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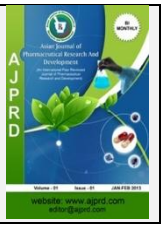

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Review Article

On Overview of Fast Dissolving Tablet

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A B S T R A C T

Fast dissolving tablets emerge as one of the popular and widely accepted dosage forms, especially for paediatric patients because of incomplete development of the muscular and nervous system and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphagia), resulting in many incidences of non-compliance and making the therapy ineffective. Oral dosage form and oral route is the most preferred route of administration for various drugs have limitations like first-pass metabolism, psychiatric patients, bedridden and uncooperative patients. FDTs are disintegrating or dissolve quickly in the saliva without a need of water. Fast dissolving tablets are designed to dissolve in saliva remarkably faster, within a few seconds (less than 60 seconds), and those are real fast-dissolving tablets. The convenience of administration and improved patient compliance are important in the design of oral drug delivery system which remains the preferred route of drug delivery in spite of various disadvantages. There are several technologies that are conventional or patented based on spray drying, cotton candy process, sublimation, melt granulation, direct compression freezes drying/lyophilization, phase transition process, mass extrusion, etc. have been developed for manufacturing of FDTs

Keywords: Fast dissolving tablet, Types, Methods, Superdisintegrants

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INTRODUCTION:

Formulation of drugs into a presentable form is the basic requirement and need of today. The dosage form is a mean of drug delivery system, used for the application of the drug to a living body. Various type of dosage forms are available such as tablets, syrups, suspensions, suppositories, injections, transdermal and patches having a different type of drug delivery mechanisms. These classical/ modern dosage forms have some advantages and disadvantages[1] The tablet is the mostly used dosage form existing today because of its convenience in terms of self-administration, compactness and ease in manufacturing[2] The oral passage of medicament administration for illness is measured as the most conventional route. Tablet is a commonly prescribed dosage form as of its accessibility in terms of self-administration, solidity and simplicity in development.[3] Fast dissolving tablets are novel drug delivery system that dissolves, disintegrate or disperse the API in saliva within few seconds with or without intake of water. The faster the dissolution of drug into the solution, quicker is the absorption and onset of clinical effect.[4] Drug delivery through oral route is the most preferred and accepted way of application by the patients.1 The most popular dosage form being tablets and capsules, one important disadvantage of these dosage forms is the difficulty to swallow Dysphagia is also associated with a number of medical conditions including stroke, Parkinson's disease, AIDS, head and neck radiation therapy and other neurological disorders including cerebral palsy. Fast dissolving tablet have major advantages that is there is no need of water for administration, rapid onset of action, reduce risk of suffocation, avoid hepatic first pass metabolism.[5] Recently, pharmaceutical preparations used. For elderly patients have been investigated to improve the treatment compliance and quality of life of such patients. A tablet which can rapidly disintegrate in saliva (rapidly disintegrating tablet) is an attractive dosage form and a patient-oriented pharmaceutical preparation.[6] Fast dissolving drug delivery systems were first developed in the late 1970s

as an alternative to conventional dosage forms for the pediatric and geriatric patient. These tablets are designed to dissolve or disintegrate rapidly in the saliva generally less than 60 seconds. To fulfill these medical needs, pharmaceutical technologists have developed a novel oral dosage forms known as orally disintegrating (dispersible) tablets (ODTs) or Fast disintegrating (dissolving) tablets (FDTs) or mouth melting tablets (MMTs) or mouth dissolving tablets (MDTs), immediate release tablets which disintegrate rapidly in saliva, usually in a matter of seconds without the need to take water.[7]

Table.1: Criteria for Fast dissolving Drug Delivery System

Parameters	Acceptance/Rejection
Water Required for swallowing	No
Compatible with Taste Masking	Yes
Portable	Yes
Fragility Concern	No
Good Mouth Feel	Yes
Patient Compliance	Yes
Sensitive to Environmental factors (humidity, temperature)	No
Suitable for Conventional tablet processing and packaging	Yes

- The tablets shouldNot require water to swallow, but it should dissolve or disintegrate in the mouth in matter ofSeconds,
- 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.
- Exhibit low sensitive to environmental condition as temperature and humidity.

Advantages of FDTs [5]

1. Improved 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 of liquid medication in the form of solid preparation.
9. Cost-effective.
10. Rapid drug therapy intervention.
11. High drug loading is possible.
12. Have acceptable taste and pleasant mouth feeling

Requirements of fast dissolving tablets Patient factors [6]

- Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of water. These include the following:
- Patients who have difficulty in swallowing or chewing solid dosage forms.
- Patients in compliance due to fear of choking very elderly patients of depression who may not be able to swallow the solid dosage forms
- An eight-year-old patient with allergies desires a more convenient dosage form than Antihistamine syrup.
- A middle aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2-blocker
- A schizophrenic patient who may try to hide a conventional tablet under his or her tongue to Avoid their daily dose of an atypical antipsychotic
- A patient with persistent nausea, who may be a journey, or has little or no access to water.

Effectiveness factor [7]

Increased bioavailability and faster onset of action are a major claim of these formulations. Dispersion in saliva in oral cavity causes pre- gastric absorption from some formulate ions in those Cases where drug dissolves quickly Buccal pharyngeal and gastric regions are all areas of absorption for many drugs. Any pre-gastric absorption avoids first pass metabolism and can be a great advantage in drugs that undergo hepatic metabolism. Furthermore, safety profiles may be improved for drugs that produce significant amounts 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 pre-gastric segments of GIT.As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop.

Manufacturing and marketing factors

A given drug entity in a new and improved dosage form. A new dosage form allows a manufacturer to extend market exclusivity, unique product differentiation and extend patent protection. For examples Eisai Inc launched Aricept FDT. A line extension of donepezil for Alzheimer's disease. In Japan in2004 and in the U. S in 2005 in response to a generic challenge filed in the U. S. By Ranbaxy.

Mechanisms of Superdisintegrants: They work by four basic mechanisms[3]-

***Swelling*:** By this mechanism, certain disintegrating agents (like starch) impart the disintegrating effect upon contact with water, cause the tablet breakdown eg Sodium starch glycolate. Plantago OvataPorosity and Capillary Action (Wicking): The disintegration action of some super-disintegrants is by the capillary action and porosity. The disintegrated particles act to enhance porosity which conveysWays for the permeation of fluid into tablets. After that via capillary action or wicking action, the liquidIs tired up, this results in inter particulate bonds breakdown and ultimately tablet disintegration e.g. Crosspovidone. Crosscarmellose

***Deformation*:** When the pressure applied to the starch grains they deformed and when pressure removed they will come into original shape. But when they compressed into tablets

they deformed permanently which release their energy when coming in contact with water

Due to Disintegrating Particle/Particle Repulsive Forces: This mechanism is associated with non-Swell able disintegrants. For that Guyot-Hermann has given particle repulsion theory. According to that disintegration electric repulsive forces between particles are responsible for the water. It is believed that no single mechanism is responsible for the action of most disintegrants. But, it is the result of inter-relationships between these major mechanisms[3]. Techniques for Preparing Fast dissolving Tablets

Many techniques have been reported for the formulation of Fast dissolving tablets or Orodispersible tablets. Here we have discussed the six major techniques which are widely used forthe formulation of these tablets[4]

1. Freeze drying/ Lyophilisation
2. Tablet moulding
3. Spray drying
4. Direct Compression
5. Sublimation
6. Mass Extrusion
7. Cotton candy process
8. Melt granulation

Freeze-Drying or Lyophilisation

Freeze drying is the process in which water is sublimed from the product after it is frozen. This technique creates an amorphous porous structure that can dissolve rapidly. A typical procedure involved in the manufacturing of FDT using this technique is mentioned here [4].

Moulding method [7]

Tablets are designed using hydrophilic ingredients with the aim to get maximum drug dissolution. Powder mass is wetted with hydroalcoholic solvent and compressed into a dosage form. The solvent system is then allowed to evaporate. Taste of drug particles is developed by spray congealing the molten mixture of hydrogenated cottonseed oil, sodium carbonate lecithin. Polyethene glycol with an active ingredient into lactose based tablet triturate. Characteristics of moulding method are very porous as solvents are removed by drying leaving porous mass which promotes rapid dissolution.

Cotton candy process: This process is so named as it utilizes a unique spinning mechanism to produce floss-like crystalline structure, which mimic cotton candy. Cotton candy process 10 involves fiklormation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is partially re-crystallized to have improved flow properties and compressibility. This candy floss matrix is then milled and blended with active ingredients and excipients and subsequently compressed to MDTs [1]

Direct Compression:

The disintegrant addition technology (direct compression) is the most preferred technique to manufacture the tablets due to certain advantages:

- High doses can be accommodated and final weight of the tablet can exceed that of other methods.
- The easiest way to manufacture the tablets.Conventional equipment and commonly available excipients are used.
- A limited no. Of processing steps are involved.
- Cost effectiveness.[7]

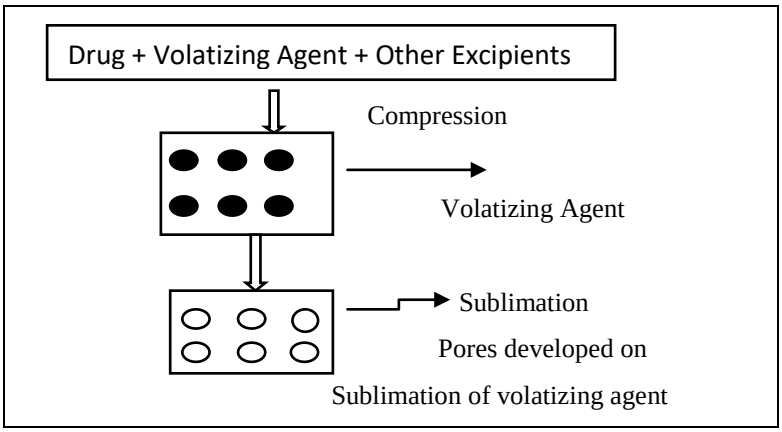
Direct compression represents the most cost effective and simplest tablet manufacturing technique. Because of the accessibility of improved excipients especially superdisintegrants and sugar based excipients, this technique can now be utilized for preparation of Fast Dissolving Tablets [5]

Milling ⇨ Sieving ⇨ Mixing Compression

Flow chart no. 1 Process of direct compression [7]

Sublimation [2]

Rapid disintegration and dissolution is acquired by formulating into porous mass by incorporating inert solid ingredients that volatilize rapidly like urea, camphor ammonium carbonate, ammonium bicarbonate and hexamethylene-tetramine. They were mixed with other ingredients and compressed. The volatile material is evolved by reduced pressure and applying slight temperature leaving the mass in porous form. Characteristics of sublimation method are, they are porous in nature, solvents like cyclohexane and benzene can be used.



Flow .2: Sublimation process

Tablet Molding

By solvent method are less compact than compressed tablets and posses a porous structure thatMolding process is of two type's le solvent method and heat method. The tablets manufactured hastens dissolution. The mechanical strength of moulded tablets is a matter of great concern. Binding agents, which improve the mechanical strength of the tablets, need to be incorporated [4] Masking of taste is an added problem to this technology and the masked drug particles are prepared by spray congealing a molten mixture of hydrogenated polyethylene glycol, cottonseed oil, lecithin, and sodium carbonate an active ingredient into a lactose based tablet triturate form. Tablets produced by the moulding technique are easy to scale up for industrial manufacturer, compared to the lyophillisation techniques

Melt granulation [7]

Melt granulation technique is a process by which the pharmaceutical powders are capablyAgglomerated by a meltable binder. The benefit of this technique compared to a conventional

Granulation is that no water or organic solvents is required. Since there is no drying step, the processIs less time consuming and requires less energy than wet granulation. It is a technique

Useful to enhance the dissolution rate of poorly water soluble drugs, such as griseofulvin.

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 spray-dried powder containing bulking agent, superdisintegrant and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate) have been reported to disintegrate in within 20 seconds in aqueous medium. This spray-dried powder, compressed into tablets showed quick disintegration and improved dissolution (4)

In this the mixed ingredients are softened by water soluble ingredient i.e. polyethene glycol, using methanol as solvent, passing through an extruder to form thin cylinders. Which further get sliced with a heated blade to form small tablets Characteristics of this method is these products can be used to mask bitter tasting drugs making small granules thus enhancing oral bioavailability.

Evaluation of fast dissolving tablet

- **Weight Variation:** Weight Variation tests are carried out according to either USP,IP.BP.
- **Hardness:** Hardness of the tablet should be lesser than conventional tablet falling in the range4kg/cm^2
- **Friability:** Friability should be within the range of 0.1-0.9%
- **Mechanical Strength:** It should possess adequate mechanical strength to absorb the transportationShock and avoid breakage of Tablet
- **Tablet Porosity:** Tablet porosity is conducted(as per ICH guideline)
- **Wetting time and water absorption:** Use of simulated saliva to check the wetting time of tablet as well as water absorption
- **In-vitro Dispersion time:** At optimum and fixed pH and temperature, time taken for dispersion of tablet in media is determined
- **Disintegration Studies:** The time period at which the tablet starts to disintegrate in given aqueous media is determined Dissolution Studies Dissolution Studies carried out according to USP IP BP Stability Studies Stability studies (including Accelerated Stability studies) are either USP.IP.BP, Evaluation parameters of FDT(4)conducted according to the ICH guidelines

CONCLUSION

FDTs are dosage forms which are formulated to dissolve/disintegrate rapidly in the saliva generally within few seconds, FDTS offer lot of advantages over conventional dosage forms such as improved efficacy, bioavailability, rapid onset of action, better patient compliance. Particularly FDTs provide more comfort to pediatric and genatric patients [5] Fast Dissolving tablets are considered to be contemporary dosage forms These dosage forms and their route of administration results in better efficacy.rapid onset of action, enhanced bioavailability, and improved patient compliance [2] This feature enables the patient to take the dose as directed at any time without water and inconvenience. There is clear medical need and clinical benefits provided by these technologies and products. [6]

REFERENCE:

1. Alok Kumar Gupta, Anuj Mittal And Prof. K. K. Jha Fast Dissolving Tablet-A Review The Pharma Journal 2012; 1(1).
2. Ashishmasih, Amarkumar, Shivamsingh, Ajay Kumar Tiwari Fast Dissolving Tablet- A Review International Journal Of Current Pharmaceutical Research 2017; 2(2).
3. Ramakant Joshi, Navneet Garud And Wasim Akram Fast Dissolving Tablets : A Review Ijpsr 2020; 11(4)
4. Kushagra Khanna, Gauravi Xavier, Suresh Kumar Joshi, Aashish Patel, Sakshum Khanna, Vipin And Bhawna Goel Fast Dissolving Tablets-A Novel Approach International Journalofpharmaceuticalresearch&Alliedsciences,2016; 5(2):311-322
5. R.D.Rahane, Dr. Punit R.Rachh A Review Of Fast Dissolving Tablet Journal Of Drug Delivery & Therapeutics.2018; 8(5):50-55
6. Ved Parkash,Saurabhmaan,Deepika[1], Shiv Kumar Yadav[2],Hemlata, Vikas Jogpal Fastdisintegratingtablets:Opportunityindrugdeliverysystem Journal Of Advanced Pharmaceutical Technology & Research Oct-Dec 2011; 2(4)
7. Ashishmasih, Amarkumar, Shivamsingh, Ajay Kumar Tiwari Fast Dissolving Tablets: A Review *Intjcurrpharm Res,Vol 9,Issue2,8-18*