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A REVIEW ON FORMULATION AND EVALUATION OF FAST DISSOLVING TABLET

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ABSTRACT

In this present scenario, the drug delivery system has become highly competitive and rapidly most evolving with ever increasing demand. Fast dissolving tablet (FDT) is such type of an innovative and unique drug delivery system which is intensly gaining much attention in the research field of rapid dissolving technology. Oral route is the most acceptable routes among all various routes for different patients of different age group because it is regarded as safest, convenient and economical route of administration. Therefore, recently many researcher and pharmaceutical companies developed fast dissolving tablet (FDT) by modifying the physio-chemical properties of drugs to their need with enhanced patient compliance and convenience. USFDA define FDTs to be the solid oral preparation that disintegrate rapidly in the buccal cavity with an in-vitro disintegration time of less than 30 seconds. FDTs improved patient compliance and also overcome the disadvantages of conventional dosage form especially dysphagia (difficulty in swallowing) in pediatric and geriatric patients. FDT formulations have the advantage over the both conventional tablet formulation as well as liquid dosage form. There are several methodologies that are conventional or patented based o spray drying, sublimation, melt granulation, direct compression, freeze drying/lyophilization, mass extrusion, etc. have been developed for manufacturing of FDTs. This review includes the requirements, advantages, limitations, various technologies developed for FDT, evaluation methods of fast dissolving tablets.

KEYWORDS: Fast dissolving tablets (FDT), Super disintegrants, Dysphagia,, Bioavailability, Evaluation.

INTRODUCTION

Despite major advances in drug delivery, Solid dosage forms are preferred route for administration of therapeutic agents because of accurate dosage, ease of self-administration, pain avoidance and most importantly the patient compliance, also having low cost as compared to other dosage forms.[1,3] The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms is that for some patients like old ages and pediatrics, it is quite difficult to swallow (Dysphagia). Drinking of water plays very important role in the swallowing of oral dosage forms. Many of times people experience difficulty in swallowing conventional dosage forms when water is not available, such as in the case of the motion sickness (kinetosis) and sudden episodes of coughing during the cold, allergy and bronchitis. For such reasons, tablet that can rapidly dissolve or disintegrate in the mouth have attracted a great attention.[2] Hence, to overcome such problems, fast disintegration tablets have initiated which gaining popularity, also acceptance as new drug delivery systems aim for providing the safety of a drug because they are easy to administer and further lead to better patient compliance.[4]

The Center for Drug Evaluation and Research(CDER), US FDA defined Fast-dissolving/disintegrating tablets (FDDTs) are "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue". Recently European Pharmacopoeia also adopted the term "Oro Dispersible Tablet" defined as uncovered tablet for buccal cavity, where it disperses before ingestion".[5]

Fast disintegrating tablets are the tablets which are when kept on tongue, disintegrates instantaneously leading to release of drug which dissolve or disperses into saliva. The Faster the drug into the solution, quicker will be the absorption and the onset of clinical action. Some of the drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. Hence, bioavailability of such drugs are significantly greater than those observed from conventional tablets dosage form. The advantage of fast dissolving dosage forms are increasing in both, industry as well as academics. The main approach in development of FDT is to use of superdisintegrants like cross linked carboxymethyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), cross linked polyvinylpyrollidone (crospovidone) etc, which provides

instant disintegration of tablet just after putting on tongue, theirby releasing the drug in saliva. Bioavailability of such drugs may increases due to absorption of drug in oral cavity and also due to pre-gastric absorption of saliva containing dispersed drugs which passes down into the stomach. Howover, the amount of drug that is subjected to first pass metabolism is reduced as compared to standard tablet.[6]

REQUIREMENTS OF FDTs

The tablets should have following requirements[7]

- No need of water to swallow, yet should be dissolved or disintegrate in the mouth within very few seconds.
- It should allow high drug loading.
- It should be viable with taste covering.
- It should have a pleasant mouth feel.
- It should leave least or no residue in the mouth after oral administration.
- It should have sufficient strength to withstand the process of the manufacturing and post manufacturing handling.
- It should exhibit low sensitivity to environmental conditions such as humidity and temperature.
- It should allow to manufacture the tablet using conventional processing and packaging equipments at regionble cost.

ADVANTAGES OF FDTs

1. Improved patient compliance/added convenient new business opportunities product differentiation, line extension and lifecycle management, exclusivity of product promotion, and patent-life extension.
2. No water needed.
3. No chewing needed.
4. Better taste.
5. Improved stability.
6. Suitable for controlled/sustained release actives.
7. Allows high drug loading.
8. Ability to provide advantages over liquid medication in the form of solid preparation.
9. Cost- effective.
10. Rapid drug therapy intervention.
11. High drug loading is possible.
12. Have adequate taste and pleasant mouth feeling.[8]

LIMITATIONS OF FDTs

- Insufficient mechanical strength, Hence, careful handling is required.
- FDT may leave unpleasant taste or grittiness in mouth if not formulated properly
- Drug with relatively large dose are difficult to formulate into FDT.

METHODOLOGIES FOR DEVLOPING FAST DISSOLVING TABLETS

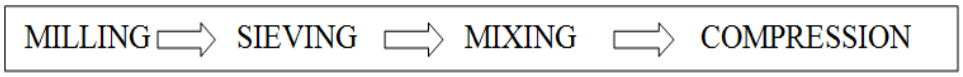
Many techniques have been reported for the formulation of Fast dissolving tablets/orodispersible tablets. Following are six major techniques which are widely used.[9,10]

1. **Freeze drying/ Lyophilisation:** Freeze drying is the process in which water is sublimated from the product after freezing. Freeze- dried forms offer more rapid-dissolution than other available solid products. The lyophilisation process imparts lusturous and uniform structure to the bulking agent and occasionally to the medicine, thereby enhancing the dissolution characteristics of the expression.[11]
2. **Tablet moulding:** Molding process is of two types named as solvent method and heat method. The tablets manufactured by solvent method are less compact than compressed tablets and posses a pervious structure that hastens dissolution. The mechanical strength of moulded tablets is a matter of great concern. Binding agents, which enhance the mechanical strength of the tablets, need to be incorporated.[12] Masking of taste is an added problem to this technology and the masked drug. Particles are prepared by spray congealing a molten mix of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate an active component into a lactose grounded tablet triturate form. Tablets produced by the moulding approach are easy to measure up for artificial manufacturer, compared to the lyophillisation approach.[13]
3. **Spray drying:** In this technique, gelatin is used as a matrix and a supporting agent, mannitol as bulking agent, and superdisintegrants like crosscarmellose or sodium starch glycolate or crospovidone. The Tablets manufactured from the spraydried powder containing bulking agent, superdisintegrant and an acidic ingredient (citric acid) and alkaline ingredients(e.g. sodium bicarbonate) have been observed to disintegrate within 20 seconds in aqueous medium. This spray-dried powder, then compressed into tablets showing quick disintegration and improved dissolution.[14]
4. **Direct Compression:** The direct compression method is the most preferred technique for manufacturing the tablets due to following advantages:

- High doses can be accommodated and final weight of the tablet can exceed that of other methods.
- The easiest and preferred way to manufacture the tablets.
- Mostly conventional equipment and commonly available excipients are used.
- A limited number of processing steps are involved.
- Cost effectiveness.

The size of tablet and hardness strongly affect the disintegrant efficacy. Hard and large tablets posses more disintegration time than normally required. Tabletes which are soft and small have low mechanical strength. Hence, an optimum kind and concentration of disintegrant should be chosen to achieve quick disintegration and high dissolution rates. Above the

critical concentration level, the disintegration time remains approximately constant or even increases.[15]



5. **Sublimation:** FDTs are acquired by formulation of porous mass by incorporating inert solid ingredients that volatilize rapidly like urea, camphor ammonium carbonate, ammonium bicarbonate and hexamethylene-tetramine. Highly volatile ingredients like benzoic acid, ammonium bicarbonate, ammonium carbonate, camphor, naphthalene, urea,and urethane may be compressed along with other excipients into a tablet. In process of sublimation, the volatile material is then removed, leaving behind a highly porous matrix. Tablets manufactured by this technique have expected to usually disintegrate in within 10-20 seconds, Solvents like benzene; cyclohexane can be used as pore forming agents.[16]

6. **Mass Extrusion:** In this process, the active blend is soften by using the solvent mixture of water-soluble methanol and polyethylene glycol and subsequent expulsion of softened mass through syringe to get a cylinder product and the product is then divided into even pieces using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking.[17]

EXCIPIENTS COMMONLY USED FOR PREPARATION OF FDTs

Excipients which are generally used in FDTs preparation should contain at least one superdisintegrant, a diluent, a lubricant and optionally a swelling agent, a permeabilizing agent, sweetening and flavoring agents as well.

Name of the excipients	Percentage Used
Disintegrants	1 to15%
Diluents	0 to 85%
Binder	5 to 10%
Antistatic Agent	0 to 10%

Name and weight percentage of different excipients[18]

SUPERDISINTEGRANTS

At present, demand for faster disintegrating formulation is increasing. So, pharmacist needs to formulate disintegrants i.e. Superdisintegrants which are effective at low concentration and having greater disintegrating efficiency and more effective intragranularly. Superdisintegrants act by swelling and as the swelling pressure exerts in the outer or radial direction, it causes tablet to burst or the accelerated absorbtion of water leading to enormous increase in the volume of granules to enhance disintegration.[19,20]

There are four major mechanisms for tablets disintegration as follows.

1. **Swelling:** When the Superdisintegrant comes in contact with water/saliva, the aqueous phase extras more adhesive force upon the superdisintegrant as compared to other excipients and drug resulting in swelling or breaking apart of the tablet.
2. **Porosity and Capillary Action (Wicking):** In this mechanism, all the particles of the tablet are surface wetted in the given aqueous medium. Water then penetrates into core of the tablet, reducing the interparticle bond, thus aiding in breaking of tablet. Hence, it is termed as capillary action or wicking as slowly, wetting rises in tablet with ultimate result of breakage of tablet. Here, the porosity of the tablet is as important as it is the fundamental requirement for easy and quick wetting or water uptake. The more porous the material the greater will be the rate of wetting and disintegration time is less.
3. **Particle/Particle Repulsive Forces:** Guyot-Hermann has proposed this particle repulsion theory. The theory states the swelling via tablet made of "non-swellable" disintegrants. This works on principle of electric repulsive force of particles. It is mandatory for tablet to come in contact with water thus generating repulsive force, making particles repel each other and this is how the tablet disintegrates.[20]
4. **Deformation:** Starch grains are generally thought to be "elastic" in nature i.e. grains that are deformed under pressure and will return to their original shape when that pressure is removed. But, with compression forces involved in tableting, these grains are believed to be deformed permanently and are said to be "energy rich" and with this energy is being released upon exposure to water. In simple words, the ability for starch to swell is higher in "energy rich" starch grains than it is for starch grains that have not been deformed under pressure.[21]

List of superdisintegrants

Superdisintegrants	Example	Mechanism Of Action	Special comment
Crosscarmellose® Ac-Di-Sol® Nymce ZSX® Primellose® Solutab® Vivasol® L-HPC	Crosslinked cellulose	-Swells 4-8 folds in < 10 seconds. -Swelling and Wicking both.	-Swells in two dimensions. -Direct compression or granulation -Starch free
Crosspovidone Crosspovidon M® Kollidon® Polyplasdone®	Crosslinked PVP	-Swells very little And returns to original size after compression but act by capillary action	-Water insoluble and spongy in nature so get porous tablet
Sodium starch glycolate Explotab® Primogel®	Crosslinked starch	-Swells 7-12 folds in < 30 seconds	-Swells in three dimensions and high level serve as sustain release matrix
Alginic acid NF Satialgine®	Crosslinked alginic acid	-Rapid swelling in aqueous medium or wicking action	-Promote disintegration in both dry or wet granulation
Soy polysaccharides Emcosoy®	Natural super disintegrant	-	-Does not contain any starch or sugar. Used in nutritional products.
Calcium silicate		-Wicking Action	Highly porous, Optimum concentration is b/w 20-40%

EVALUATION OF FAST DISSOLVING TABLETS

- **Organoleptic parameters:** The size and shape of tablet can be dimensionally described, covered and controlled. Tablet thickness is an important parameter in reproducing appearance and also in counting by using filling outfit. Some filling outfit utilizes the even consistence of the tablets as a counting procedure. Ten tablets wer taken and their thickness was recorded using micrometer.[22,23,24]

- **Tablet hardness:** Hardness of tablet is defined as the force applied across the diameter of the tablet in order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before usage depends upon its hardness. Ten tablets are taken from each batch for testing of hardness by Pfizer tablet tester.[25,26,27,28]

- **Uniformity of weight:** This is done by sampling and weighing 20 tablets at random and average weight was calculated. Not more than two of the individual weights deviate from average weight by more than the percentage and none deviate by more than twice of the percentage.[29,30]

- **Friability test:** Friability test is done by using Roche friabilator. The weight of 10 tablets are noted initially (W1) and then placed in the friabilator for 4min/100rpm. The tablets will be reweighted and note as (W2). The difference in the weight is noted and express as percentage.[31,32]
  Percentage friability= (initial weight-final weight/initial weight) ×100

- **Water absorption ratio:** A piece of tissue paper is folded twice placed in small petri-dish containing 6 ml of water. A tablet is kept on the tissue paper and allowed to completely wet. The wetted tablet is then weighed. Water absorption ratio R is determined by using equation as followed.[33,34]
  R= 100* Wa- Wb/ Wa

- **In-Vitro Disintegration:** The test is tested on 6 tablets using tablet disintegration apparatus and distilled water at 37C±20C is use as a disintegration media and time in second taken for completedisintegration of th tablet with no palable mass remaining in the apparatus is measure in seconds.[37]

- **In-Vitro Dissolution:** In vitro dissolution studies of fast dissolving tablets are performed by using apparatus as specified at 50 rpm and Sorenson's buffer (900 ml) is use as dissolution medium at 370C±0.50C. Sample of dissolution medium I withdrawn at a specific time interval and filter. Adsorption of filtered solution is checked by UV spectroscopy and drug content is determined from standard calibration curve.[36,37]

CONCLUSION

FDTs are dosage forms which are formulated to dissolve/disintegrate rapidly in the saliva generally within very few seconds. FDTs offers a lot of advantages over conventional dosage forms such as improved efficacy, bioavailability, rapid onset of action, and better patient compliance. FDTs provide more comfort to pediatric and geriatric patients. FDTs can be prepared by several methods based on the drug and additives used. Usually FDTs possess less mechanical strength. But by applying some new methodologies and technologies,

additives FDTs with sufficient mechanical strength can be prepared41. **Rev 01** The future of FDT may be most preferred and prescribed dosage form due to its quick onset of action (within minute). Their advantages such as administration without water, anywhere, anytime lead to increased patient compliance in today's scenario of running life. The successful FDTs in market have good taste and rapid release properties. With rapid preferance of FDTs by patients and pharmaceutical companies, market for this particular dosage form is promising, and the product cycle continues to grow rapidly. The clinical studies show that FDTs can enhance patient compliance, provide a rapid onset of action, and also increase bioavailability. By considering the many benefits of FDTs, it is a only matter of time until a majority of oral formulations are prepared in FDT forms.

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