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Review Article

Review On Formulation, Challenges And Characteristics Features Of Fast Dissolving Drug Delivery System

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ABSTRACT

Pharmacological management of chronic condition, the oral route is preferred. still, due to their limited water solubility, numerous important lipophilic medicines have low oral bioavailability. The rate-controlling stage in the absorption process for this family of chemicals, known as the 'low solubility/high permeability class,' involves dissolution in the ambient lumen. To improve the therapeutic effectiveness of lipophilic drugs, experiments are working to improve their oral bioavailability. Surfactants, cyclodextrins, nanoparticles, solid dispersions, micritization, liposomes, and lipids are among the formulation ways shown in the literature, with each formulation strategy having its own set of benefits and drawbacks, with a focus on self-emulsifying drug delivery systems (SEDDS). SEDDS are isotropic mixes of oils and surfactants, with or without co-surfactants, that emulsify when gently agitated. These combinations are comparable to those seen in the gastrointestinal (GI) system, where the agitation necessary for self-emulsification in vivo is provided by the digestive motility of the stomach and intestine.

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Introduction

Past four decades, the pharmaceutical industry has invested vast amounts of time and money in the study of tablet compaction. The expenditure is quite reasonable when one considers how valuable tablets, as a dosage form, are to the industry. Because oral dosage forms can be self-administered by the patient, they are obviously more profitable to manufacture than parenteral dosage forms that must be administered, in most cases, by trained personnel. In the last several years, novel medication delivery systems have achieved their apex.

Sustained drug delivery systems provide a longer medicine release mechanism, which is beneficial from a therapeutic standpoint for chronic pain syndromes such as nocturnal asthma, angina pectoris, and rheumatoid arthritis. 1 Sustained drug delivery systems keep medicine levels in the blood at therapeutic levels, which are required in a variety of clinical diseases. As a result, one of the most significant jobs of a pharmaceutical technologist is to prepare a regulated and sustained drug delivery system. Prodrug, pH, time dependent, and polysaccharide-based drug delivery systems have all shown disappointing results, hence more research into natural gum-based microspheres has begun.

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Advantages of FD Tablets

The oral route represents a convenient and safe way of drug administration. Tablets can be mass produced, with robust and rugged quality-controlled production procedures giving an elegant preparation of consistent quality. Tablets are the manufacturer's dosage form of choice because of their relatively low cost of manufacture, package and shipment, increased stability, and virtual tamper resistance.

Disadvantage of tablets

The disadvantages of tablets are dysphasia or difficulty in swallowing is seen to affect nearly 35% of the population. This disorder is also associated with number of medical conditions including stroke, Parkinson's disease, head and neck radiation therapy and other neurological disorders including cerebral palsy. Many elder persons will have difficulty in taking conventional dosage forms because of hand tremors and dysphasia. Others who may experience problems in swallowing are the mentally ill, developmentally disabled un- cooperative patients, reduced liquid intake plan, and nausea.

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In some cases such as motion sickness, sudden episode of allergic attack or coughing and unavailability of water for swallowing tablets may become difficult.14 However, geriatric and pediatric patients experience difficulty in swallowing conventional tablets which leads to poor patient compliance. To overcome this weakness, scientists have developed innovative drug delivery systems known as fast dissolving tablets [1].

Fast dissolving drug delivery system

Fast dissolving tablets dissolve or disintegrate in the oral cavity without the need of water[2]. Their characteristic advantages such as administration without water, anywhere, anytime lead to their suitability to geriatric and pediatric patients. They are also suitable for the mentally ill, the bedridden, and patients who do not have easy access to water. [3, 4].

Criteria for fast dissolving drug delivery system[5,6]

The tablets should-

- Not require water to swallow but it should disintegrate in the mouth in few seconds.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration

Characteristics of Fast Dissolving Delivery Systems[7]

1. Ease of administration
2. Hygroscopicity
3. Taste of the medicament
4. Friability
5. Mouth feel

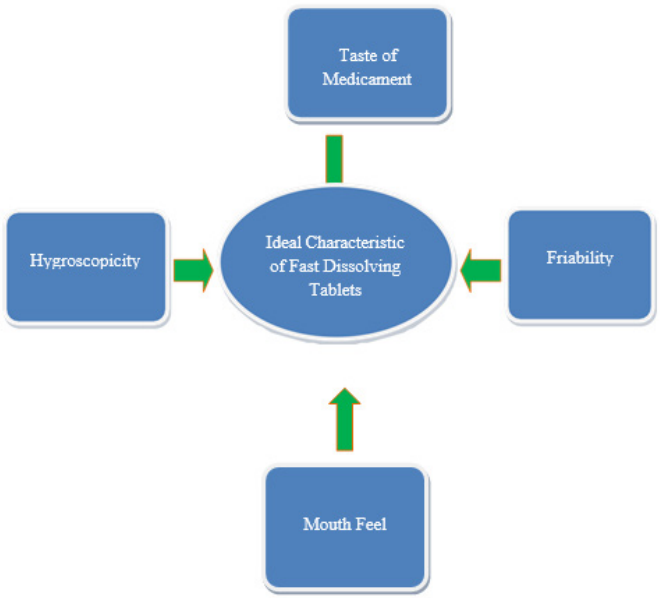
1.Ease of administration

Ease of administration Fast dissolving delivery systems are easy to administer and handle, hence leads to better patient complianceelderly people experience difficulty in swallowing the conventional dosage forms (tablets, capsules, solutions and suspensions) because of tremors of extremities and dysphasia.

2. Hygroscopicity

Hygroscopicity Several fast dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal condition from moisture which calls for specialized product packaging.

Figure no 1: Ideal characteristics of fast dissolving tablets



3.Taste of the medicament

Mouth dissolving delivery systems generally contain the component in taste masked form. Taste-masking is of critical significance in the preparation of an acceptable FDTs. Traditional tablet formulations generally do not address the issue of taste masking, because it is assumed that the dosage form will not dissolve until it passes the oral cavity.

Many oral suspensions, syrups and chewable tablets simply contain flavours, sugars and other sweeteners to complement the bitter taste of the medicine. Current methods of taste masking in fast dissolving/ disintegrating tablets include sweeteners and flavours however; these are not a sufficient means for taste-masking many bitter drug.

4. Friability

In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either soft moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle which are difficult to handle, frequently requiring specialized peel- off blister packaging.

5. **Mouth feel**

Mouth feel is critical and patient should receive a product that feels pleasant. Any large particle from the disintegrating tablet that are insoluble or slowly soluble in saliva would lead to an unpleasant gritty feeling. This can be overcome by keeping the mostly of the particles below the detectable size limit. In some cases, certain flavours can imbibe an improved mouth feel perception, resulting in a product that is perceived as being less gritty, even if the only change is the flavour. Effervescence can be added to aid disintegration and improves mouth feel by decreasing the "dryness" of a product.

Features of Fast Dissolving Drug Delivery System [8]

No need of water to swallow the dosage form, which is mostly convenient route for patients who are traveling and don't have immediate access to water.

Rapid dissolution and absorption of the drugs, which will produce quick onset of action.

Pre-gastric immersion can affect in better bioavailability and as a result of reduced dosage; improve clinical performance through a reduction of unwanted effects.

The risk of chocking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing safety.

Challenges in Formulating Fast Dissolving Tablets

Palatability

As most drugs are unpalatable, orally disintegrating drug delivery systems generally contact with the taste buds; hence, taste-masking of the drugs becomes critical for patient compliance.. Hence, taste-masking of the drugs becomes critical to patient compliance.

Mechanical strength

In order to allow ODTs to disintegrate in the oral cavity, they are made of either very porous and soft-molded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, difficult to handle, and frequently required special peel-off blister packing that may add to the cost. Only few technologies can produce tablets

Hygroscopicity

Several orally disintegrating dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and moisture. Hence, they need protection from moisture which calls for specialized product packaging.

Amount of drug

The use of this technologies used for ODTs is limited by the amount of drug that can be incorporated into each unit dose. This parameter is particularly challenging when formulating a fast-dissolving oral films or wafers.

Aqueous solubility

Water-soluble drugs pose different formulation challenges because they form eutectic mixtures, which result in freezing-point depression and the formation of a glassy solid that may collapse upon drying because of loss of supporting structure during the sublimation process. Such collapse sometimes can be prevented by using various matrix-forming excipients such as mannitol than can affect crystallinity and hence, impart rigidity to the amorphous component.

Size of tablet

Literature survey reported that the easiest size of tablet to swallow is 7-8 mm while the easiest size to handle was one larger than 8 mm. Therefore, the tablet size that is both easy to take and easy to handle is difficult to achieve [9,10].

Mechanism of Fast Dissolving Tablets

Bioavailability of a drug depends on absorption of the drug which is affected by solubility of the drug in gastrointestinal fluid and permeability of the drug across gastrointestinal membrane. The solubility of a drug mainly depends on physiochemical properties of the drug. The rate of drug dissolution is greatly influenced by disintegration of the tablet.

Disintegrants are important excipient of the tablet formulation they are always added to tablet to induce breakup of tablet when they are in contact with aqueous fluid and this process of disaggregation of constituent particles before the drug dissolution occurs, is known as disintegration process and excipients which induce this process are known as disintegrants.

The objectives behind addition of disintegrants are to increase surface area of the tablet fragments and to overcome cohesive forces that keep particles together[11].

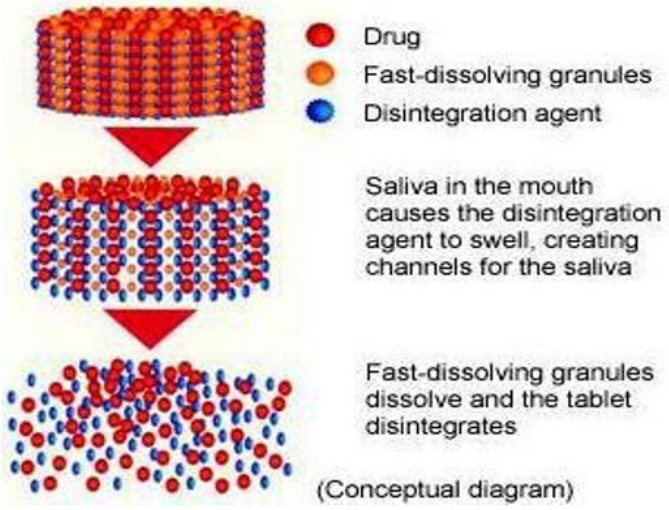


Figure no 2: Mechanism of fast dissolving tablets

Limitations of Fast Dissolving Tablets

The tablets usually have insufficient mechanical strength.

The tablets may leave unpleasant taste and/or grittiness in mouth if not formulated properly [12].

Selection of Fast Dissolving Tablets drug candidates

Several factors must be considered while selecting drug candidates for delivery as FDT dosage forms.

The medicine which have significantly different pharmacokinetic profiles compared with the same dose administered in a conventional dosage form.E.g. Selegiline, Apomorphine, Buspirone, etc.

The drugs that produce a significant amount of toxic metabolites mediated by first pass liver metabolism and gastric metabolism and for drugs that have a substantial fraction of absorption in the oral cavity and parts of the pre-gastric GIT. Drugs having capability to diffuse and partition into the epithelium of the upper GIT (log P > 1, or preferable > 2); and those able to permeate oral mucosal cells are considered ideal for FDT formulations.

Pharmaceutical Companies have formulated FDT for various categories of drugs such as neuroleptics, cardiovascular agents, analgesics, antiallergic, antiepileptic, anxiolytics, sedatives, hypnotics, diuretics, anti asthmatic agents, anti-parkinsonism agents, anti- bacterial agents and drugs used for erectile dysfunction[14].

Formulation of Fast Dissolving Tablets

Drug

The ultimate characteristics of a drug for dissolution in the mouth and pregastric absorption from FDTsinclude:

•Free from bitter taste.
•Small to Moderate molecular weight.
•Good solubility in saliva.
•Ability to permeate through oral mucosal tissue.

Advantages

Effective in lower concentrations.

Less effect on compressibility and flow ability[15].

Techniques for preparing Fast Dissolving Tablets[16]

•Freeze drying / Lyophilization
•Tablet Molding
•Spray drying
•Sublimation
•Mass extrusion
•Direct compression

Conclusion

Various and significant changes in tablet manufacturing have passed transition from direct compression to wet and dry granulation. In wet granulation and dry granulation technique multiple, lengthy and challenging processing steps are involved leading to higher cost and time of tablet production. The direct compression technique involves the compression of a dry blend of powders that comprises drugs and various excipients.

The simplicity and low capital investment of the direct-compression process have positioned it as a preferred alternative. However, the direct compression process is highly influenced by functionality of parent excipients. Most formulations contain higher amount of excipients compared to the active drug and, as a consequence, excipients play a important role in deciding the formulation‟s functionality and processability. The development of new grade of excipient is time consuming and lengthy procedure and requires regulatory approval as well.

Developing new grades of existing excipients or combination of existing excipients is successful alternative and that can be achieved by means of coprocessing. so,it is a need to have excipients with various characteristics built into them such as better flow, low/no humidity sensitivity, superior compressibility and rapid disintegration capability.

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