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Review Article

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A Comprehensive Review on Orodispersible Tablet

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Abstract Rapidly disintegrating tablets or fast dissolving tablets are gaining prominence as new drug delivery systems. These dosage forms dissolve or disintegrate in oral cavity within a matter of seconds without need of water or chewing. These are useful for paediatric, geriatric and also patients suffering from dysphagia, leading to improved patient compliance. It is reported that ODTs have several advantages over other conventional tablets. Since some of them are absorbed from the mouth, pharynx, and esophagus as the saliva passes down into the stomach, in such cases, the bioavailability of the drug improves meaningfully. ODTs have all the benefits of strong dosage forms; they have good consistency, precision dosing, fast development, compact packet size, and patients are easy to manage.

Keywords Rapidly disintegrating tablets, Patient Compliance, Dysphagia, Bioavailability

1. Introduction

Oral drug delivery has been known for decades as the most widely utilized route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharmaceutical products of different dosage forms. The reasons that the oral route achieved such popularity may be in part attributed to its ease of administration as well as the traditional belief that by oral administration the drug is as well absorbed as the food stuffs that are ingested daily.

In fact, the development of a pharmaceutical product for oral delivery, irrespective of its physical form involves varying extents of optimization of dosage form characteristics within the inherent constraints of GI physiology. Therefore, a fundamental understanding of various disciplines, including GI physiology, Pharmacokinetics, Pharmacodynamics and formulation design are essential to achieve a systemic approach to the successful development of an oral pharmaceutical dosage form.

The more sophisticated a delivery system, the greater is the complexity of these various disciplines involved in the design and optimization of the system. In any case, the scientific framework required for the successful development of an oral drug delivery system consists of a basic understanding of the following three aspects:

i. Physicochemical, pharmacokinetic and pharmacodynamic characteristics of the drug.
ii. The anatomic and physiologic characteristics of the GIT, and
iii. Physicochemical characteristics and the drug delivery mode of the dosage form to be designed.

1.1 Criteria's for Mouth Disintegrating Drug Delivery System

Mouth dissolving tablets should:

- Not require water to swallow, but it should dissolve or disintegrate in the mouth in a matter of seconds.
- Have a pleasing mouth feel.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensitivity to environmental conditions as humidity and temperature.
- Allow the manufacture of tablet using conventional processing and packaging equipment at low cost.

1.2 Significance of orodispersible tablet

- Since ODTs are unit solid dosage types, they provide good stability, precise dosing, fast development, compact package size, and patient ease of handling.
- No hazard of obstruction of the drug type when it dissolves quickly in saliva.
- Administration without heating, anytime and at any moment, thus useful for patients travelling who do not have water access.
- Rapid tablet disintegration leads to rapid dissolution and rapid absorption, ensuring a rapid onset of action. As a "bitter pill" drug, the use of flavours and sweeteners in ODTs has altered the excellent mouth sensation property.
- Suitable for the procurement of comparatively low molecular weight and easily permeable medicines.
- The minimum number of ingredients is required and the dosage type is thus cost-effective.
- The rapid breakdown and absorption of the drug would result in a rapid onset of action.

1.3 Advantage of orodispersible tablet:

- ODTs have all the benefits of strong dosage forms; they have good consistency, precision dosing, fast development, compact packet size, and patients are easy to manage.
- Liquid formulations such as simple treatment and no chance of suffocation arising from physical blocking by a drug shape have the benefits of ODTs.
- Patients who are unable to swallow, such as the elderly, stroke victims, bedridden patients, patients with renal disease and patients who refuse to swallow, such as paediatric, geriatric & medical patients, are easy to administer.
- No chance of obstruction of the dosage form and no need for water to ingest the dosage form, which for patients who are driving and do not have direct access to water is particularly convenient.
- Rapid tablet disintegration leads to rapid dissolution and rapid absorption, ensuring a rapid onset of action.

Table 1: Approved excipient used in ODTs Formulation

S. No.	Ingredient type	Example
1.	Superdisintegrant	Crospovidone, croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl cellulose, microcrystalline cellulose, spray-dried lactose, acrylic acid, alginic acid, sodium alginate, soy polysaccharides, Isphagula husk pregelatinized starch, modified corn starch, ion exchange resins, gas evolving disintegrants
2.	Bulking material	Sugar and sugar-based derivatives (dextrose, fructose, isomalt, lactilol, maltitol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose, and xylitol)
3.	Emulsifier	Alkyl sulfates, propylene glycol, lecithin, sucrose esters, sodiumdoecylsulfate, sodium lauryl sulfate, polyoxyethylene sorbitan fatty acid esters (Tweens)
4.	Sweetener	Sodium saccharin, sugar alcohols, natural sugars (sugar, dextrose, fructose), sugars derivatives, aspartame, vanilla, bubble gum, grapefruit
5.	Flavor	Peppermint flavor, clove oil, bay oil, anise oil, eucalyptus oil, thyme oil, oil of bitter almonds, vanilla, citrus oils, fruit essences

2. Techniques for preparing ODTs:

2.1 Freeze drying or Lyophilization

Freeze drying is the process in which, when frozen, water is sublimated from the commodity. This approach produces an amorphous porous construction that can quickly dissolve. To freeze the medication solution or dispersion, the trays containing the blister packs are pushed into the liquid nitrogen freezing tube. To finish the freezedrying, the frozen blister packs are then packed into refrigerated cabinets. The aluminium foil backing on a blister sealing system is useful after freeze-drying. The blisters are finally packaged and shipped. The key benefit of using this technique is that the tablets provided by this technology have a very low period of disintegration and excellent mouth feeling due to the rapid melting effect.

2.2 Moulding

This method is one of the most suitable methods for the formulation of oral dispersible tablets. Only the water-soluble ingredients are selected so that the product dissolves quickly. Here all the solid ingredients are dissolved in hydro-alcoholic solvents, after that at a lower pressure the dispersible tablets are compressed. After compression the solvent is shelved by air-drying method. The resultant product is very porous in nature which offer great dissolution.

2.3 Sublimation

The slower dissolution of the compact tablet with also extremely water-soluble materials is due to the fact that water dispersion into the matrix is reduced by the low porosity of the drugs. In addition to other tablet excipients, after inert volatile solid ingredients such as ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethylene tetra mine, naphthalene, phthalic anhydride, urea and urethane, the blend was packed into a tablet that was subsequently subjected to a sublimation process that resulted in unnecessary porosity. Compressed tablets exhibition Strong mechanical strength and have high penetrability easily dissolved within 15 seconds in saliva.

2.4 Mass extrusion

This technology includes the softening of the active blend utilising the water-soluble polyethylene glycol solvent combination, the use of methanol and the expulsion of softened mass through the extruder or syringe to acquire an extrude cylinder designed to eventually cut through even segments with the heated blade to shape tablets. To disguise their flavour, this procedure can also be used to coat granules of bitter products. This process is used to prepare masked granules for flavour.

2.5 Nanonization

The reduction in the particle size of the drug to nano size by milling the drug using a proprietary wet milling technique is used in this technology. The drug's nano-crystals are stabilised by surface absorption against agglomeration on chosen stabilisers that are then inserted into mouth dissolving tablets. This system is sufficient for medications that are poorly water-soluble.

3. Evaluation of orodispersible tablets

3.1 Hardness/crushing strength

The hardness of the tablet is measured by using conventional hardness testers like Monsanto hardness tester. The limit is toward the lower range in order to help early disintegration in mouth.

3.2 Friability

It is a difficult job to maintain the percentage of friability within the limit, since all the methods of preparation of orodispersible tablets have a tendency to increase the percentage of friability. In all aspect, the range is within limit of 0.1%-0.9%. Roche friabilator is used in conventional form in order to measure friability of the tablets.

3.3 Wetting time

Wetting time is the indication of the inner structure of the tablets and to the hydrophilicity of the excipients. Thus, wetting time of a dosage form is related with the contact angle. The lower the wetting time the quicker is the disintegration of the tablets. The wetting time can be measured by using five circular tissue papers of 10 cm in diameter, which are placed in a petridish of 10 cm diameter. Ten millilitres of water-soluble dye like eosin solution are added to the petridish. A tablet is carefully placed on the surface of the tissue paper. The time required for water to reach upper surface of the tablet is noted as the wetting time. For measuring water-absorption ratio, the weight of the tablet before keeping in the petridish is noted (Wb). The wetted tablet from the petridish is taken and reweighted (Wa). The water-absorption ratio, R can be determined according to the following equation: $R = 100 (Wa – Wb)/Wb$.

3.4 Disintegration Test

The in-vitro disintegration time was determined by disintegration test apparatus. The time for disintegration of orodispersible tablets is generally 1 min and actual disintegration time that patient can experience ranges from 5 to 30 s. A tablet is placed in each of the six tubes of the apparatus, and one disc is added to each tube. The standard procedure of performing disintegration test for these dosage forms has several limitations.

3.5 Dissolution test

It is an important test as the drug-release profile can be obtained by performing this test. Both the USP dissolution test apparatus can be used. Dissolution of orodispersible tablets is very fast. Therefore, USP 2 Paddle-type apparatus at 50-100 r/min is used for dissolution testing. It is carried out in vitro dissolution study of pheniramine maleate orodispersible tablets in type II apparatus with r/min 550 using 900 ml phosphate buffer of pH 6.8 at 37 ± 0.5°C as a dissolution medium. USP type I basket apparatus have certain application in the case of orodispersible tablets, but tablet fragments or disintegrated tablet masses may become trapped on the inside top of the basket at the spindle. An erroneous-dissolution profile is obtained, where little or no effective stirring occurs. Thus, type II is more preferred due to reproducible-dissolution profile.

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