International Journal of Pharmaceutical Drug Design
IJPDD (JANUARY, 2024)
Website: https://ijpdd.org/
Vol.-1, Issue-2
Page No: 1-8

Fast-Dissolving Tablets for the Treatment of Acute and Chronic Diseases

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Article History
Received : 15/12/2023
Revised : 02/01/2024
Accepted: 20/01/2024

Abstract:
Oral dose forms that dissolve quickly in the mouth are known as fast-dissolving tablets (FDTs). The effects will be felt sooner, patient compliance will increase, and it will be more convenient than taking a medication. FDTs are also easier to make and store than traditional tablets. A multitude of distinct technologies are capable of manufacturing FDTs. A popular method involves spray-drying the pharmacological ingredient into a thin film, which is then coated onto a carrier medium. Creating a solid dispersion of the medicinal component in a carrier material can also be done by the use of a technique called melt extrusion, which is another method. Drugs, including small compounds and biologics, can be formed into FDTs. FDTs are useful in treating a wide range of therapeutic indications, including the treatment of pain, the avoidance of migraines, and disorders related to the respiratory system. Patients who have trouble swallowing regular pills, such as younger children, the elderly, and those with dysphagia, may find these more manageable. Overall, FDTs have several benefits that traditional tablets lack. They work quickly in the body, boost patients' adherence, and are simple to produce and keep on hand. Various medications can be effectively delivered with the use of FDTs.

Keywords: Fast dissolving tablet, bioavailability, rapidly absorbed, rapid disintegration, Innovative medication

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Introduction:

The most popular and extensively used method of delivery is by mouth. The most glaring problem with conventional oral dose forms like tablets and capsules is that they can be difficult to swallow, which can lead to noncompliance, especially in younger and older patients.[1] When making medication forms, ease of use and patient cooperation are becoming more and more important. Organoleptically beautiful and patient-friendly drug delivery methods for young and geriatric patients have been getting more attention lately.[2] Therefore, melt-in-your-mouth pills, also known as oral fast-dissolving/disintegrating (FDDS) tablets, are becoming increasingly popular as a novel method of drug administration. You don't have to chase down these pills with a glass of water since they dissolve in your mouth quickly.[3]

Formulating medications into a presentable form is essential now a days. Dosage forms are means of medication delivery used to provide drugs to living individuals. Various dosage forms, including tablets, syrups, suspensions, suppositories, injections, transdermal, and patches, have distinct drug delivery processes.[4] These traditional and new dose forms have pros and cons. Developing an effective medicine delivery method is a significant problem for pharmacists in the present situation.[2] For optimal therapeutic effects, the medicine should be administered at the right pace and concentration to the site of action, minimizing unwanted effects. To create an effective dosage form, scientists must first learn everything they can about the physicochemical laws that control a certain drug's composition.[5]

The development of novel dosage forms intended for oral administration constitutes a broad spectrum of pharmaceutical research. The majority of these initiatives have been directed toward either the development of innovative medication delivery methods or the improvement of patient compliance. Orally disintegrating systems have emerged as the product development scientists' top choice among the several dose forms designed to make taking medication more convenient. The oral cavity is readily accepted by patients, the mucosa is permeable with a good blood supply, and the absence of Langerhans cells makes it allergen-tolerant.[6]

Dosage Form:

Any chemical entity that is intended to serve a therapeutic purpose is referred to as a drug. Because a drug cannot be consumed in its pure state, it is compounded into appropriate dosage forms for the delivery of the drug into the body. Dosage forms are pharmaceutical products in the form in which they are marketed for use, typically involving a mixture of active drug components, as well as other non-reusable material that is not considered either an ingredient or packaging. The oral route has attracted more attention due to its advantages such as ease of administration, feasibility for solid formulation and patient compliance. [7]

Oral route of drug administration is by far the most common and acceptable route for drug administration. It is the first choice for the administration of drugs due to its characteristic advantages like ease of administration, patient compliance, and feasibility. Orally administered drugs usually pass through the gut wall and liver where they undergo a series of several enzymatic activities (first-pass metabolism), into the gastro-intestinal fluid. As a result, only a fraction of the administered drug actually reaches the systemic circulation (this fraction is referred to as the oral bioavailability of a drug).[8] The popularity of this dosage form is because of advantages such as ease of manufacturing, convenience in administration, and high accuracy in dosage, stability and safety. [9] Swallowing is also a common problem in the young individuals because of their under developed muscular and skeletal system. Other groups that may experience problems using conventional oral dosage form include mentally ill, developmentally disabled patients and patients who are uncooperative or who are suffering from severe nausea.[10]

Classification of dosage forms:

Dosage forms are classified on the basis of following ways shown in figure 1: [11]

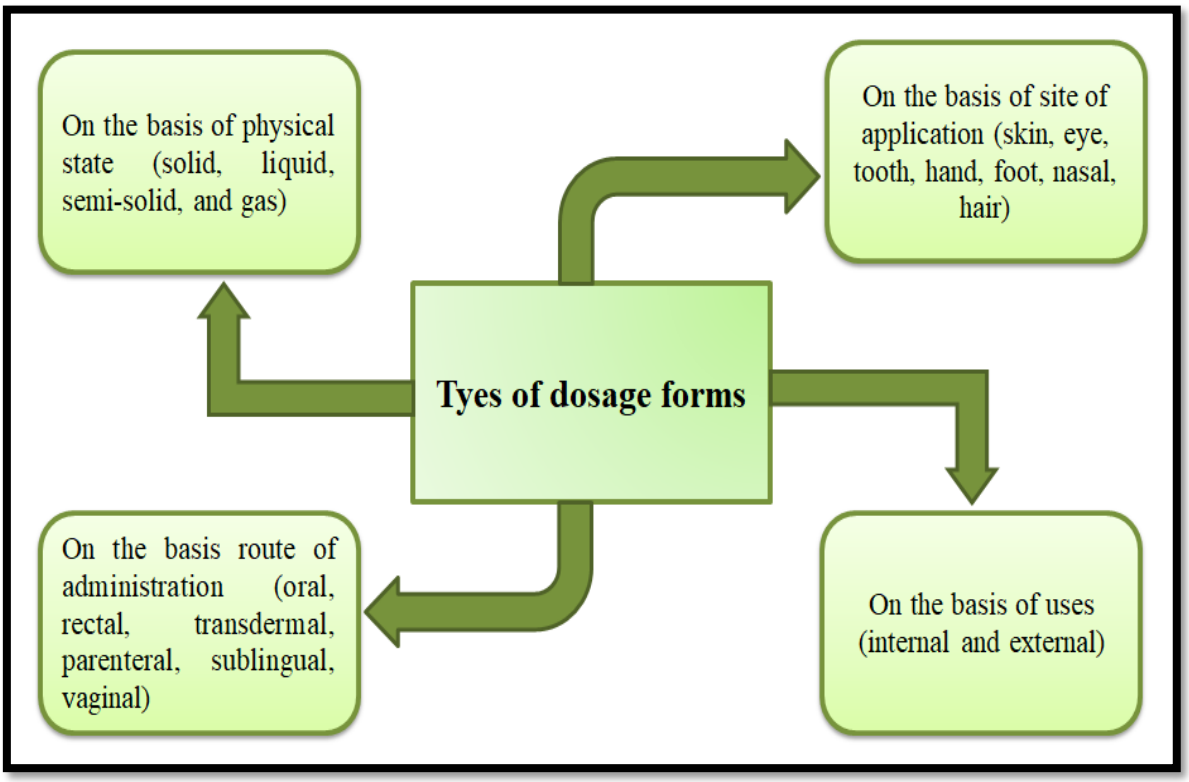

Fig. 1: Classification of dosage forms

- On the basis of physical state – solid, liquid, semi-solid, and gas.
- On the basis of route of administration – oral, rectal, transdermal, parenteral, intrarespiratory, intranasal, urethral, vaginal, intraocular, sublingual.
- On the basis of site of application – skin, eye, tooth, hand, foot, nasal, hair.
- On the basis of uses – internal and external.

Tablets:

Tablets are solid dosage forms that have been crushed and contain medication, either with or without excipients. According to the quantity of medication used and their intended manner of administration, they fluctuate significantly in size, weight, and form. Throughout ancient times, tablets have been the most popular medication due to their low cost, great availability, convenience of administration, acceptance for a variety of conditions, improved patient compliance, more effective stability, etc. [12]

Classification of tablets:

Tablets are classified on the basis of following ways shown in figure 2:

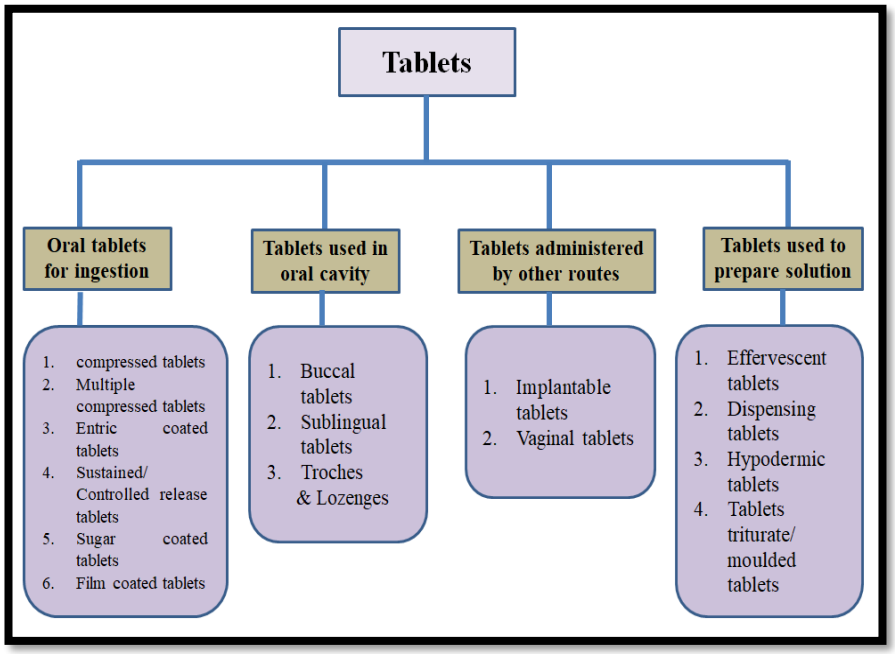

Fig. 2: Classification of tablets

- Tablets for ingestion: Standard compressed tablets, multiple compressed tablets, targeted tablets, chewable tablets, and fast dissolving tablets.
- Tablets meant to disintegrate in oral cavity: Lozenges and troches, sublingual tablets, buccal tablets, dental cones, and mouth dissolving / rapidly dissolving tablets.
- Tablets given by other routes: vaginal tablet, rectal tablet, and implants.
- Tablets used to prepare a solution in vivo/ in vitro: Effervescent tablets, molded tablets and tablet triturates.
- Based on structure: Divisible tablets, aperture tablets, concave convex tablets, and core tablets.
- Based on mechanism of action: Modified release tablets (sustained release, controlled release etc.). [13]

Advantages of Tablets:

- Tablets are a unit-solid dosage form that provides the most precise doses and smallest content fluctuation of any oral medication form.
- When compared to alternative oral dose forms, tablets are cheaper.
- They are easy to administer.
- It is possible to create sustained release activity.
- It is possible to cover up offensive smells and harsh tastes.
- These are suitable for large scale production.
- Greatest chemical and microbial stability over all other dosage form.
- Rapid dissolution of drug and absorbance may produce rapid onset action.
- The medication may take effect quickly if it dissolves and absorbs quickly.

Disadvantages of Tablets:

- Tablets should not be given to people who are asleep or lying on the bed.
- It's also not ideal for anyone who have trouble swallowing, such young children or the elderly.
- Pharmaceuticals with poor wetting and delayed dissolve may be difficult or impossible to produce and manufacture into tablets with complete bioavailability.
- Patients who are experiencing vomiting and diarrhea are unable to ingest or absorb the substance.
- When taken in tablet form, several medications might irritate the stomach and the digestive tract. [14]

Fast Dissolving Tablets:

Fast-dissolving tablets can be broken up, dissolved, or suspended by saliva in the mouth, making water unnecessary during this process. Orally disintegrating tablets (ODTs) are a relatively new dosage type that was defined by the Food and Drug Administration in 1998. It said that "The ODT is a solid dosage form containing medical compounds which disintegrate swiftly, generally within a couple of seconds once brought the tongue".[15] Drugs that were not easily soluble presented a bigger challenge for the formulation process. Improving a dosage form's solubility should be one of the priorities when trying to achieve maximum bioavailability. [16] It has been used to speed up the dissolution rate, which in turn improves the mouth

absorption and bioavailability of drugs that don't dissolve in water. [17] Powder particles are also smaller and salts are formed. The solid dispersion approach has shown to be a useful method for increasing the bioavailability and solubility of medications that dissolve poorly in water. Fast dissolving tablets disintegrate in water or disperse immediately in the mouth shown in figure 3. [18]

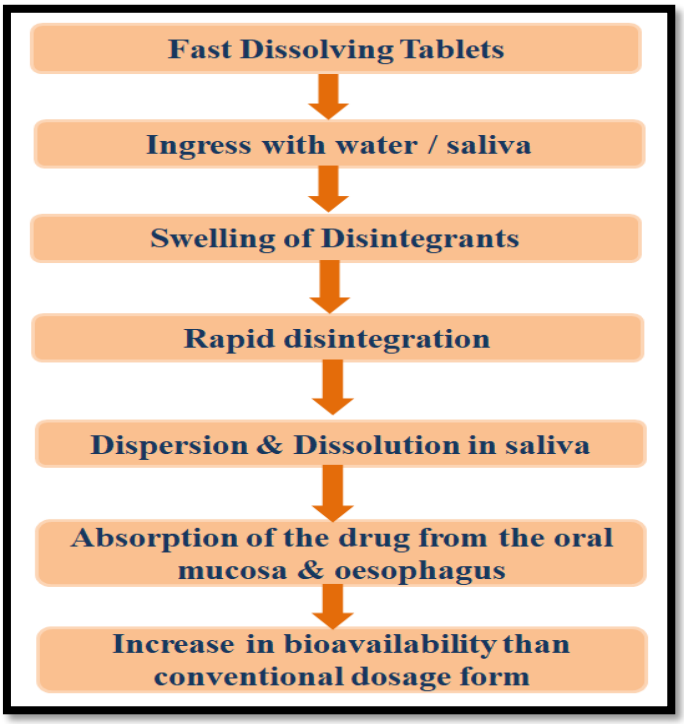

Fig. 3: Action of Fast Dissolving Tablets

Tablets that dissolve quickly in saliva are helpful for patients who have trouble ingesting larger dose forms, such as children, those undergoing chemotherapy, and those with mental health issues. Extremely porous, soft-molded matrices or tablets with an exceptionally low compressive force constitute these varieties of tablets. [19]

Mechanism of fast dissolving tablets:

Tablets break up into tiny bits and dissolve in water or other liquids. The following step is de-aggregation when the granules are broken down into their parent particles. Primary particles dissolve fast due to their enormous surface area, but complete tablets and aggregates generated during tablet breakdown take longer to dissolve. [20] The FDTs should disperse or disintegrate in less than three minutes. Super disintegrates including crospovidone, croscarmellose, and sodium starch glycolate serve as the backbone of FDTs shown in figure 4. [21]

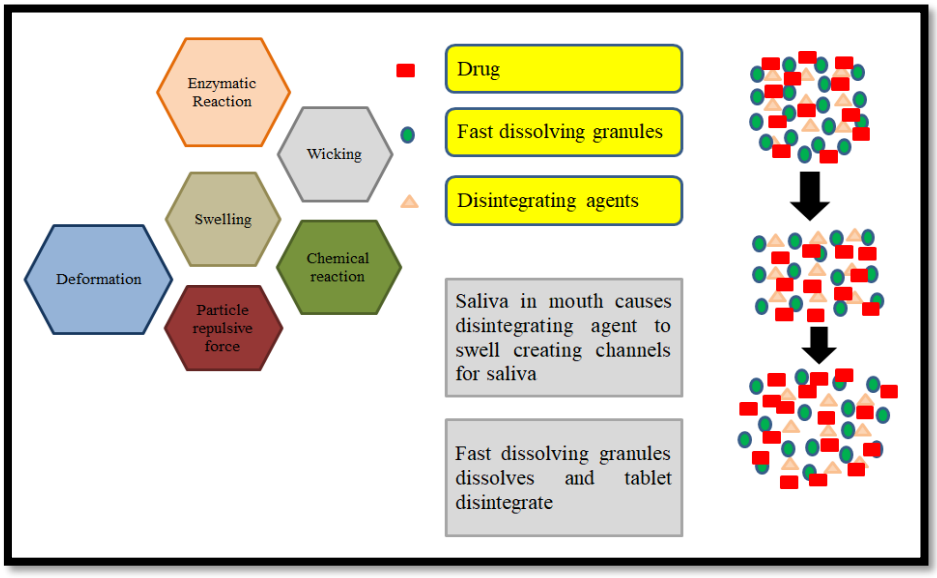

Fig. 4: Mechanism of Fast Dissolving Tablets

Important characteristics of fast-dissolving tablet:

- Facilitates administration for mentally ill, impaired, and unwilling individuals.
- Solid dosages can be swallowed without water.
- Rapid disintegration and dissolving of the dose form.
- With saliva in the stomach, drugs are absorbed from the mouth, throat, and esophagus. Such circumstances boost drug bioavailability.
- Overcomes unacceptable taste of the drugs. [22]

Advantages of fast-dissolving tablets:

- Conventional dose forms require liquid for ingestion, whereas FDTs do not.
- This makes it easier for patients who travel or don't have water to comply.
- The quick disintegration and dissolving of tablets increases bioavailability, especially for insoluble and hydrophobic medicines.
- Tablets dissolve and absorb quickly in the mouth.

Disadvantages of fast dissolving tablets:

- Drugs required to be absorbed at specific sites cannot be delivered as fast dissolving tablets.
- Careful handling of these tablets is necessary as they have low friability than theconventional tablets.
- Once removed from the blister packaging, they should be used immediately astheir stability outside the blister cannot be guaranteed
- They pose less physical strength then conventional tablets.
- Uniformity in dosing is quite difficult.
- Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations. [23]

Formulation Constituents (Besides API) of Fast Dissolving Tablets:

Table 1. List of excipients used in fast dissolving tablets formulation. [24]

S. No.	Excipients	Role	Synthetic	Natural
1	Disintegrants/ Super disintegrants	They facilitate tablet breaking when it comes in contact with water as well as in GIT.	Croscarmellose sodium, crospovidone, SSG, starch etc.	Fenugreek seed mucilage, Chitin and chitosan, Guar gum etc.
2	Binders	Impart cohesiveness to powdered materials.	Gelatin, glucose, lactose, MC, EC, HPMC, starch, povidone, sodium alginate, CMC, Acacia etc.	Rice starch, maize starch, potato starch etc.
3	Diluents	Make required bulk of tablet, improve cohesion, flow properties, compatibility, and stability.	Lactose, spray dried lactose, MCC, mannitol,sorbitol, dibasic calcium phosphate etc.	Starches, hydrolyzed starches and partially pre-gelatinized starches etc.
4	Lubricants	Prevent adhesion of tablet material to surface of dies and punches and reduce inter particulate friction.	Insoluble stearic acid, magnesium stearate, talc, paraffin, sodium benzoate, PEG etc.	Aloe vera, yogurt, olive oil and virgin coconut oil.
5	Glidants	Improve flow characteristics of powder mixture.	Colloidal silicon dioxide, talc etc.	Corn starch
6	Sweeteners	Produce a palatable dosage form.	Sucrose, sucralose, saccharin, aspartame etc.	Honey, dates, coconut sugar etc.
7	Flavoring agents	Enhance palatability.	Peppermint, vanilla, orange, banana, cinnamon, mango etc.	Caraway, clove, lemon, spearmint, rose etc.

Tablet Disintegration:

Powder compacts disintegrate into tiny pieces when a pill comes into contact with a liquid substance. Disintegration, the first step in the bioavailability cascade, makes it easier for the tablet to break up into smaller pieces after being digested in the gastrointestinal system. This makes it possible for the medicine to dissolve more quickly, which improves its bioavailability.[25] When it comes to tablets with a quick release, the processes of disintegration and dissolving are closely connected. The International Conference on Harmonization (ICH) Tripartite Guideline Q6A examines the utilization of disintegration as an alternate test to dissolution.[26] Together, APIs and excipients compose the tablet formulation, which is used to create tablets as a dosage form.[27] Excipients made in tablets, in general, are responsible for performing several critical activities, such as facilitating the penetration of liquid into the tablet matrix and kicking off the subsequent disintegration process. Disintegrates, on the other hand, are added to tablets to facilitate this process. As a result,

disintegrates are regarded as being among the most crucial excipients.[28]

Manufacturing of Fast Dissolving Tablet:

The manufacturing of fast-dissolving tablets, and particularly orally fast-dissolving tablets, can be broken down into two types based on recent advances in the industry.[29] Manufacturing of tablets using traditional methods comes initially, followed by manufacturing of tablets with cutting-edge technology. There is a wide number of processes that may be used in the production of quick-dissolving tablets; however, the following are the most frequent methods are shown in figure 5: [30]

- **Direct compression:** Tablets may be made in a variety of ways, but the quickest and cheapest is direct compression since it requires fewer manufacturing stages. The most efficient and streamlined approach to making tablets is through direct compression. Direct compression is the process of making tablets directly from powder mixtures of the active ingredient and excipients that flow evenly through dies film compressed. This type of compression is referred to as "direct compression."
- **Wet granulation:** This method makes grains by mixing the active ingredient with fillers and a liquid that granulates to make a wet mass. The mass is then dried and sieved to remove any impurities. Following this step, the granules are combined with various additional excipients before being compacted into tablets.
- **Dry granulation:** Dry granulation is a process that includes first combining the active ingredient with the excipients, and then compressing the resulting mixture into granules. These granules are then combined with more additives and crushed into tablets.
- **Freez drying:** The preparation of a suspension or solution containing the active ingredient and the excipients is the first step in the freeze-drying process. After that, the mixture is placed in a vacuum and allowed to freeze solid before being dried. Following this step, the lyophilized substance is crushed into tablet form.
- **Molding:** The active component and excipients are combined into a molten or plastic substance, that is subsequently shaped into tablets. [31-34]

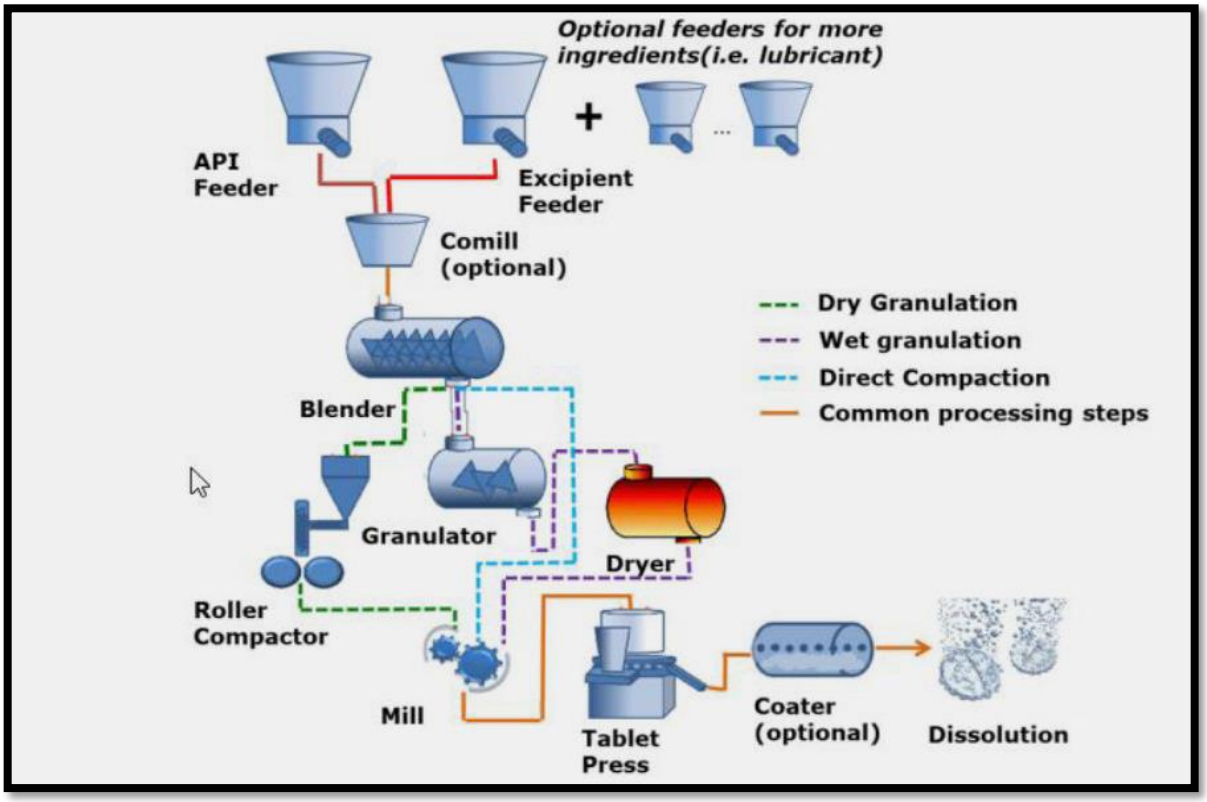

Fig. 5: Steps involved in direct compression method of tablet manufacturing

Conclusion:

In conclusion the Fast-dissolving tablets (FDTs) are a rapidly emerging dosage type with various potential advantages over standard tablets and capsules. Dissolving or disintegrating quickly in the mouth without the need for water makes them a useful and effective choice for people who struggle with swallowing or who need immediate results. These applications are not the beginning; FDTs have also been demonstrated to have promising medicinal applications. FDTs can be used to provide active pharmaceutical ingredients (APIs) that have been

developed for oral absorption rather than hepatic first-pass metabolism, hence increasing their bioavailability. This is useful for a wide range of active pharmaceutical ingredients (APIs), including certain antibiotics, antifungals, and hormones. FDTs are also being examined as a viable delivery technique for controlled-release APIs. Controlling the disintegration and dissolution rates of FDTs allows for a slow, steady release of the API over time. Regular dosing may help individuals who need to take medicine yet are adversely affected by high peak drug concentrations. All things considered, FDTs are an exciting new dosage form with numerous opportunities to advance medical practice and benefit patients. They have useful qualities that make them an attractive alternative for many different kinds of patients, and their potential therapeutic benefits are currently being researched.

Acknowledgement:

I would like to express my sincere gratitude to IPS Academy College of Pharmacy for providing access to resources and facilities that facilitated my above article.

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