



DEVELOPMENT AND EVALUATION OF FAST-DISSOLVING TABLET FOR ENHANCED PATIENT COMPLIANCE.

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Abstract

Fast dissolving Tablets are disintegrating and/or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva remarkably fast, within a few second and are true fast-dissolving tablets. Others contain agents to enhance the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets, as they may take up to a minute to completely disintegrate. Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance. This tablet format is designed to allow administration of an oral solid dose form in the absence of water or fluid intake. Such tablets readily dissolve or disintegrate in the saliva generally within <60seconds. Fast- or mouth dissolving tablets have been formulated for pediatric, geriatric, and bedridden patients and for active patients who are busy and traveling and may not have access to water. Such formulations provide an opportunity for product line extension in the Many elderly persons will have difficulties in taking conventional oral dosage forms (viz., solutions, suspensions, tablets, and capsules) because of hand tremors and dysphagia. Swallowing problems also are common in young individuals because of their underdeveloped muscular and nervous systems. Other groups that may experience problems using conventional oral dosageforms include the mentally ill, the developmentally disabled, and patients who are uncooperative, on reduced liquid-intake plans, or are nauseated. In some cases such as motion sickness, sudden episodes of allergic attack or coughing, and an unavailability of water, swallowing conventional tablets may be difficult

Keywords: Fast Dissolving Tablet (FDT),Rapid Disintegration,Quick Dissolution,Superdisintegrants ,Direct Compression,Oral Disintegrating Tablets (ODT),Mouth Dissolving Tablets,Bioavailability Enhancement,Patient Compliance,Swallowing Difficulties,Pediatric and Geriatric Care,Instant Release Formulation Solubility Enhancement,Taste Masking, Mucoadhesive Tablets

1.Introduction

Recently, fast-dissolving drug delivery systems have started gaining popularity and acceptance as new drug delivery systems, which aim to enhance safety and efficacy of a drug molecule by formulating it into a convenient dosage form for administration and to achieve better patient compliance. Some companies introduced more robust forms of fast-dissolving drug delivery; for example Lavipharm Laboratories Inc.

(Lavipharm), invented an ideal fast-dissolving drug delivery system, which satisfied the unmet needs of the market. This novel intraoral drug delivery system, trademarked Quick-Dis™, is Lavipharm's proprietary patented technology, and is a thin, flexible, and quick-dissolving film. The film is placed on the top or the floor of the tongue.[1] When put on the tongue, this film disintegrates instantaneously, releasing the drug which dissolves in the saliva. Some drugs are absorbed from the mouth, pharynx, and esophagus as the saliva passes down into the stomach. In such cases, the bioavailability of the drug is significantly greater than that observed for conventional tablets.[2]

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. Therefore, the development of an ideal drug delivery system is a big challenge to the pharmacist in the presence scenario. In order to get the desired effect, the drug should be delivered to its site of action at such rate and concentration to achieve the maximum therapeutic effect and minimum adverse effect. For the development of a suitable dosage form a thorough study about the physicochemical principles that governs a specific formulation of a drug should be subjected [3]

Ideal property of fast dissolving tablets a mouth dissolving tablet should possess following characteristics.[4]

1. It should not require water for oral administration.
2. It should be incentive to environmental conditions such as humidity and temperature.
3. It should not leave any residue in the mouth after disintegration.
4. It should have sufficient hardness to withstand the rigors during manufacturing processes and packaging machinery.
5. It should be adaptable to current processing and packaging machinery.
6. It should allow high drug loading.
7. It should have pleasant mouth feel.
8. It should be cost effective

Advantages[5]

* The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety

* The new business opportunity like product differentiation, product promotion, patent extension, and life cycle management become easy after the

* First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.

* Can be easily administered to pediatric, elderly and mentally disabled patients.

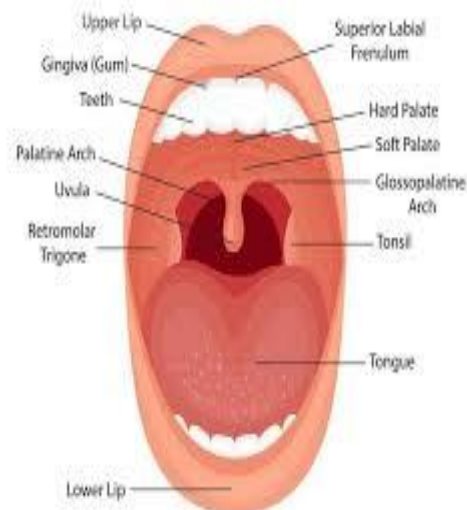


Figure 1: Advantages of MDT

Disadvantages [5]

1. Drug with relatively large doses are difficult to formulate into FDTs.
2. Patients who concurrently take anti-cholinergic medications may not be the best candidate for FDTs.
3. Tablets usually have insufficient mechanical strength. Hence, it requires careful packaging and handling.
4. Tablets may leave unpleasant taste and / or grittiness in mouth if not formulated properly.
5. They are more susceptible to degradation by humidity and temperature.
6. Fast dissolving tablet is hygroscopic in nature so must be kept in a dry place.
7. Drugs with larger doses are difficult to formulate into FDT. Eg. Rifampin (600 mg), ethambutol (1000 mg)

Limitations of fdt [6,7]

- * The major disadvantages of FDTs is related to the mechanical strength of tablets.
- * FDT are very porous and soft molded metrics or compressed in a tablet with low compression, which makes tablet friable and brittle which difficult to handle.
- * Bad tastes drugs are difficult to formulate as FDT; special precaution should have to be taken before formulate such kind of drug.
- * Several FDT are hygroscopic cannot maintain physical integrity under normal condition from humidity which requires specialized package.
- * Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.
- * Rate of absorption from the saliva solution and overall bioavailability.

Salient features of fast dissolving tablets or fast dissolving drug delivery system [8,6,9]

- * Ease of Administration to the patient who cannot swallow, such as the elderly, stroke victims, bedridden patients, a patient affected by renal failure and patient who refuse to swallow such as paediatric, geriatric and psychiatric patients.

- * No need of water to swallow the dosage form, which is a highly convenient feature for patients who are travelling and do not have immediate access to water.
- * Rapid dissolution and absorption of the drug, which will produce the quick onset of action.
- * Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases, the bioavailability of the drug is increased.
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- * Pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage;
- * Good mouth feels property helps to change the perception of medication as a bitter pill particularly in the pediatric patient.
- * The risk of choking or suffocation during oral administration of conventional formulation due to physical obstruction is avoided, thus providing improved safety.
- * New business opportunity like product differentiation, product promotion, patent extensions and life cycle management.
- * Beneficial in cases such as motion sickness, sudden episodes of allergic attack or coughing, where an ultra-rapid onset of action required.
- * An increased bioavailability, particularly in cases of insoluble and hydrophobic drugs, due to rapid disintegration and dissolution of these tablets. Stability for a longer duration of time, since the drug remains in solid dosage form till it is consumed. So, it combines the advantage of the solid dosage form in terms of stability and liquid dosage form in terms of bioavailability.
- * Adaptable and amenable to existing processing and packaging machineries.
- * Allow high drug loading, Cost effective.

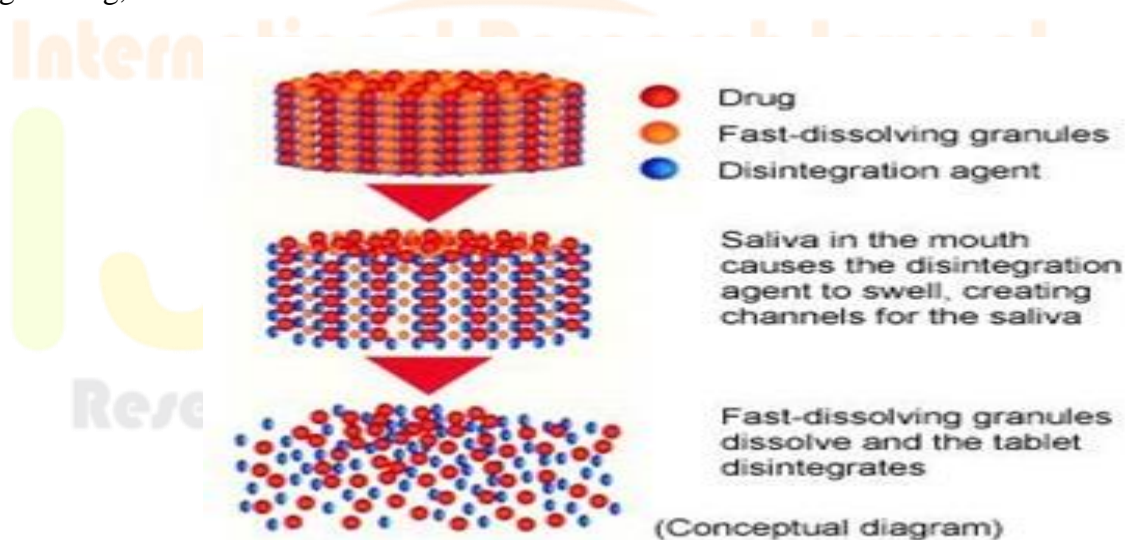


Fig.2:Conceptual diagram of FDTs

Requirements of fast dissolving tablets

Patient factors [3]

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.
- * 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 [5]

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.

Manufacturing and marketing factors [9]

As a drug nears the end of its patent life, it is common for pharmaceutical manufacturers to develop 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 in 2004 and in the U. S. in 2005 in response to a generic challenge filed in the U. S. by Ranbaxy.

Superdisintegrants:

Disintegrating agents are substances routinely included in the tablet formulations to aid in the break-up of the compacted mass into the primary particles to facilitate the dissolution or release of the active ingredients when it is put into a fluid environment. They endorse moisture penetration and dispersion of the tablet matrix. The major function of disintegrants is to oppose the efficiency of the tablet binder and physical forces that act under compression to structure the tablet.[10] Recently new materials termed as "superdisintegrants" have been developed to improve the disintegration processes. Superdisintegrants are another version of super-absorbing materials with tailor-made swelling properties. These materials are not planned to absorb significant amounts of water or aqueous fluids, but planned to swell very fast. They are physically dispersed within the matrix of the dosage form and will expand when the dosage form is exposed to the wet environment.[11] These newer substances are more effective at lower concentrations with greater disintegrating efficiency and mechanical strength.[12] Superdisintegrants are generally used at a low level in the solid dosage form, typically 1-10 % by weight relative to

the total weight of the dosage unit.[13] Their particles are generally small and porous, which allow for rapid tablet disintegration in the mouth without an objectionable mouth-feel from either large particles or gelling.

The particles are also compressible which improves tablet hardness and its friability.[14] Effective superdisintegrants provide improved compressibility, compatibility and have no negative impact on the mechanical strength of formulations containing high-dose drugs. Generally, one gram of superdisintegrant absorbs 10-40 g of water or aqueous medium. After absorption, swelling pressure and isotropic swelling of the superdisintegrants particles create stressconcentrated areas where a gradient of mechanical properties will exist due to which whole structure will break a part.

TYPES OF SUPERDISINTEGRANTS

The Superdisintegrants can be classified into two categories on the basis of their availability:

1. Natural Superdisintegrants
2. Synthetic Superdisintegrants

PLAN AND WORK

1. To study the preformulation factor of Hydrochlorothozide such as solubility, melting point, pH, max and standard calibration curve of drug in phosphate buffer pH 7.8.
2. To study FTIR spectroscopy of Hydrochlorothozide.
3. To study the pre-compression parameters.
4. Formulation of Hydrochlorothozide Fast disintegrating tablets.
5. To evaluate prepared tablets by different post-compression parameters.
6. To study in-vitro dissolution of dissolving tablets Hydrochlorothizide in phosphate buffer pH 7.8

PREFORMULATION STUDIES

1. Solubility of Drug
2. Partition coefficient
3. UV Spectral Studies

ISOLATION AND CHARACTERIZATION OF POLYMERS

1. Isolation of natural polymers: Isapghula and Banana Powder.
2. Solubility of Polymer.
3. Swelling Index.
4. Moisture absorption.
5. Thermal stability.

METHODOLOGY

1. Preparation of Preliminary formulations
2. Selection of Excipients and Optimization of their Concentration
3. Formulation compositions of preliminary batches

CHARACTERIZATION AND EVOLUTION OF FORMULATION

1. Angle of repose
2. Bulk density
3. Carr's index
4. Hausner's ratio

POST-COMPRESSION PARAMETERS

1. Thickness
2. Uniformity of weight
3. Drug Content uniformity
4. Hardness
5. Friability
6. Wetting time
7. Water absorption ratio
8. In-vitro disintegration time
9. In-vitro dispersion time

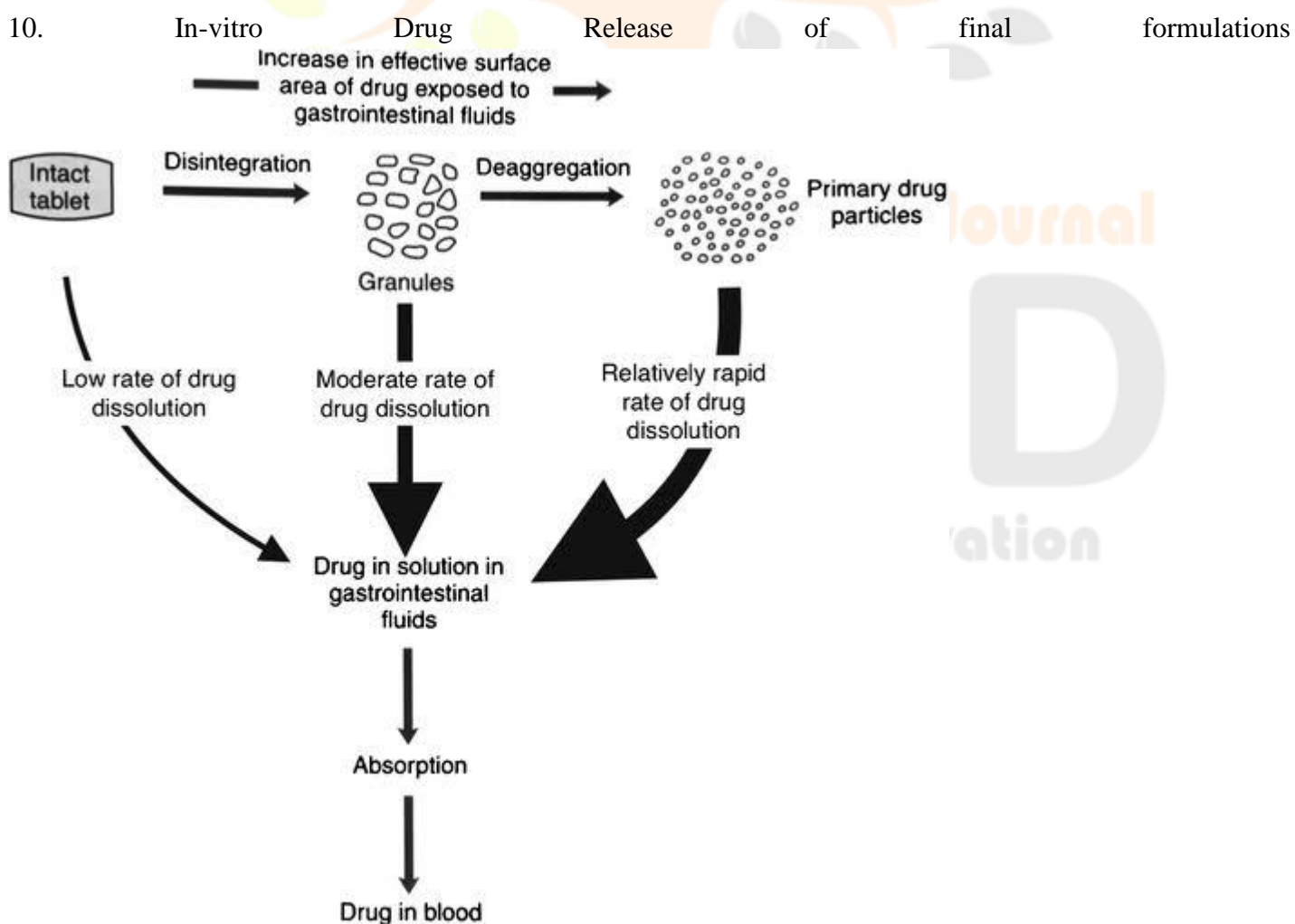


Fig3:Disintegration mechanisms and measurements

Evaluation:**General appearance:**

The general appearance of a tablet, its visual identity and over all elegance is essential for consumer acceptance. Size, shape, colour, odour, taste, texture of the tablet's surface, physical flaws, consistency, and legibility of any identifying markings are all considered.[15]

Hardness:

Using hardness testers such as those made by Pfizer and Monsanto, among others, the tablets' hardness was tested. The amount of force needed to break the tablets is proportional to how hard they are (kg/cm²). The measured values must match the standard value[16]

Friability:

It is estimated of mechanical strength of tablets. The Roche friabilator was used to evaluate the friability tests from each batch, and it was operated at a speed of 25 revolutions per minute for 4 minutes. The tablets were removed from the apparatus, cleaned, and reweighed before the percentage of friability was determined. Friability and is communicated in rate as %Friability = $(WO_{initial}) - (W_{final}) / (WO_{initial}) \times 100$ [17].

Uniformity of weight:

Twenty tablets were weighed using the IP Procedure on a digital weighing balance both individually and collectively. The total weight was used to calculate the average weight of one tablet. Calculating the uniform of the drug content could be done using the weight variation test[18].

Thickness uniformity:

It is possible to estimate each tablet's thickness using a micrometre, giving for accurate measurements and revealing the differences between them. Tablet thickness should not deviate from the standard value by more than 5%. For the product to be accepted by consumers, any thickness difference within a specific batch of tablets or between manufacturer's lots should not be visible to the unaided eye. To make packaging easier, thickness must also be controlled. The tablet's weight is determined by the tablet's physical dimensions, density of the material used in its formulation, and their proportions. The selection of tablet machine to use, appropriate granulation particle size, production lot size, appropriate tableting processing to use, packaging procedures, and production cost can also be influenced by the tablet's shape and size[19].

Wetting time:

Five circular tissue papers were arranged in a Petri dish with a diameter of 10 cm. 10 ml of water containing 0.5% eosin, a water-soluble dye, were added to the Petri plate. The dye solution was used to calculate how completely the tablet surface had been wet. A tablet was carefully placed on top of the tissue paper in the Petri dish at 25°C. The wetting time was defined as the time required for water to completely wet the upper surface of the tablets. Six times were repeated for these measurements. The amount of wetting was measured with the use of a timer[20].

Stability study:

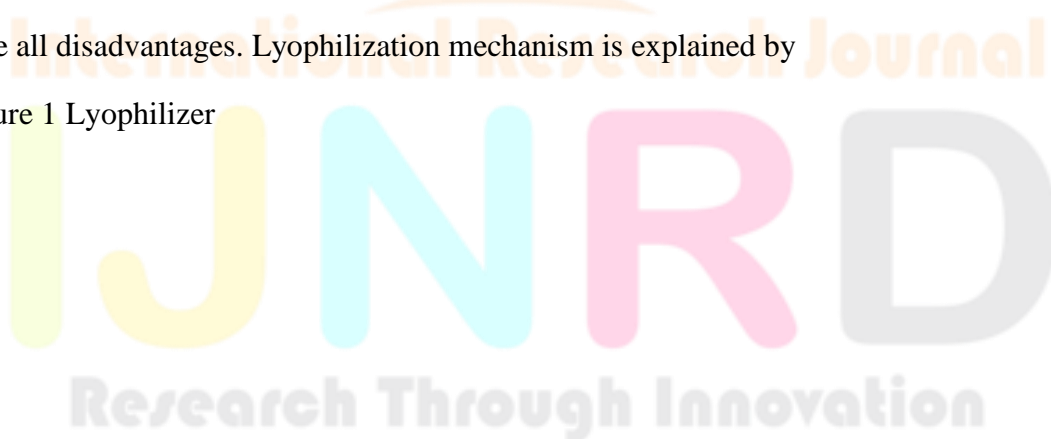
Fast-dissolving tablets are packed appropriately and kept under the following circumstances for the duration of an accelerated study as directed by ICH guidelines. • 40 ± 1°C • 50 ± 1°C • 37 ± 1°C and RH 75% ± 5% After 15 days, the tablets were removed and their physical characteristics (such as visual defects, hardness, friability, disintegrations, etc.) and drug content were analysed. To determine the kinetics of degradation, the collected data is fitted into first order equations. To calculate the shelf life at 25°C, accelerated stability data are shown using the Arrhenius equation [21].

- Lyophilization
- Direct Compression
- Tablet Moulding
- Cotton Candy process
- Mass Extrusion
- Spray Drying
- Nanotization Sublimation

-Lyophilization

Lyophilization, also known as freeze-drying, is a method that involves removing water from a frozen product and placing it under a vacuum, allowing the ice to transition directly from solid to vapour without passing through a liquid phase.

Freezing, primary drying (sublimation), and secondary drying are three different, unique, and interrelated processes (desorption). The advantages include the ease of processing a liquid, which facilitates aseptic handling, the increased stability of a dry powder, and the ease of processing a solid. Water removal without overheating the product, improved product stability in a dry state increased handling and processing time, as well as the need for sterile diluent during reconstitution, are all disadvantages. Lyophilization mechanism is explained by the following figure 1 Lyophilizer



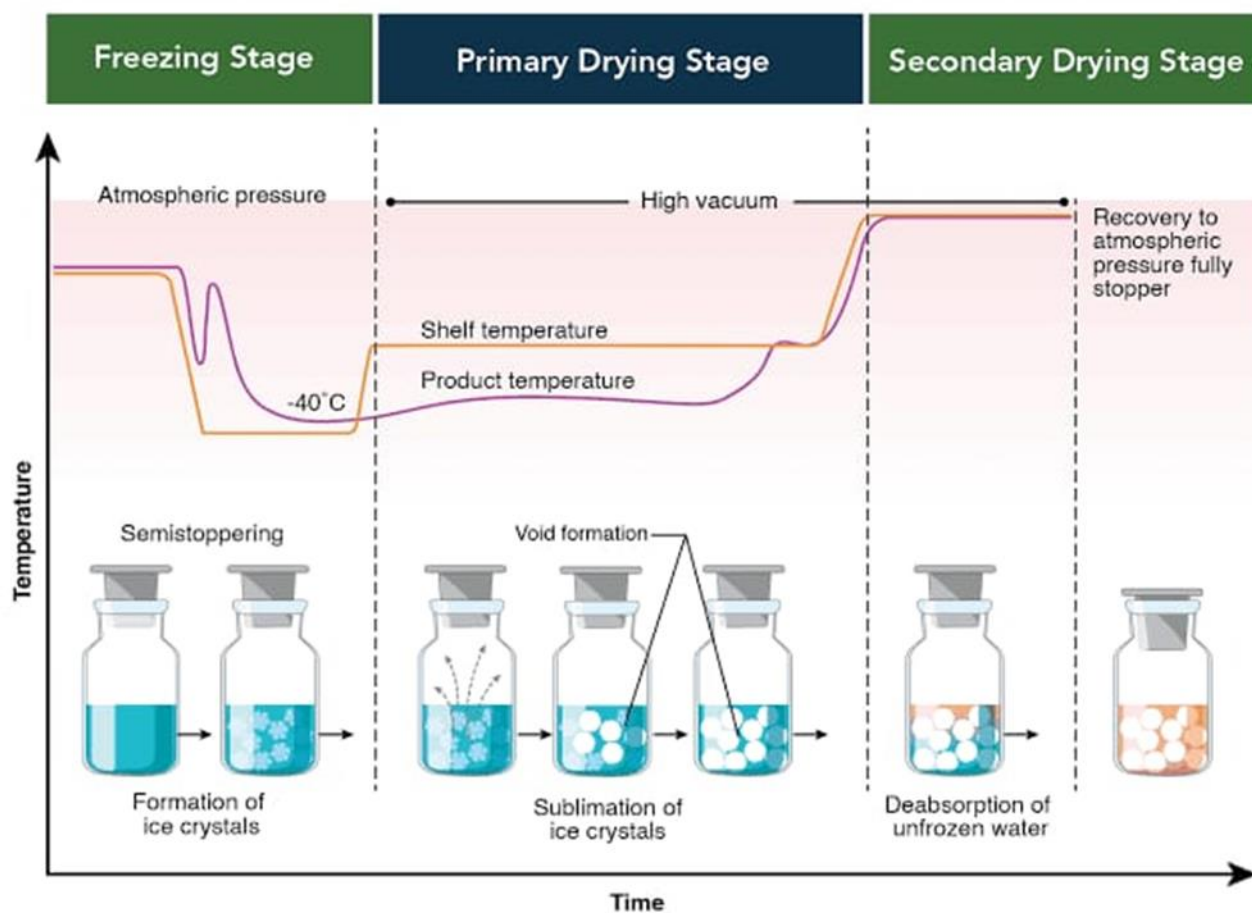


Fig-4: Lyophilisation Technique

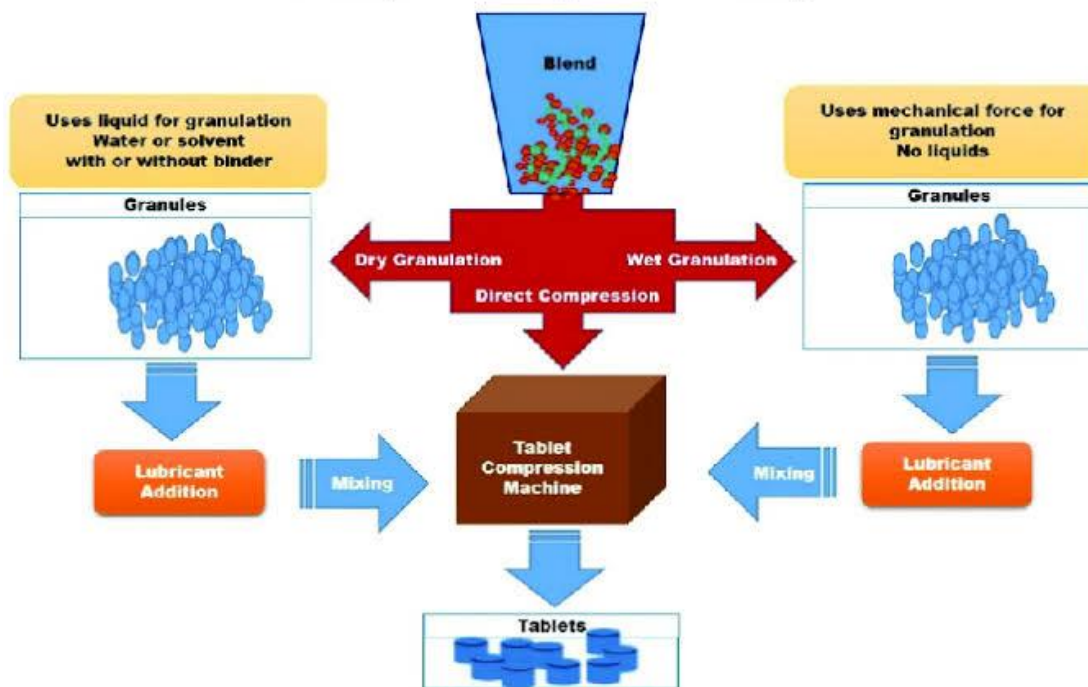
Direct Compression Method

“A solid dosage form containing medical material or active component that disintegrates

fast, usually within a matter of seconds when placed over the tongue (Deshmane SV et., al 2010), manufactured by direct compression method,” according to the United States Food and Drug Administration (FDA). The compressibility of a tablet determines its strength.

Tablet Moulding method

A tablet that dissolves or disintegrates in the oral cavity without the need for water or chewing is known as a fast-dissolving medication delivery device. Most fast-dissolving delivery system films must contain ingredients that hide the active ingredient's flavour. It's made with a water-soluble component and hydro-alcoholic solvents. The moulding is then carried out using various heating techniques and under certain pressure settings. The pressure used should be less than that used for traditional tablet compression. The method is depicted in Figure 2 below.

Tablet Compression Techniques – Schematic Diagram**Fig – 5: Tablet Moulding Process****Cotton Candy Method**

In order to make an orally disintegrating tablet with greater mechanical strength and the ability to hold larger pharmaceutical dosages, the candy floss matrix is crushed and mixed with active ingredients as well as excipients. When flash melting and spinning are done at the same time, a polysaccharide or saccharide matrix is created. The partially re-crystallized matrix's flow and compressibility have both improved.

Mass Extrusion Method

This process comprises softening the active blend with a solvent mixture of water-soluble polyethylene glycol and methanol, then extruding or syringing the softened mass into a cylinder of the product and cutting it into even segments with a hot blade to produce tablets. The dried substance can be used to cover bitter-tasting medications to hide their taste.

Spray Drying Method

When using spray drying, a hot gas is used to quickly turn a liquid or slurry into a powder. This is the preferred drying method for many thermally sensitive items, such as food and pharmaceuticals. It is necessary to spray dry certain industrial products, such as catalysts, in order to achieve a uniform particle size distribution. Although air is used as the hot drying medium, nitrogen can be used if the liquid is a flammable solvent like ethanol or if the final product is oxygen-sensitive. All spray dryers use an atomizer or spray nozzle to disperse the liquid or slurry into a fine mist. Figure 3 illustrates how this works.

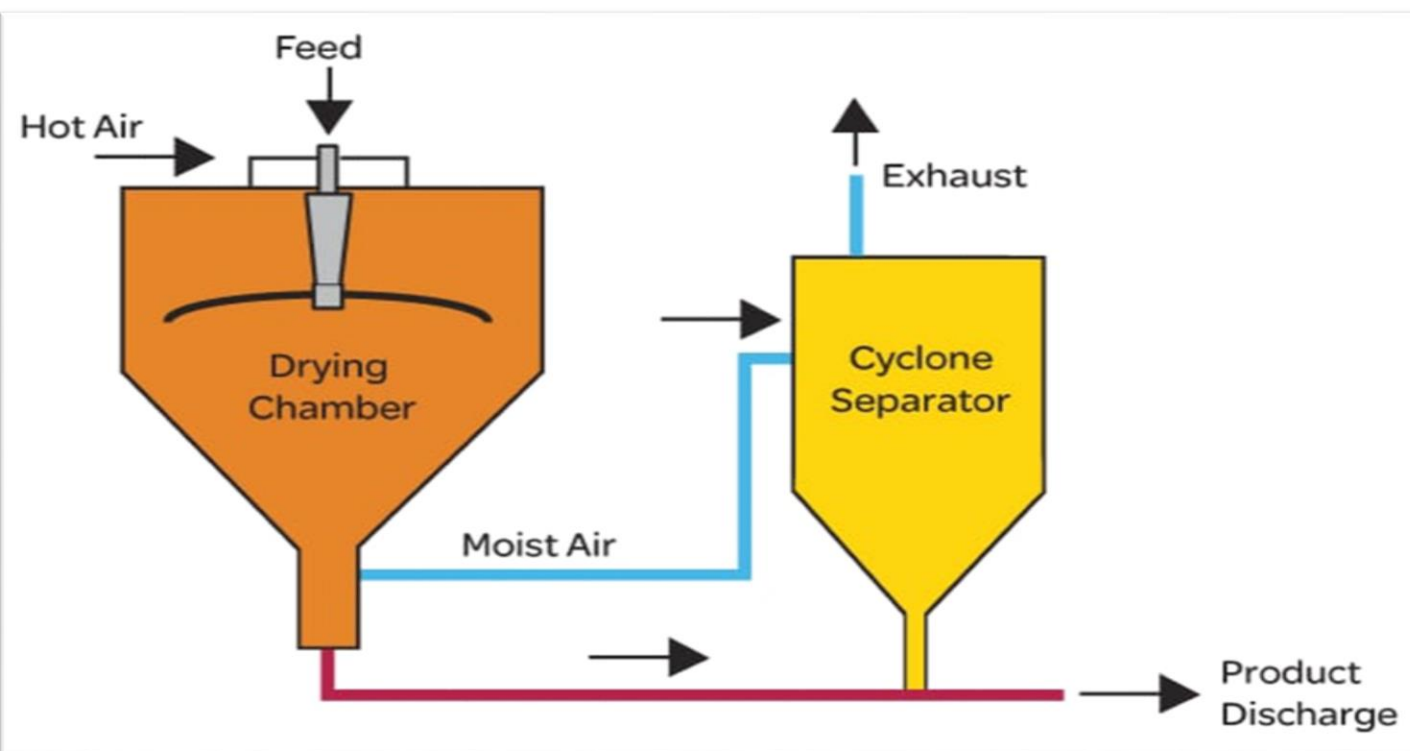


Fig – 5: Spray Dryer

Nanotization

The drug particles are reduced to nanoparticles in this procedure by grinding the drug in a patented wet milling process. Surface adsorption of the nanocrystals prevents agglomeration, which is subsequently crushed and transformed into a tablet, which is particularly effective for medications that are less water-soluble. The drug's bioavailability is increased as the disintegration time is significantly reduced.

Sublimation

Sublimation is a method for creating high-porosity, fast-dissolving tablets. By compressing a mixture of excipients with volatile substances such as urea, urethane, naphthalene, and camphor into a tablet, a porous matrix is created. Sublimation generates pores in the tablet

structure, allowing the tablet to dissolve when it comes into contact with saliva. As pore generating agents, a variety of solvents such as cyclohexane, benzene, and others can be utilised. This approach was used to create oral dispersible tablets with a porous structure and excellent mechanical strength. Sublimation is explained in figure 4 given below.

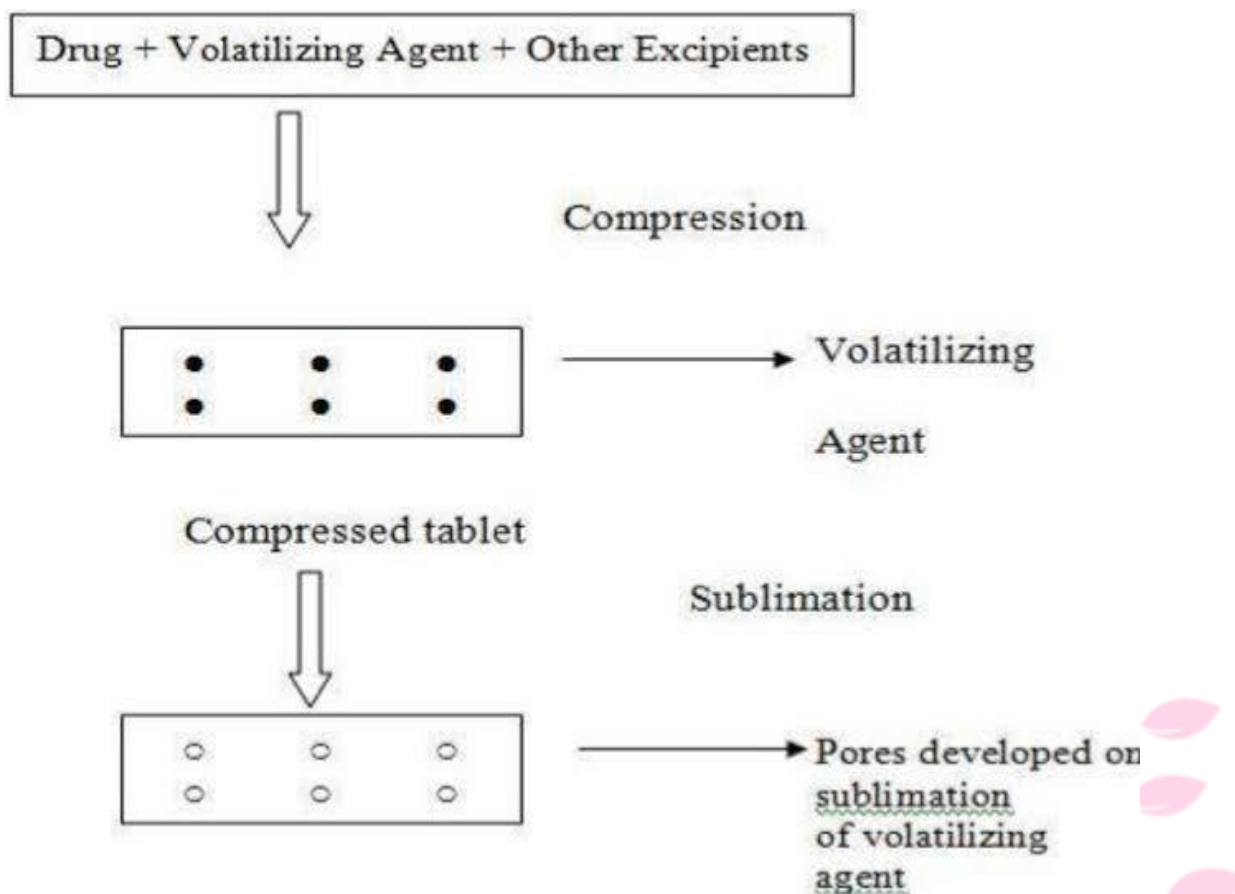


Fig -6: Sublimation Method

- A key aspect of a fast-dissolving drug delivery system is the ease with which it can be administered to patients who are unable to swallow.
- The dose form can be swallowed without the use of water.
- The medicine will dissolve and absorb quickly, resulting in a speedy commencement of effect.
- As saliva goes down into the stomach, some medications are absorbed from the mouth, pharynx, and oesophagus (pregastric absorption).
- In such circumstances, the drug's bioavailability is enhanced, which enhances clinical performance by reducing undesired side effects.
- It has a pleasant mouth sensation.
- Physical blockage reduces the danger of choking or suffocation during oral delivery of traditional formulation
- It's useful in situations when there's a lot of movement.

Conclusion:

Improved patient compliance, efficacy, and biopharmaceutical characteristics have been demonstrated with fast dissolving drug delivery systems. Some of these technologies can access FDT dosage forms, which have sufficient mechanical strength and dissolve quickly in the mouth. Patients who are mad, chronic (like diabetes, thyroid, and cancer), geriatric, or paediatric, or who may not approach water, or who are voyaging, should

have FDTs performed. Allergies, asthmatic episodes, and heart attacks necessitate prompt treatment. To get around these issues, scientists have created the FDT, or a new type of drug delivery system.

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