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Fast Dissolving Tablet by Sublimation Technique: - A Review

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Abstract

Fast dissolving Tablets are breaking down or potentially disintegrate Fast in the saliva without the requirement for water. Few tablets are intended to break down in saliva strikingly quick, inside a couple of moments, and are valid quick dissolving tablets. Others contain agents to upgrade the pace of tablet breaking down in the oral cavity, and are all the more suitably named fast disintegrating tablets, as they might take up to a minute to completely disintegrate. Oral delivery is presently the best quality level in the pharmaceutical industry where it is viewed as the most safe, generally advantageous and most economical method for drug delivery having the most elevated patient compliance. This tablet design is intended to permit administration of an oral solid dose form in the absence of water or fluid intake. FDT formulations have the benefit of both conventional tablet formulation and liquid dosage form. There are a several technologies that are conventional or patented based on spray drying, cotton sweets process, sublimation, melt granulation, direct compression freezes drying/lyophilization, phase transition process, mass extrusion, etc. so forth have been created for assembling of FDTs. In this review contain brief data about FDTs including definition, benefits, needs or requirements of FDTs, features of FDTs, limitations, challenges to developing FDT, marketed formulations of fast dissolving tablets, etc.

Keywords

Fast dissolving tablets, Patient's compliance, Mass extrusion, Super disintegrants, Dysphasia.

1. Introduction

Many patients express difficulty in swallowing tablets and hard gelatin capsules, coming about in resistance and insufficient treatment. Ongoing advances in novel drug delivery system (NDDS) plan to forming a measurement type of drug molecules for advantageous organization and to accomplish patient compliance. One such technique prompts improvement of fast dissolving/ disintegrating tablets. Benefits of

this drug delivery system include convenience of administration and exact dosing when contrasted with liquids, easy portability, capacity to give benefits of liquid medication in the form of solid preparation, ideal for pediatric and geriatric patients and fast disintegration/dissolution, which may produce rapid onset of action. A few drug are absorbed from mouth, pharynx and throat as the saliva passes down into the stomach and in such cases bioavailability of the drug is increased: pre-gastric absorption can result is superior bioavailability and as after effect of reduced dose, improved clinical performance through a decrease of undesirable impacts.(Gaur K. A, et.al. 2011). Most proper course for drug administration is oral route due to adaptability, simplicity of administration and patient compliance. Fast dissolving tablets are gaining greatness as modern system of drug delivery since breaking down season of such formulations is inside the space of seconds to minutes (El-Enin, 2014). Fast dissolving tablets are exceptionally advantageous in administration of drug to kids; confined to bed patients, in patients having dysphagia, stroke, thyroid problem, Parkinson's infections and numerous sclerosis, patients with queasiness, heaving and movement ailment prompting worked on patient compliance. (Kuchekar, Badhan, Mahajan, 2003). Rate of drug dissolution can be improved by various techniques which include Direct compression, Wet granulation, Molding, Spray drying, Freeze drying, Lyophilization and Sublimation (Mettu, Veerareddy, 2013; Nagar et al., 2011). The fundamental goal of preparation of Fast Dissolving Tablets (Fdt's) is to prepare a permeable matrix of tablets. In sublimation method for the preparation of such a permeable structure of different highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane, thymol and phthalic anhydride and so on are fused in the formulation. Various solvents can likewise be utilized for development of permeable matrix, these solvents includes cyclohexane, benzene and many others. (Shaheen N, Zaman S. 2018). Formulation of drug into a presentable form is the essential 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. Different type of dosage form are available like tablets, syrups, suspensions, suppositories, infusions, transdermal and patches having an different type of drug delivery mechanisms. These traditional/current dosage form enjoy a few benefits and disadvantages. Subsequently, the development of an ideal drug delivery system is a major test to the drug specialist in the presence situation. To get the ideal impact, the drug should be delivered to its site of action at such rate and concentration to accomplish the maximum therapeutic effect and minimum adverse effect. For the development suitable dosage form through a study about the physicochemical principles that governs a specific formulation of a drug should be subjected. (Masih A, et.al. 2017). Drug delivery system is an effective tool for improving marketed product, broadening product life cycles and making opportunities. DDS make a huge commitment to worldwide drug deals through market division, and are moving quickly. Fast Dissolving Drug Delivery Systems (FDDTs) can be accomplished by different conventional technique events like direct compression, wet granulation, moulding, spray drying, freeze drying, sublimation. Fast disintegrating tablets are made of either extremely permeable and soft molded matrices or compressed into tablets with very low compression force in order to allow FDTs to dissolve in the mouth as shown in Fig 1 and Fig 2., respectively. (Kashyap S, et.al 2018), (Babu. A, Akhtar MD. S. 2020).

The Ideal Properties of FDT shown in table no. 1 (Babu. A, Akhtar MD. S. 2020).

2. Advantages of Fast Disintegrating Tablets

- ❖ Patients who have difficulty in chewing or swallowing solid dosage forms.
- ❖ Patients in compliance due to fear of choking.
- ❖ Very elderly patients of depression who will most likely unable to swallow the solid dosage forms
- ❖ An eight-year-old patient with sensitivities wants a more convenient dosage form than antihistamine syrup.
- ❖ A moderately aged patient going through radiation therapy breast cancer may be too nauseous to swallow her H2-blocker.
- ❖ A schizophrenic patient who may try to hide a conventional tablet under their tongue to keep away from their daily dose of an atypical antipsychotic.
- ❖ A patient with persistent sickness, who may be a journey, or has little or no access to water. (Masih A, et.al. 2017), (Rewar S, et.al. 2014). Schematic representation is given in Fig 3 (Babu. A, Akhtar MD. S. 2020).

3. Limitations of FDT

- ❖ FDT are very porous and soft moulded 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.
- ❖ Drug and dosage form stability (Masih A, et.al. 2017), (Rewar S, et.al. 2014).

4. Need to formulate mouth dissolving tablets

The requirement for non-invasive drug delivery systems proceeds because of patient's poor compliance with existing delivery regimes, restricted market size for drug companies. FDT is one such dosage form which is valuable for:

- ❖ Geriatric patients mainly suffering from conditions like hand quakes and dysphasia.
- ❖ Pediatric patients who can't swallow easily because their central nervous system and internal muscles are not developed completely.
- ❖ Traveling patients suffering from motion sickness and diarrhoea that don't have easy access to water.
- ❖ Patients with persistent nausea for a long period of time are unable to swallow. Especially cancer patients after taking their chemotherapy are too nauseous to swallow the H2 blockers, which are prescribed in order to stay away gastric ulceration.

❖ Mentally challenged patients, bedridden patients and psychiatric patients (Kashyap S, et.al 2018).

5. Selection of excipients

The property of the active ingredients in fast-dissolving tablets is balanced by excipients. This requests a concentrated comprehension of the science of those excipients to stop connection with the actives. These inactive food-grade ingredients, once incorporated within the formulation, impart the specified organoleptic properties and products effectively.

6.1 Bulk agents

Quick dissolving tablets arrangement bulking agent are imperative. This upgrades the physical characteristics, improves the crumbling inside the mouth and decreases the convergence of the dynamic compound within the composition. The building specialists for this conveyance framework should be extra sugar-based like polydextrose, mannitol, lactitol, DCL and starch hydrolysate for higher liquid solubility and good sensory perception. Mannitol most importantly has high fluid dissolvability and great sensory perception. Bulking agents are additional within the range of ten percent to concerning ninety percent by weight of the ultimate composition. The excipients may be ranked in descendant order in terms of their brittleness: crystalline polysaccharide>spray-dried lactose>beta lactose>alpha lactose>alpha lactose monohydrate>di calcium phosphate dihydrate. The sugar essentially based excipients that are normally utilized as especially building operators (like dextrose, fructose, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol) that show high fluid dissolvability and sweetness, and in this manner bestow style veiling property. Sugar-situated excipients on the basis of molding and dissolution fee. Form one saccharides (lactose and mannitol) showcase low mold capacity nevertheless excessive dissolution rate. Type a pair of saccharides (maltose and malitol) show off high mold capability however the low dissolution rate.

6.2 Emulsifying agents

A large range of emulsifiers is suggested for fast dissolving tablet formulation, Emulsifying agent are obligatory excipients for formulating fast dissolving tablets they avail in expeditious disintegration and drug release without masticating, swallowing or drink. Additionally, emulsifying agent's addition is good at stabilizing the immiscible mixes and improving bioavailability. Examples-alkyl group sulfates, propylene glycol esters, lecithin, sucrose esters and others. These agents are regularly consolidated within the vary of 0.05% to about 15% by weight of the final composition.

6.3 Lubricants

It will formulate the tablets more palatable after they disintegrate within the mouth. Lubricants take away grittiness and advantage within the drug conveys mechanism from the mouth down into the stomach. Some lubricating agents are stearic acid, Mg stearate, Zinc stearate, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulphate, colloidal silicon oxide

6.4 Flavors and sweeteners

Flavors and taste-masking agents build the product addition palatable and pleasant feel for patients. The additament of those ingredients adavantage in surmounting acerbity and discrepant tastes of some active ingredients. Each natural and synthetic flavors are often used to upgrade the organoleptic characteristics of

FDTs. Peppermint flavor, flavoring aromatic oil, peppermint oil, clove oil, bay oil, anise oil, eucalyptus oil thyme oil, oil of acerbic almonds. Flavoring agents include vanilla, citrus oils, fruit essences. Formulators can make a pick from a good range of sweeteners together with sugar, dextrose, and fructose, as well as non-nutritive sweeteners such as aspartame, sodium saccharin, sugar alcohols and sucralose.

6.5 Surface active agents

Sodium doecyl sulfate, sodium lauryl sulphate, polyoxy ethylene sorbitan fatty acid esters (Tweens), sorbitan fatty acid esters (Spans), polyoxy ethylene stearates.

6.6 Binder

Polyvinyl pyrrolidone (PVP), polyvinyl alcohol (PVA), hydroxy propyl methyl cellulose (HPMC).

6.7 Colour Sunset yellow, Amaranth etc. (Chauhan. K, et.al. 2018).

7. Techniques for Preparing Fast dissolving Tablets

Many techniques have been reported for the formulation of Fast dissolving tablets or Orodispersible tablets.

1. Freeze drying / lyophilization
2. Tablet Moulding
3. Spray drying
4. Sublimation
5. Direct compression
6. Mass extrusion

7.1 Freeze-Drying or Lyophilization

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 ODT using this technique is mentioned here. The active drug is dissolved or dispersed in an aqueous solution of a carrier/polymer. The mixture is done by weight and poured in the walls of the preformed blister packs. The trays holding the blister packs are passed through liquid nitrogen freezing tunnel to freeze the drug solution or dispersion. Then the frozen blister packs are placed in refrigerated cabinets to continue the freeze-drying. After freeze-drying the aluminum foil backing is applied on a blister-sealing machine. Finally the blisters are packaged and shipped. The freeze-drying technique has demonstrated improved absorption and increase in bioavailability. The major disadvantages of lyophillization technique are that it is expensive and time consuming; fragility makes conventional packaging unsuitable for these products and poor stability under stressed conditions.

7.2 Tablet Molding

Molding process is of two types i.e., solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followed by compression at low pressures in molded plates to form a wetted mass (compression molding). The solvent is then removed by air-drying. The tablets manufactured in this manner are less compact than compressed tablets and possess a porous structure that hastens dissolution. The heat molding process involves preparation of a suspension that contains a drug, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the blister packaging wells, solidifying the agar at the room temperature to form a jelly and drying at 30○C under vacuum. The mechanical strength of

molded tablets is a matter of great concern. Binding agents, which increase the mechanical strength of the tablets, need to be incorporated. Taste masking is an added problem to this technology.

The taste masked drug particles were prepared by spray congealing a molten mixture of hydrogenated cottonseed oil, sodium carbonate, lecithin, polyethylene glycol and an active ingredient into a lactose based tablet triturate form. Compared to the lyophillization technique, tablets produced by the molding technique are easier to scale up for industrial manufacture.

7.3 Spray Drying

In this technique, gelatin can be used as a supporting agent and as a matrix, mannitol as a bulking agent and sodium starch glycolate or crosscarmellose or crospovidone are used as superdisintegrants. Tablets manufactured from the spray-dried powder have been reported to disintegrate in less than 20 seconds in aqueous medium. The formulation contained bulking agent like mannitol and lactose, a super disintegrant like sodium starch glycolate & croscarmellose sodium and acidic ingredient (citric acid) and/or alkaline ingredients (e.g. sodium bicarbonate). This spray-dried powder, which compressed into tablets showed rapid disintegration and enhanced dissolution.

7.4 Sublimation Method

To generate a porous matrix, volatile ingredients are incorporated in the formulation that is later subjected to a process of sublimation. Highly volatile ingredients like ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane and phthalic anhydride may be compressed along with other excipients into a tablet. This volatile material is then removed by sublimation leaving behind a highly porous matrix. Tablets manufactured by this technique have reported to usually disintegrate in 10-20 sec. Even solvents like cyclohexane; benzene can be used as pore forming agents. (Bhowmik. D, et.al. 2009).

The presence of a highly porous structure in the tablet matrix is the key factor for rapid disintegration of FDT. Even though the conventional tablets contain highly water soluble ingredients, they often fail to disintegrate rapidly because of low porosity. To improve the porosity, volatile substances such as camphor can be used in tableting process, which sublimated from the formed tablet. Recently, it has been confirmed that a compressed tablet prepared with crystalline cellulose and L-HPC rapidly disintegrated (within 15 seconds) in saliva (or a small amount of water) in the mouth of human being. However, patients sometimes feel a rough texture in their mouth due to incomplete solubilization of this type of tablets in saliva. To eliminate the rough texture in the mouth, the researchers attempted to use a water-soluble material (mannitol) as an excipient instead of crystalline cellulose and L-HPC, in the preparation of this type of tablet. Koizumi et al. developed FDT utilizing camphor; a subliming material that is removed from compressed tablets prepared using a mixture of mannitol and camphor. Camphor was sublimated in vacuum at 80°C for 30 minutes after preparation of tablets (Parkash. V, et.al. 2011). Fig 4. Shows sublimation technique (Babu. A, Akhtar MD. S. 2020).

7.5 Direct Compression:

Direct compression represents the simplest and most cost effective tablet manufacturing technique. This technique can now be applied to preparation of ODT because of the availability of improved excipients especially superdisintegrants and sugar based excipient.

(a) Superdisintegrants:

In many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants principally affects the rate of disintegration and hence the dissolution. The presence of other formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration.

(**b) Sugar Based Excipients**:

This is another approach to manufacture ODT by direct compression. The use of sugar based excipients especially bulking agents like dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence impart taste masking property and a pleasing mouthfeel.

Type 1 saccharides (lactose and mannitol) exhibit low mouldability but high dissolution rate.

Type 2 saccharides (maltose and maltilol) exhibit high mouldability and low dissolution rate.

7.6 Mass-Extrusion:

This technology involves softening the active blend using the solvent mixture of water-soluble polyethylene glycol and methanol and subsequent expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablet. The dried cylinder can also be used to coat granules for bitter drugs and thereby achieve taste masking (Bhowmik. D, et.al. 2009), (Rewar S, et.al. 2014), (Khanna K, et.al. 2016).

8. Some drugs formulated as FDT

The eligibility criteria for drugs to be formulated as Fast Dissolving Tablets are low dose, good stability in aqueous media, good mechanical strength and compatibility with excipients (Rahane. R.D, et.al. 2018), (Khanna K, et.al. 2016). List is given in Table no 4.

9. CONCLUSION

FDTs are dose shapes that normally dissolve / dissolve in the saliva within a few seconds. FDTs provide many advantages over traditional types of dosage such as increased effectiveness, bioavailability, fast start of action, better patient compliance. Particularly FDTs give pediatric and geriatric patients greater comfort. Different methodologies may be used to produce FDTs depending on the product and additives used. Normally, FDTs are less electronic. But the introduction of certain modern technology and additives will equip FDTs with an innovation mechanical power. The trick to improving its composition is to manufacture rapidly dissolving tablets. Scientists have sought to refine the structure of tablet matrix pore through vacuum drying and freezing techniques. Freeze is a bulky drying process which produces a fragile and hygroscopic product. Therefore, following the application of a sublimating agent to boost the porosity of tablets, a vacuum drying technique was executed during the present inquiry. Through utilizing flavour masking chemicals, even sour drugs be used in FDTs. FDTs are also under study. FDTs often deliver large promotions to keep the dosage type attractive on the market. With their commercial value, other drugs are to be developed in future as FDTs.

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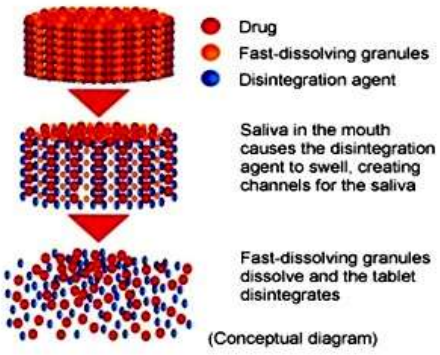

Figure 1: Diagram of FDTs

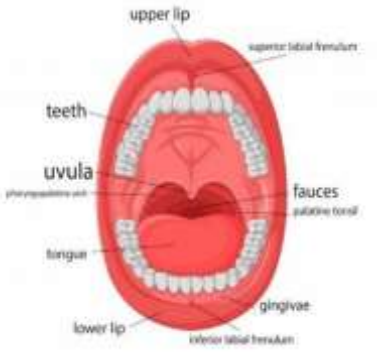

Figure 2: Penetration of fast dissolving tablets

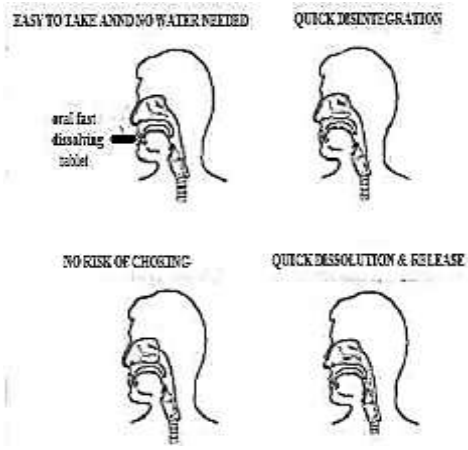

Figure 3: Advantages of FDT

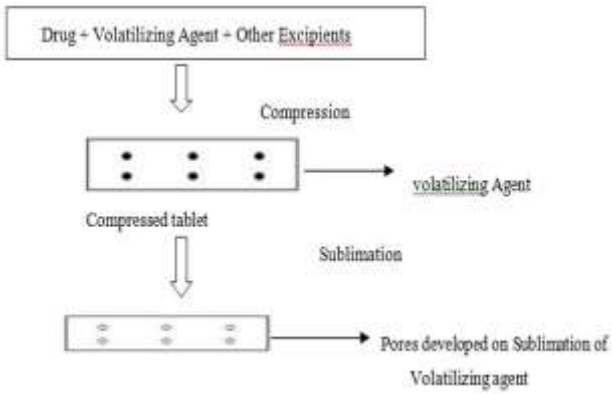

Figure: 4. Schematic diagram of sublimation techniques

Table 1. Ideal Properties of FDT

Properties	**Yes /No**
Suitable for manufacturing and packing traditional tablets	Yes
Compact	Yes
Fragility Concern	No
Nice sensation in the mouth	Yes
Environmental adaptation (humidity, temperature)	No
Air enough to drink	No
Economic	Yes
Leave waste in oral cavity.	No
Compatible with Taste Masking	Yes
Patient Compliance	Yes

Table 2. Name and weight percentage of different excipients (Rahane. R.D, et.al. 2018).

Sr. No.	**Name of the excipients Percentage**	**Used**
1	Disintegrants	1 to15%
2	Diluents	0 to 85%
3	Binders	5 to 10%
4	Antistatic Agent	0 to 10%

Table 3. List of super Disintegrant (Masih A, et.al. 2017)

Sr. No.	Super disintegrant	Mechanism of Action	Specific properties
1.	Croscarmellose Sodium	Swells 4–8 folds in <10s. Swelling and wicking action	Effective in low concentration (0.5–2.0%), high swelling capacity, cross-linking of the carboxyl ester groups.10s
3.	Crospovidone	Combination of swelling and wicking action.	Effective low concentration (0.5- 2.0 %), high swelling.
4.	Cross linked algenic acid	Hydrophilic colloidal substance which has high sorption capacity.	The effective concentration in 1-3%. Rapidly disperse and sweels in water, available in micronized grades.
5.	Gellan gum	Strong swelling properties upon contact with water.	Anionic polysaccharide of linear tetrasaccharides, good superdisintegrant.
6.	Sodium starch glycolate	Strong swelling properties upon contact with water.	Anionic polysaccharide of linear tetrasaccharides,good superdisintegrant.
7.	Soy polysaccharides	Rapid dissolving	Does not contain starch or sugar so can be used in products meant for diabetics.
8.	Xanthan gum	Extensive swelling properties for faster disintegrant.	High hydrophilicity and low gelling tendency, low water solubility.

Table 4. List of Drugs and Category

Therapeutic Category	Drugs
Anti-fungal	Griseofulvin, Miconazole
Anti-bacterial	Doxycycline, Erythromycin, Rifampin, Tetracycline
Anti-Malarial	Chloroquine, Amodiaquine
Anti-hypertensive	Amlodipine, Nifedipine, Prazocin23
Anti-thyroid	Carbimazole
Analgesic/Anti-inflammatory	Ibuprofen, Mefenamic acid, Piroxicam
Anticancer	Acyclovir
Antiemetic	Ondensatron25