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A Brief Review On Tablet As A Dosage Form With Special Reference To Fast Dissolving Tablets (FDTs)

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ABSTRACT :

An ideal dosage regimen in the drug therapy of any disease is the one, which immediately attains the desire therapeutics concentration of drug in plasma (or at the site of action) and maintains it constant for the entire duration of treatment. This is possible through administration of conventional dosage form in a particular dose and at a particular frequency Thus drug may be administered by variety of routes in a variety of dosage forms. The oral route of drug administration is popular, convenient and widely accepted method of administering the drugs. The formulation of solid oral dosage forms and tablets in particular has gone rapid change and development over the last several decades with the emergence of pre compression, ultra high speed press, induced die feeding. Most recently, new concept and federal regulation bearing on bioavailability and bio equivalence, and on validation, are impacting on tablet formulation, design and manufacture.

KEYWORDS: Tablet, wet granulation, dry granulation, FDT, fast dissolving, mouth dissolving.

INTRODUCTION :-

Drugs are more frequently taken by oral administration. Although a few drugs taken orally are intended to be dissolved within the mouth, the vast majority of drugs taken orally are swallowed. Compared with alternate routes, the oral route of drug administration is the most popular and has been successfully used for conventional delivery of drug. It is considered most natural, uncomplicated, convenient, safe means of administering drugs, greater flexibility in dosage form design, ease of production and low cost. Drugs are administered by the oral route in a variety of pharmaceutical dosage forms. The most popular are tablets, capsules, suspensions, various pharmaceutical solutions. Among the drugs that are administered orally, solid dosage form represent the preferred class of product. They are versatile, flexible in dosage strength, relatively stable, present lesser problem in formulation, packaging and it is convenient to manufacture, store, handle and use. Solid dosage form provides best protection to the drug against light, temperature, humidity, oxygen, and stress during transportation. Amongst the solid oral dosage form tablets are widely used.

DEFINITION :-

" Tablets may be defined as solid pharmaceutical dosage forms containing medicament or medicaments with or without suitable excipients & prepared either by compression or moulding. "

ADVANTAGES OF TABLET :-

Some of the potential advantages of tablets are as follows.

1. They are the unit dosage form having greatest capabilities amongst all the oral dosage form for the dose precision and least content variability.

2. Their cost is lowest amongst all the oral dosage forms.

3. They are the lightest and the most compact amongst all the oral dosage form.

4. They are easiest and cheapest for packaging and transportation.

5. They lend themselves to certain special release profile products such as enteric or delayed release products.

6. Tablets are better suited to large-scale production than other unit oral dosage forms.

7. They have the best-combined properties of chemical, mechanical, microbiological stability amongst all the oral dosage forms.

DISADAVANTAGES OF TABLET :-

(1) Difficult to swallow in case of children and unconscious patients.

(2) Some drugs resist compression into dense compacts, owing to amorphous nature, low density character.

(3) Drugs with poor wetting, slow dissolution properties, optimum absorption high in GIT may be difficult to formulate or manufacture as a tablet that will still provide adequate or full drug bioavailability.

(4) Bitter testing drugs, drugs with an objectionable odor or drugs that are sensitive to oxygen may require encapsulation or coating. In such cases, capsule may offer the best and lowest cost.

(5) Irritant effects on the GI mucosa by some solids (e.g., aspirin).

(6) Possibility of bioavailability problems resulting from slow disintegration and dissolute.

CLASSIFICATION OF TABLET :-

Based on the route of administration or the function, the tablets are classified as follows,

1) Tablets ingested orally.

a) Compressed tablet

b) Multiple compressed tablet

i) Layered Tablet

ii) Compression coated Tablet

c) Repeat action Tablet

d) Delayed action and enteric coated Tablet

e) Sugar and chocolate coated tablet

f) Film coated tablet

g) Chewable Tablet

2) Tablets used in the oral cavity.

a) Buccal Tablet

b) Sublingual Tablet

c) Troches and Lozenges

d) Dental cones

3) Tablets administered by other routes.

a) Implantation Tablet

b) Vaginal Tablets

4) Tablets used to prepare solution.

a) Effervescent Tablet

b) Dispensing Tablet

c) Hypodermic Tablet

d) Tablets Triturates

1) Tablets ingested orally.

a) Compressed tablet :- Are formed by compression, simple one , It contain no special coating. They are made from powdered, crystalline of granular materials, alone or in combination with binders, disintegrates, controlled-release polymers, lubricants, diluents and In many cases colorants eg- simple paracetamol tablets.

b) Multiple compressed tablet :- These are Compressed tablet. made by other than one compression cycle. layerel or laminated tablet. Such tablets are prepared by compressing additional tablet on a previously compressed granulation .• the operation may be repeated to produce multiplayered tablet of two or three layers tablet Special tablets presses are required to make layered tablets.

Eg -Coldrin**,**

i) Layered Tablet

ii) Compression coated Tablet

c) Repeat action Tablet :- Repeat action tablets mutiple dose in single tablet one dose in core-coated with enteric . polymer another dose sugar coated tablet. Now a days it was outdated , uncontrolled , unpredictable time consuming.

d) Delayed action and enteric coated Tablet :- Intended to release a drug after some time delay or after the tablet has passed through one part of GIT to another.

eg Dealayed action tablet is enteric Coated tablet

All enteric Coated tablets delayed action are tablets but not all delayed action tablets are enteric coated tablets are used for those drug which are inactivated or destroyed in acidic media of which irritate gastric mucosa.

eg: cellulose acetate phthalate (CAP) , polyvinyl acetate phthalate. (PAP)

e) Sugar and chocolate coated tablet :- These are compressed tablets containing a sugar coating Automated spray coating gain with high efficient drying pan used for sugar coating.

Coating is relatively brittle prone to chipping & cracking, 50% weight gain.

forts main stages involved in process.

1) sealing : shellac or CAP which prevent moistune also prevent Impairment of drug release.

2) subcouting:- Adhesive coat gum like, acacia, gelatin sucrose used to round off the edge and kaolin or cal. Carbonate like dusted substance used to harden the coat.

3) Smoothing:- 70 % v/v sucrose syrup of opacifiers such as Tio2.

4) Polishing :- solution of wax like material in organic solvent apply in final sterge colorent is added into final polishing stage .

Eg :- Brafen tablet. Premarin tablet , colofac tablet .

f) Film coated tablet :- Those are compressed tablet which are covered with a thin layer por film of a water soluble material A number of polymeric substances with film forming properties may be used. weight gain significantly less .

g) Chewable Tablet:- Tablets are chewed in moth prior to swallowing and are not intended to be Swallowed intact,specially used for children, elderly & those who have difficulty in swallowing a tablet intact.

Eg:- vitamin C, antacid tablets .

2) Tablets used in the oral cavity:-

a) Buccal Tablet & Sublingual Tablet:- these are small, flat, oval tablets. tablets intended for buccal administration by inserting into between cheek & teeth or in the cheek pouch where as Sublingual placed beneath the tongue. Tablet must containing sweetening agent & excipients used in tablet formulation which are not stimulate salivation.

b) Troches and Lozenges :- Intended to exert local action in mouth Or throat, these are commonly used to treat sore throat or to control coughing In common cold. Lozenges are originally formed as Pastilles, but are commonly called cough drops, containing sugar candy base.

C) Dental cones :- Are relatively minor tablet that are Intended to be placed in a empty socket remaining follow tooth extraction. their usually purpose is to prevent multiplication of bacteria & reduce bleeding by antibiotics & astringent, or anticoagulants.

3) Tablets administered by other routes:-

a) Implantation Tablet:- tablets usually small, cylindrical, rod shaped ete, typically not more than 8mm length I are sterile in form.purpose is to prolong release of drugs running from one months to year.Genertly water in soluble and steroidal drugs use.

b) Vaginal Tablets:- tablets are typically ovoid or pear shaped to facilitate retention in Vagina Generally antibacterial, antiseptic astringent are used to treat vaginal Infections. eg:- Intimate (vaginal tablets) 4 in 1 pac.

4) Tablets used to prepare solution:-

a) Effervescent Tablet ;- In addition to the drug substance , these contain Sodium bicarbonate and an org. acid as tartaric acid. In the prescense of water, these additives s react of liberating carbon dioxide which acts as a disintegrators & Produces effervescence. Except for small quantities of lubricants Present, effervescent tablets are soluble.

b) Dispensing Tablet :- These tablets provide a convenient quantity of potent drug that can be used to produce solution by pharmacist or consumer by dissolving in a given volume . of water these tablets are supplied primerily as a convenience for extemporcineous compoundings and should never be dispensed as a dosage for these tablets are highly toxic if taken orally by mistake.These tablets contain excipients which gets dissolved quickly to form a clear Solutions .

c**) Hypodermic Tablet :-** These are Compressed tablets which are composed of one of more drugs with readily water soluble ingredients.These tablets are dissolved in sterile water or water for injections of adminstered by parenteral route.

d) Tablets Triturates :- molded Tablets (tablet triturates) certain tablets may be prepared by molding rather than by compression. The resultant are very soft & soluble and are designed for rapid dissolution. such tablets must be ·Completely and rapidly soluble T.T are soft and friable .Alcohol is commonly used in T.T to wet the powder mass .

TABLET MANUFACTURING METHODS :-

Tablets are manufactured by wet granulation, Dry granulation or direct compression method as shown in table .

1) **Wet Granulation** :- Wet granulation is the process in which a liquid is added to a powder in a vessel equipped with any type of agitation that will produce agglomeration or granules. These granules after drying are compressed to form tablets.

2] **Dry Granulation** :- In this technique, there is no use of liquids. The process involves the formation of slugs. Then the slugs are screened or milled to produce granules. The granules formed are then compressed to form tablets.

3) **Direct compression** :- The term direct compression is used to define the process by which tablets are compressed directly from powder blends of active ingredient and suitable excipients, which will flow uniformly in the die cavity & forms a firm compact.

Processing steps	Wet Granulation	Dry Granulation	Direct Compression
Raw materials	√	√	√
Weight	√	√	√
Screen	√	√	√
Mix	√	√	
Compress (slug)		√	
Wet mass	√		
Mill	√		
Dry	√		
Mill	√	√	
Mix	√	√	
Compress	√	√	√

Table : Processing steps commonly required in the various tablet granulation preparation techniques.

FAST DISSOLVING TABLET :-

For the past two decades, there has been enhanced demand for more patient compliant dosage forms. As a result, the demand for the technologies has been increased 3 fold annually. Since the development cost of a new chemical entity is very high, the pharmaceutical companies are focusing on the development of new drug delivery systems for existing drug with an improved efficacy and bioavailability together with reduced dosing frequency to minimize the side effects. Dysphagia or difficulty in swallowing is seen to afflict nearly 35% of general population. This disorder is also associated with number of medical condition including Stroke, Parkinson's disease, AIDS, head and neck radiation therapy and other neurological disorder including cerebral palsy. Recently pharmaceutical preparations used for elderly patients have been investigated to improve the treatment compliances and quality of life of patients. Recent advances in Novel Drug Delivery System (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach is "Mouth/Fast Dissolving Tablet". This is an innovative tablet technology where the dosage form containing active pharmaceutical ingredients disintegrates rapidly, usually in a matter of seconds, without the need for water, providing optimal convenience to the patient. Innovators and inventor companies have given these tablets various names such as orally disintegrating tablets (ODT), mouth dissolving (MD), fast melting, fast dissolving or ordisperse. The concept of Fast Dissolving Drug Delivery System emerged from the desire to provide patient with conventional mean of taking their medication. Difficulty in swallowing (Dysphagia) is a common problem of all age groups, especially elderly and pediatrics, because of physiological changes associated with these groups of patients. Other categories that experience problems using conventional oral dosage forms includes are the mentally ill, uncooperative and nauseated patients, those with conditions of motion sickness, sudden episodes of allergic attack or coughing. Sometimes it may be difficult to swallow conventional products due to unavailability of water. These problems led to the development of novel type of solid oral

dosage form called "Fast Dissolving Tablets". On placing fast-dissolving tablet in the mouth, this dissolved rapidly. When tablet comes contact with water it swelled and the drug is absorbed in the normal way. Drugs are easily absorbed in stomach & it may produce rapid onset of action. In such a cases Bioavailability of drug is significantly greater than those observed from conventional tablet dosage form.The growing importance of fast dissolving tablet was underlined recently. According to European Pharmacopoeia fast dissolving tablet means tablet which dissolve in the oral cavity in about 10 second to 3 minutes .

Example :- sodium starch glycolate , alginic acid , calcium silicate etc .

Significance of the Fast Dissolving Tablet :-

1) Ease of administration.

2) Rapid dissolution of drug & absorption.

3) Better Bioavailability in some selected cases.

4) Advantages of liquid medication in solid preparation.

5) Ideal for pediatric and geriatric patients.

6) Better patient's compliance.

7) Accuracy of dosage.

Fundamentals of Fast Dissolving Tablet :-

For rapid dissolution or disintegration of dosage form, water must rapidly penetrate into the tablet matrix to cause quick disintegration & instantaneous dissolution of the tablet. Several techniques are used to achieve these fundamentals, to formulate fast-dissolving tablet .

Technique for Preparing Mouth Dissolving Tablets:-

1) Freeze Drying

2) Moulding

3) Sublimation

4) Spray Drying

5) Direct compression

1) Freeze Drying :- Freeze-drying or lyophillazation can be utilized to prepare mouth-dissolving tablets, which are very porous in nature and which quickly disintegrate or dissolve upon contact with saliva. This method involves incorporation of the drug in water-soluble matrix, which is then transferred to the preformed blister with peelable foil, as the zydis units are not strong enough to withstand being pushed through the lidding foil of a conventional blister, Freeze drying is then done to remove water by sublimation. R.P. Scherer patented zydis technology by employing freeze drying process for the preparation of mouth dissolving tablet on the basis of patent issued to Gregory et al. Seager discussed formation, process technology & Bioavailability of fast dissolving tablets prepared by zydis technology.The major disadvantage associated with freeze dried fast dissolving tablets is fragility, which creates difficulty in conventional packaging & posses stability problems during storage. However in order to improve stability problems, Blank et al., used a mixture of mannitol & natural gum as carrier material in formulation of freeze dried tablets and concluded that the tablets showed improved stability in blister pack even when they were stored in stressful conditions.

2) Moulding :- Moulded tablets are prepared by using water-soluble ingredients so that the tablet dissolve or disintegrate rapidly and completely. Powder is moistened with the help of hydro alcoholic solvent and then moulded into tablets under pressure less than the conventional dosage form. The solvents are removed by air-drying. The tablet possesses porous structure, which facilitates easy dissolution. Adding sucrose, acacia or PVP K-30, 22, may increase the mechanical strength of the tablet. The scope for taste masking in moulded tablets is very limited. To mask the unpalatable taste of medicaments, Van Scoik had developed a particulate cotton seed oil, lecithin, polyethylene glycol, sodium bicarbonate and drug and incorporates the same into a lactose-based triturate form to produce taste masked mouth dissolving tablets.

3) Sublimation :- The basic principle involved in preparing fast dissolving tablets by sublimation technique is addition of a volatile salt to the tabletting components, mixing the components to obtain a substantially homogeneous mixture & volatizing a volatile salt. The removal of volatile salts creates pores in the tablet, which help in achieving rapid disintegration when the tablet comes in contact with saliva. Camphor, Naphthalene, Urea, ammonium bicarbonate, etc, can be used to prepare porous tablets of good mechanical strength. Koizumi et.al. used mannitol as diluent and camphor as a volatile material to prepare porous compressed tablets. The tablets were subjected to vacuum at 800C for 30 min to eliminate the camphor and thus form the pores in the tablet. Makino et.al.utilized water as a pore forming material in order to prepare porous tablets with excellent mechanical strength and dissolution character.

4) Spray Drying :- Spray Drying can be used to prepare rapidly dissolving tablet. This technique is based upon a particulate support matrix that is prepared by spray drying and aqueous composition containing support matrix and other components to form a highly porous & fine powder. This is then mixed with active ingredient & compressed into tablet. The fast dissolving tablet prepared from spray drying technique disintegrated within 20 seconds.

5) Disintegrant addition (Direct compression) :- Disintegrant addition technique is one of the popular techniques for formulating mouth dissolving tablets because of its easy implementation and cost effectiveness. The basic principle involved in formulating mouth-dissolving tablets by disintegrant addition technique is addition of superdisintegrants in optimum concentration so as to achieve rapid disintegration along with good mouth feel. The incorporation of microcrystalline cellulose and low substituted hydroxy propyl cellulose in the ratio of 8:2 to 9:1 gives shortest disintegration time. Fast dissolving tablet having analgesic activity was formulated using a combination of different superdisintegrants. Fast dissolving tablet of efavirenz (anti HIV agent) were formulated by using combination of microcrystalline cellulose and sodium starch glycolate as superdisintegrant. Disintegrants can help to facilitate drug dissolution and consequently can improve bioavailability. Despite a long and proven record of starch, as a disintegrant, it possesses disadvantages when used in direct compression formulation. The relatively high levels required and the lack of compressibility often weakens the tablet structure. Therefore the development of new disintegrants that are effective at lower concentrations and help in rapid disintegration is of great importance in formulations for direct compression. A number of disintegrants, known as superdisintegrants like crosslinked carboxymethyl cellulose (Ac-di-sol®), Sodium starch glycolate (Explotab®) and crospovidone (polyplasdone XL®) markedly improve the tablet disintegration by swelling and exerting sufficient pressure in the tablet to break it apart into small segments. These superdisintegrants have a high swelling index at lower concentrations. So they are used in the formulation of mouth dissolving or dispersible tablets.

SUMMARY AND CONCLUSION :- Fast dissolving tablets can be concluded as a novel drug delivery approach which will be convenient to formulate and administer without the need for water, negligible side effects, will offer immediate release and bioavailability enhancement, so as to achieve improved patient convenience and compliance. Due to the constraints of the current technologies, there is an unmet need for improved manufacturing processes for immediate release tablets that are mechanically strong, allowing ease of handling, packaging and with low production costs. A new dosage format is possible combine with immediate release bilayer tablet, one who provide one half immediate release portion and another half extended release portion for the better efficacy from the therapy also bilayer is possible for combination dose, which also may offers the combine advantage of ease dosing and convenience for dosing. An extension of market exclusivity, which can be provide by immediate release dosage form, leads to increased revenue, while also targeting underserve and undertreated patient populations.

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