral Dispersible Tablets (ODTs) have gained significant attention due to their ability to disintegrate rapidly in the mouth without the need for water, offering improved compliance for patients with dysphagia, pediatric, geriatric, bedridden, and mentally ill populations. ODTs dissolve within seconds through pregastric absorption, reducing hepatic first-pass metabolism and enhancing oral bioavailability. Their formulation commonly includes superdisintegrants such as croscopolidone, croscarmellose sodium, sodium starch glycolate, and MCC, which promote rapid disintegration. Despite their advantages, ODTs face several challenges including sensitivity to moisture and temperature, unpleasant after-taste, limitations in high-dose drug loading, and the need for specialized packaging to maintain stability. An ideal ODT must possess adequate mechanical strength, rapid disintegration, patient-acceptable size, and must leave no residue in the mouth. Regulatory definitions vary; the European Pharmacopoeia defines ODTs as tablets that disintegrate within three minutes, while the US FDA describes them as rapidly acting dosage forms that dissolve within seconds on the tongue. Overall, ODTs combine the stability of solid dosage forms with the ease of administration of liquid preparations, making them a preferred and evolving platform in modern drug delivery systems.

Keywords: Preformulation, superdisintegrants, Sodium starch glycolate; Patient compliance.

I. INTRODUCTION

The oral route is regarded as the most convenient, economical, and widely accepted method for drug administration. It offers advantages such as ease of intake, accurate dosing, and high patient compliance, which make oral dosage forms like tablets and capsules the preferred choice across all age groups. However, despite their popularity, traditional solid dosage forms can pose swallowing difficulties for certain populations, including pediatric, geriatric, dysphagic, mentally challenged, and bedridden patients. These limitations have encouraged the development of more patient-friendly oral formulations, among which Oral Dispersible Tablets (ODTs) have gained significant attention.

ODTs are advanced solid dosage forms that disintegrate or dissolve rapidly in the oral cavity—often within seconds—without the need for water. This feature makes them extremely suitable for patients who experience fear of choking, difficulty swallowing, or limited access to water, such as travellers or emergency-care situations. The rapid breakdown of ODTs is achieved through the incorporation of potent super disintegrants including croscopolidone, croscarmellose sodium, sodium starch glycolate, and microcrystalline cellulose (MCC). These excipients promote fast disintegration and ensure immediate release of the active pharmaceutical ingredient (API). One of the major advantages of ODTs is their ability to permit pregastric absorption, which allows part of the drug to be absorbed through the oral mucosa before reaching the gastrointestinal tract. This can reduce hepatic first-pass metabolism, enhance bioavailability, and improve therapeutic efficiency. Additionally, because the drug remains in a solid state until administration, ODTs exhibit excellent stability, longer shelf-life, and more precise dosing compared to liquid formulations. Despite their numerous benefits, ODTs also present formulation and manufacturing challenges. They are generally more sensitive to moisture and temperature, making them susceptible to degradation if not properly packaged. Furthermore, high-dose drugs may be difficult to incorporate due to limitations in tablet size and mechanical strength. ODTs must maintain sufficient hardness to withstand handling and transportation, yet still disintegrate rapidly in the mouth without leaving any gritty or unpleasant residue. Taste masking is another critical factor, as undesirable drug flavours can affect patient acceptability. Regulatory authorities provide clear definitions and standards for ODTs. The European Pharmacopoeia classifies them as tablets that must disintegrate in the mouth within three minutes, whereas the US FDA defines ODTs as solid dosage forms that dissolve within a few seconds on the tongue. With increasing global demand and positive patient preference studies showing that over 70% of patients inquire about or opt for ODTs, these dosage forms continue to expand in therapeutic applications.

Overall, ODTs represent a significant advancement in oral drug-delivery technology, combining the stability of conventional solid dosage forms with the ease of administration of liquid formulations, ultimately improving patient adherence and clinical outcomes.

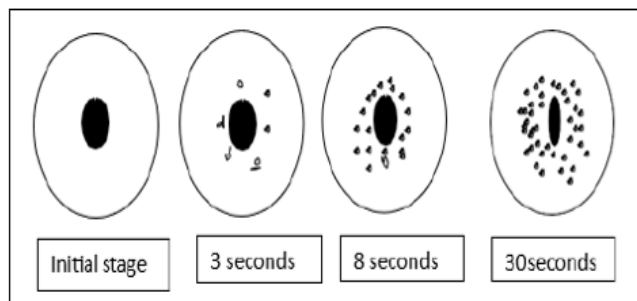


Figure 1.1 Disintegrations of tablet

II. OBJECTIVES

- To explain the need for Oral Dispersible Tablets (ODTs) as an alternative to conventional oral dosage forms.
- To understand the role of ODTs in improving patient compliance, especially for dysphagic and elderly patients.
- To study the formulation components of ODTs, particularly the use of superdisintegrants.
- To evaluate the mechanism of rapid disintegration and drug release in the oral cavity.
- To assess the impact of pregastric absorption on bioavailability and first-pass metabolism.
- To highlight the advantages of ODTs in terms of stability, dosing accuracy, and ease of administration.
- To identify challenges in ODT formulation, including moisture sensitivity and taste masking.
- To compare regulatory standards for ODTs set by the European Pharmacopoeia and US FDA.
- To review current market demand and patient preference trends for ODT formulations.
- To summarize the overall significance of ODTs as an emerging, efficient, and patient.

III. MECHANISM OF ORALLY DISPERSIBLE TABLETS

Orally Dispersible Tablets (ODTs) are designed to disintegrate rapidly when placed on the tongue. The mechanism begins when saliva enters the tablet structure, allowing the incorporated superdisintegrants to absorb moisture, swell, and break the tablet apart into fine granules.

This rapid breakdown enables quick drug release and enhances absorption through the oral mucosa.

ODTs contain two types of superdisintegrants—natural and synthetic—each contributing to fast disintegration.

Natural superdisintegrants are preferred for being biodegradable, economical, non-irritating, and environmentally friendly.

Synthetic superdisintegrants, such as croscopovidone, sodium starch glycolate, croscarmellose sodium, chitin, and chitosan, provide strong and consistent disintegration performance even at low concentrations.

IV. MECHANISM OF ACTION

- Superdisintegrants enable rapid tablet breakdown through multiple mechanisms:
- *Swelling*: Disintegrants absorb saliva, expand, and exert pressure that bursts the tablet matrix.
- *Capillary Action (Wicking)*: Saliva is drawn into the tablet's pores, weakening interparticle bonds.
- *Deformation*: Disintegrants regain their original shape after compression, creating stress that breaks the tablet apart.
- *Combination Action*: Most ODTs use more than one mechanism for faster performance.

V. CONCLUSION

The proposed research aims at the development of a novel herbal formulation in the form of Oral Dispersible Tablets (ODTs) of Giloy (*Tinospora cordifolia*). By utilizing modern pharmaceutical techniques and suitable superdisintegrants, Giloy can be delivered in a more acceptable, palatable, and patient-friendly dosage form. This formulation is expected to overcome the drawbacks of conventional herbal dosage forms such as poor palatability, low compliance, and variable bioavailability.

The study will not only contribute to the modernization of herbal medicine but also provide a standardized and scientifically evaluated dosage form of Giloy. Ultimately, the development of Giloy ODTs can bridge traditional Ayurvedic wisdom with modern pharmaceutical innovation, ensuring faster onset of action, improved patient compliance, and enhanced therapeutic effectiveness.

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