



ORAL DISPERSIBLE TABLET- DOSE OF CHOICE IN EMERGENCIES

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ABSTRACT

Oral Dispersible drug delivery are often an alternate and better choice of route in comparison to other oral drug delivery as Oral administered dosage forms bypass hepatic metabolism. A rapid onset of pharmacological effect is usually desired for a few drugs, especially those utilized in the treatment of acute disorders and need onset of action. Oral Dispersible tablets disintegrate rapidly and therefore the bit of saliva present is typically sufficient for achieving disintegration of the dosage form including better dissolution and increased bioavailability with effective therapeutic range. Oral Dispersible tablets were found to possess better characteristics in comparison to standard conventional dosage forms. Oral Dispersibly administered tablets achieved better bioavailability, rapid onset of action and better dissolution properties increasing the fast disintegration. The addition of Superdisintegrants facilitated rapid disintegration and this approach is often needed to treat acute disorders or emergency conditions with showing onset of action. The Oral Dispersible route of administration is often used for drugs which undergo first pass metabolism or degradation within the GIT process. Drugs administered Oral Dispersibly tend to possess better bioavailability which is better approach other than conventional tablets.

KEYWORDS: Fast dissolving/disintegrating tablets, orodispersible tablets, GIT, bioavailability, first pass metabolism, superdisintegrants.

INTRODUCTION

Novel delivery of drugs is popular from most recent multi decade because of its better quiet consistence and better choice in emergencies for onset action. Fundamental medication route through the Oral Dispersible course had risen up out of the longing to give prompt beginning of pharmacological action and efficacy. Dysphagia (trouble in gulping) might be a typical issue of all age gatherings, particularly geriatric and pediatric patients who are intellectually unsuitable in gulping these dose structures. Oral Dispersible course of organization of the medication implies situation of the medication under the tongue and medication comes too straightforwardly in to the circulatory system through the ventral surface of the tongue and floor of the mouth. The ingestion of the medication through the Oral Dispersible course is 3 to multiple times more noteworthy than oral course and is just outperformed by hypodermic infusion. For these plans, the little volume of salivation is generally adequate to end in tablet deterioration inside the mouth. Oral Dispersible ingestion is normally fast in real life, yet in addition short acting in term. The best plan for use by the older is one that is not difficult to swallow and simple to deal with. Thinking about these prerequisites, endeavors have been made to foster a quick dissolving tablet. Since such a tablet can break

down in just a limited quantity of water in the oral hole, it is not difficult to take for any age patient, paying little heed to time or place. For instance, it very well may be taken anyplace whenever by any individual who don't have simple admittance to water. It is likewise simple to portion the matured, out of commission patients, or newborn children who have issues gulping tablets and containers. As of late, many organizations have investigated and created different kinds of quick crumbling measurements structure innovations with the possibility to oblige different physicochemical, pharmacokinetic and pharmacodynamics qualities of medications. Nitroglycerine, is the best model that, is a powerful antiangina drug however is broadly used when taken orally (>90%). it's quickly retained through the Oral Dispersible mucosa, and its pinnacle plasma level is reached inside 1-2 min.^[1-6]

Patent Technology

1 Zydis Technology

Zydis definition is an exceptional freeze dried tablet where medication is genuinely entangled or broken up inside the lattice of Oral Dispersible transporter material. When zydis units are placed into the mouth, the freeze-dried construction crumbles promptly and doesn't expect water to help gulping. The zydis grid is made out of

numerous material intended to accomplish various targets. To bestow strength and flexibility during dealing with, polymers like gelatin, dextran or alginates are consolidated. These structure a lustrous indistinct design, which bestows strength. To get crystallinity, tastefulness and hardness, saccharides like mannitol or sorbitol are joined. Water is utilized in the assembling system to guarantee creation of permeable units to accomplish quick breaking down while different gums are utilized to forestall sedimentation of scattered medication particles in the assembling system. Breakdown protectants, for example, glycine forestall the shrinkage of zydis units during freeze-drying measure or long haul stockpiling. Zydis items are pressed in rangle packs to shield the definition from dampness in the climate.^[7-9]

2 Durasolv Technology

Durasolv is the protected innovation of CIMA labs. The tablets made by this innovation comprise of medication, filler and an ointment. Tablets are ready by utilizing customary tableting hardware and have great unbending nature. These can be bundled into customary bundling framework like rankles. Durasolv is a proper innovation for item requiring low measures of dynamic fixings.^[10-12]

3 Orasolv Technology

CIMA labs have created Orasolv Technology. In this framework dynamic medicament is taste veiled. It additionally contains bubbly breaking down specialist. Tablets are made by direct pressure method at low pressure power to limit oral disintegration time. Customary blenders and tablet machine is utilized to create the tablets. The tablets created are delicate and friable.^[13-15]

4 Flash Dose Technology

Streak portion innovation has been protected by fuisz. Nurofenmeltlet, another type of ibuprofen as liquefy in mouth tablets arranged utilizing streak portion innovation is the primary business item dispatched by biovail company. Streak portion tablets comprise of self-restricting shear structure framework named as "floss". Shear structure frameworks are ready by streak heat handling.^[16-18]

5 Wow tab Technology

Wow tab innovation is protected by Yamanouchi Pharmaceutical Co. WOW signifies "Without Water". In this interaction, mix of low mouldability saccharides and high mouldability saccharides is utilized to get a quickly dissolving solid tablet. The dynamic fixing is blended in with a low mouldability saccharide (eg. lactose, glucose, and mannitol) and granulated with a high mouldability saccharide (eg. Maltose, oligosaccharides) and compacted into table.^[19]

6 Flash tab Technology

Prographarm research centers have licensed the Flash tab innovation. Tablet arranged by this framework comprises of a functioning fixing as miniature gems. Medication

miniature granules might be ready by utilizing the traditional methods like coacervation, miniature epitome and expulsion spheronisation.^[20]

Mechanism of Oral Dispersible absorption

BASIC PRINCIPLE OF ORAL DISPERSIBLE TABLETS

There are four major mechanisms for tablets disintegration as follows

- Wicking
- Due to Deformation
- Particle Repulsive Forces
- Swelling

The mucosal lining consists of three distinct layers. The outermost layer is that the epithelial membrane, which consists of stratified squamous epithelial cells and features a protective barrier function. The innermost layer of the epithelial membrane is termed the basement membrane that replenishes the epithelium. Below the epithelium lies the lamina propria followed by the submucosa. The lamina propria may be a hydrated and fewer dense layer of connective tissue containing collagen and elastic fibres. The oral submucosa is additionally richly furnished with blood vessels.^[21-22]

Advantages

- Liver bypassed and also drug is protected against degradation because of pH and digestive enzymes of the GI tract.
- Improved patient compliance because of the minimizing of associated pain with injections; administration of medication in unconscious or incapacitated patients
- Convenient and easy to administer as does not require water for oral administration.
- Durable and sufficient strength to withstand the rigors of the manufacturing process and manufacturing handling.
- Pleasant mouth feel.
- Compatible with taste masking.
- Rapid drug therapy intervention.
- Patient having difficulty in swallowing tablet can easily administer this type of dosage form
- Useful for paediatric, geriatric and psychiatric patients.
- Good chemical stability.
- All given Low dosage gives high efficacy as hepatic first-pass metabolism is avoided. The large contact surface of the oral contributes to rapid and extensive drug absorption for onset of Action.
- A relatively rapid onset of action is often achieved as compared to the oral route.
- Rapid absorption and better blood levels due to higher bioavailability.

- They also present the advantage of providing fast dissolution and disintegration in mouth without any water or Chewing.⁵⁻⁸

Disadvantages

- Oral Dispersible medication can't be used when a patient is uncooperative.
- Since Oral Dispersible administration of medicine interferes with eating, drinking, and talking, this route is usually considered unsuitable for prolonged administration.
- The patient shouldn't smoke while taking Oral Dispersible medication because smoking causes vasoconstriction of the vessels. This may decrease the absorption of the medication.^[9]

Formulation aspects of Oral Dispersible tablet

The distinct feature within the formulation of Oral Dispersible tablets involves the choice of suitable excipients of bland taste that shall ultimately leading to a rapidly disintegrating tablet their by enhancing the dissolution of active ingredient.^[10]

There are two differing types of the Oral Dispersible tablet.

1. Molded Oral Dispersible Tablets.
2. Compressed Oral Dispersible Tablets.

Molded Oral Dispersible tablets

Molded Oral Dispersible tablets are usually prepared from soluble ingredients in order that the tablets are completely and rapidly soluble. They contain, additionally to the drug, an excipient or base namely lactose, dextrose, sucrose, mannitol or other rapidly soluble materials or mixtures of those ingredients. Tablets containing insoluble excipients could also be prepared from finely divided kaolin, carbonate, phosphate or other insoluble powders. To insure rapid solubility of the soluble tablets, the excipients are usually skilled a fine screen or # 120 mesh bolting cloth. After the excipients are blended with the drug, the powder mix is moistened with the solvent, which is most ordinarily alcohol and water mixture. Other volatile solvents, like acetone or hydrocarbons, can also be used. Antioxidants like sodium bisulphate and buffers or other ingredients could also be added to enhance the physical and chemical stability of the merchandise. to extend the hardness and reduce the erosion on the sides of the tablets during handling, agents like glucose, sucrose, acacia or povidone could also be added to the solvent mixture.^[22-24]

Compressed Oral Dispersible tablets

Compressed Oral Dispersible tablets are often prepared by two different methods.

- a) Wet Granulation method
- b) Direct compression method

The directly compressible Oral Dispersible tablet formulation contains directly compressible soluble

excipients, an excellent disintegrant, and lubricant. it's going to also contain microcrystalline cellulose, a dry binder, buffers, surface-active agents, sweeteners, and flavors. Sugar-based excipients are widely used as bulking agents due to their high aqueous solubility, sweetness, pleasant feeling within the mouth, and good taste-masking. Nearly all Oral Dispersible formulations incorporate some saccharide-based material. the selection of an appropriate disintegrant and its amount are critical for achieving a quick disintegration and dissolution rate. Sometimes effervescent agents are wont to increasing disintegration and dissolution of Oral Dispersible tablets.^[25]

In vitro and in vivo evaluation

Physical evaluation

- All batches of Oral Dispersible formulations like tablets and films were evaluated for weight variation and drug content. But hardness and friability were calculated for tablets.
- As the hardness of Oral Dispersible tablet is a crucial factor because if the Oral Dispersible tablet is just too hard, the solvent-borne drug attenuation might not occur into the inside portion of the tablet and thus remain on a surface portion of the tablet, where the drug attenuation might not adhere to the Oral Dispersible tablet.^[26]
- If the Oral Dispersible tablet is just too soft, the Oral Dispersible tablet could also be disintegrated by the solvent of the drug attenuation. Preferably, the solvent-borne drug attenuation should be absorbed into the inside of the Oral Dispersible tablet.
- Weight variation test is conducted by selecting 20 tablets randomly as per I. P.^[28]

Disintegration time (DT)

A relatively simple method with rigorous conditions has been developed to gauge the DT of Oral Dispersible tablets. Each individual tablet is dropped into 10-mL glass tube (1.5-cm diameter) containing 2 ml water, and therefore the time required for complete tablet disintegration is observed visually and recorded employing a stopwatch. The visual inspection are often enhanced by gently rotating the tube at a forty five ° angle, without agitation, to distribute any tablet particles which may mask any remaining undisintegrated portion of the tablets.^[25]

Wetting time (WT)

Although a wetting test isn't a USP standard test, it's useful for internal control and provides a supportive evaluation of those Oral Dispersible tablets. Using this test, the time required for moisture to penetrate the tablet completely is measured and possibly represents the time required to release the drug within the presence of minute volumes of saliva.^[26]

Friability

Twenty tablets are to be weighed and placed during a Roche friabilator and therefore the equipment has got to

be rotated at 25 rpm for 4 min. Tablets are often calculated by.

$$\% \text{ Friability} = \frac{\text{Initial Weight} - \text{Final Weight}}{\text{Initial Weight}} \times 100$$

In vivo evaluation

Pharmacokinetic data analysis and bioavailability evaluation Rabbits are described together of the few laboratory animals that don't have keratinized mucosa, thus closely resembling human Oral Dispersible mucosal tissue [25]. The maximal plasma concentration (C_{max}) and therefore the time to achieve maximum plasma concentration (T_{max}) are often directly obtained from the plasma data. The area under the plasma concentration curve (AUC) also can calculate using the trapezoidal rule then the bioavailability.^[22]

Recent developments

Nitroglycerine-delivering Oral Dispersible aerosol formulation (nitro-glycerine in propellants) during a metered-dose spraying pump, Nitrolingual spray, was developed. It delivers nitroglycerine by spraying onto or under the tongue within the sort of spray droplets, which ultimately increase the absorption and hence the bioavailability of nitroglycerine. The rapid onset of action is usually required in case of hypertension.^[26-28]

CONCLUSION

In conclusion, this review demonstrates that there are variety of commercially available Oral Dispersible formulations manufactured using various technologies. The publically available information on Oral Dispersible tablets implies that this dosage form has good potential to enhance drug delivery in treating variety of indications. In most reported cases, it's been shown that the Oral Dispersible dosage form not only improves the patient's compliance, but also reduces the time for the onset of the drug action, and increases the bioavailability of drugs as compared to standard tablets.

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