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AN OVERVIEW OF THE LATEST IN INNOVATIVE MEDICINE DELIVERY SYSTEMS: FAST-DISSOLVING TABLETS

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Abstract
Fast dissolving tablet are the dosage form which dissolve or disintegrate in saliva within few secs with or without need of water. Fast dissolving tablet gives fast onset of action, good bioavailability and avoid first pass metabolism. Fast dissolving tablet mainly used in diseases like stroke, Parkinson's, neurological disorders, schizophrenic patient, hand tremor. FDT formulations contain super disintegrants to increase the rate of tablet degradation in the buccal cavity. FDTs have advantages because they are easy to manufacture, have the right dosage, good chemical and physical strength, and are an ideal alternative for children and adult patients.

Keywords: Nanoparticles, Fast disintegrating tablet, super disintegrants, Bioavailability.

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Introduction
Recent development in Novel drug delivery system (NDDS) aims to improve safety and efficacy of already used drug molecule by formulating a acceptable dosage form for administration and to accomplish better patient compliance. A large amount of money, hard effort, and time are required to produce a chemical entity. As a result, the focus is now on developing new DDS for previously existing drugs with increased efficacy and bioavailability, therefore lowering the amount and frequency of dosing to prevent side effects [1]. Sometimes people cannot swallow the usual dosage forms such as a tablet without water, in case of motion sickness (kinetosis) and sudden bouts of coughs in colds, allergies and bronchitis. For this reason, tablets that dissolve or disintegrate easily in the mouth have attracted a great deal of attention [2].

Advantages of fast dissolving tablets

FDTs are easily accessible to children, the elderly and patients with mental disabilities.

- Appropriate dosing compared to fluids.
- The drug is easily digestible and absorbable, offering a rapid onset of action.

Fig.1. Advantages of FD

Limitations of FDTs
- FDT has very porous and softly shaped metrics or compressed into low compression tablets.
- This makes the tablets fresher and more fragile, which is difficult to hold.
- It is difficult for my taste buds to prepare FDT; special care should be taken before developing such a drug.
- Many hygroscopic [3], FDTs may not maintain physical integrity under normal humidity conditions requiring special packaging.

Palatability
Most drugs are not tasty, FDTs often contain the active ingredient in a form that lurks in the taste. After administration, the FDTs break down or dissolve in the patient's oral cavity and release the active ingredients that come into contact with the taste buds. rather, concealing the taste of the medication could be critical to patient compliance[4].

Hygroscopicity

Many oral disintegrant dosage forms are hygroscopic and cannot maintain physical integrity under normal conditions of temperature and humidity. Therefore, they require protection against moisture requiring special product packaging [5].

Amount of drug

The use of technologies used for FDT is limited by the amount of drug that can be included in each unit dose. In lyophilized dosage forms, the drug dose should be less than 400 mg for insoluble drugs and 60 mg for soluble drugs.

Excipients Used in FDT Preparation

Among the further excipient like one super disintegrant, a diluent, a lubricant and optionally a swelling agent, a permeabilizing agent, sweeteners, and flavouring agents FDTs should contain at least one [6].

Table 01: Factors which are used to consider for selection of super disintegrants Disintegration the disintegrant should be easily incorporated into the saliva of the tablet to create the volume expansion and hydrostatic pressure required for rapid disintegration in the mouth.

Sr. No.	Name of excipient	% used
1	Super disintegrants	1-15 %
2	Binders	5-10 %
3	Antistatic agent	0-10 %
4	Diluents	0-85 %

Table0 2: List of super disintegrants

S.no	Super-disintegrant	Mechanism of action	Specific properties
1	Croscarmellose sodium	Swell 4-8 fold in <10s Swelling and wicking action	Effective in low concentration, high swelling Capacity cross-linking of carboxyl ester group
2	Crospovidone	Combination of swelling and wicking action swell 7-12 folded in <30 s	The effective concentration is 1-3% rapidly disperses and swells in water
3	Cross-linked alginic acid	Hydrophilic colloidal substance which has high sorption capacity	The combination of swelling and wicking action causes disintegration.
4	Gellan gum	Strong swelling properties upon contact with water	Anionic polysaccharide of linear tetra saccharides, good super disintegrant
5	Sodium starch glycolate	Strong swelling properties upon contact with water swell 7-12 folds in <30s	Rapid absorption of water result in swelling upto 6 % high concentration cause gelling
6	Soy polysaccharide	Rapid Dissolving	Does not contain starch and sugar so can be used in products meant for diabetics
7	Xanthan gum	Extensive swelling properties for faster disintegration	High hydrophilicity and low gelling tendency, low water solubility

Bulking Materials

Bulk materials are important to support the rapid melting of tablets. They contribute to the functions of the diluent, filler and cost reduction. Bulking agents help to improve the texture of the tablets,.thereby improving disintegration in the mouth, in addition to increasing the volume and reducing the concentration of the active ingredient in the formulation [7].

Emulsifying Agents

Emulsifiers are widely used to form and rapidly dissolve tablets because they help to rapidly disintegrate and release the drug without the need for rubbing, swallowing or drinking water. Emulsifiers also improve essential ingredients and increase bioavailability [8].

Lubricants

Although they are not essential excipients, they can help make the pills tastier after they have been broken down in the mouth. Lubricants can reduce discomfort and aid in the process of drug transfer from the mouth to the stomach [9].

Flavours (taste masking agents) and Sweeteners

Mixing these ingredients helps to overcome the bitterness and bad taste of some active. Natural and synthetic flavors can be used to increase the organoleptic properties of fast tablet digestion [10].

Various techniques used in fast melt tablet (fmts) formulation:

Conventional technology for FMT's formation-

Fast-melt tablet formulation has been accomplished through a range of techniques [11].

- Lyophilization
- Direct Compression
- Tablet Molding
- Mass Extrusion
- Spray Drying
- Nanonisation

Lyophilization or Freez-Drying

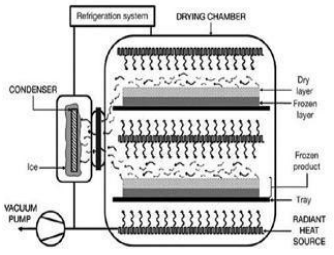

Fig 02: Lyophilization or Freez-drying

Direct Compression Method [12]

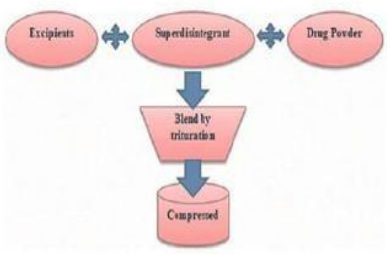

Fig 03: Direct Compression Method

Tablet Molding Method [13]

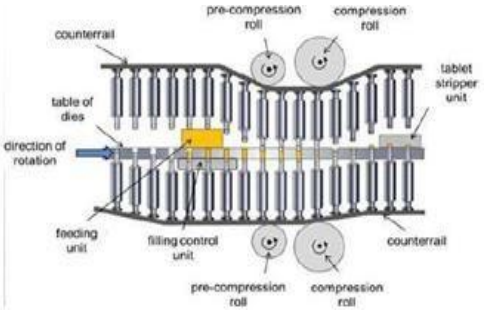

Fig 04: Tablet molding method

Mass Extrusion Method [14]

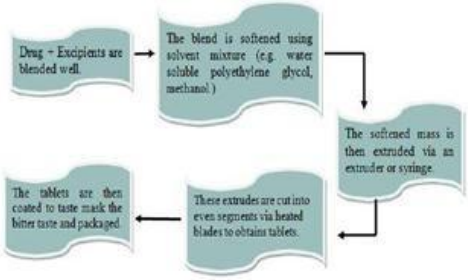

Fig.5.Mass extrusion method

Spray-Drying Method [15]

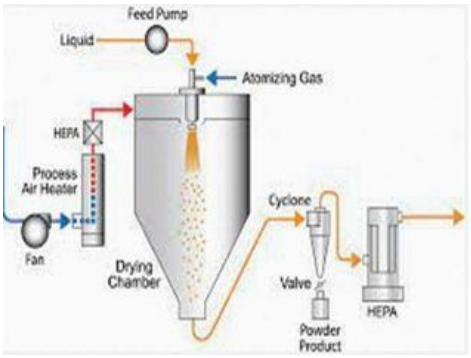

Fig 06: Spray-Drying method

Sublimation Method

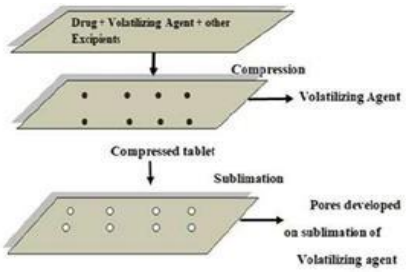

Fig 07.Sublimation method

Patented Technologies for Fast Dissolving Tablets

The nature of the rapid melting of the FDT is often attributed to the rapid entry of water into the tablet matrix, leading to its rapid decomposition. Many technologies have been developed based on formulation aspects and various processes and patents of many pharmaceutical companies. The patented technology is described below Zydis technology, Zydis is a special lyophilised tablet in which the drug is physically trapped or dissolved in a matrix of fast-melting carrier material.

Advantages

The composition of Zydis is self-preserving because the final water concentration in the lyophilized product is too low to allow microbial growth.

Disadvantages

This lyophilization process is a relatively expensive manufacturing process.

Durasolv Technology

Durasolv is a patented technology of CIMA laboratories. Tablets made with this technology consist of a drug, filler and lubricant.

Advantages

DuraSolv technology is ideal for tablets with a small amount (125 mcg to 500 mg) of active ingredient and the tablets are compressed to a maximum hardness of 15-100 N, resulting in a more robust ODT.

Disadvantages

- The technology is not compatible with larger doses of active ingredient because the formulation is exposed to high pressure during compression.
- There was no significant change in bioavailability.

Flash Dose Technology

Twelve flash technology implemented by Fuisz. Nurofen melt let, a new form of ibuprofen as an orodispersible tablet, prepared using flash dosing technology.

Advantages

- High surface area for dissolution Disadvantage
- The high temperature required to melt the matrix may limit the use of heat-sensitive, moisture-sensitive and moisture-sensitive drugs.

Pharmabust Technology

Pharmaburst technology is patented by SPI pharma. Tablets made in this way contain a dry mixture of the drug, flavor and also lubricant, followed by compression of the tablets, which then dissolve within 30-40 seconds.

Flashtab technology

Flashtab technology is another fast melting / Dissolving tablet formulation. Prographarm labs implement flashtab technology.

Oraquick Technology

K.V.S. Pharmaceutical has a patent on this technology. It uses a taste microsphere mask technology called micromask, which provides a better mouthfeel than a taste mask alternative, significant mechanical strength and rapid degradation / melting of the product.

Advantages

Faster and more efficient production, suitable for heat-sensitive drugs

Advatab Technology

Advatab tablets disperse rapidly orally, usually in less than 30 seconds, to allow rapid administration of the oral drug without water.

Oraquick Technology

K.V.S. Pharmaceutical has a patent on this technology. It uses a taste microsphere mask technology called micromask, which provides a better mouthfeel than a taste mask alternative, significant mechanical strength and rapid degradation / melting of the product. Not all types of solvents are used in the taste secretion process. This will therefore lead to greater and faster efficient production.

Pharmabust technology

Pharmaburst technology is patented by SPI pharma. Tablets made in this way contain a dry mixture of the drug, flavor and also lubricant, followed by compression of the tablets, which then dissolve within 30-40 seconds. Tablets made in this way have sufficient strength to be packaged in blisters and vials.

Table 03: Different fast Dissolving tablets products available in Indian market

Sr.No	Author	Drug	Method /polymer	inference
1	Durga bhavani etal (2016)	valsartan	Vacuum drying technique	Improve disintegration time
2	Karia etal (2015)	Olmesartan medozoinil	Co-processed excipient technique	Better in vitro drug release
3	Subbaiah etal (2015)	Amoxicillin trihydrate and potassium clavunate	Direct compression	Improve disintegration time and in vitro drug release
4	Munde etal (2015)	Lansoprazole	Direct compression	Improve in vitro drug release.
5	Metkari etal (2014)	Carbamazepine	Direct comp. using solid dispersion	Good dissolution profile with short disintegration time.
6	Babu etal (2014)	Carbamazepine	Direct compression	In vitro drug release increased.
7	Arunachalam etal (2013)	Levofloxacin	Direct compression	Improve disintegration time.
8	Valera etal (2013)	Amoxicillin trihydrate and potassium clavunate	Dry granulation method	Improve in vitro drug release.

Table 4: patented technologies for fmts formation

SR.NO	Brand (trade) name	Active drug	Manufacture/company
1	Benadryl Fastmelt	diphenhydramine and psudoephedrine	Warner-Lambert, NY, USA
2	Claritin redi tab	Loratadine	Schering- plough corp. USA
3	Domperidone Ebb	Domperidone	Ebb medical, Sweden
4	Domperon	Domperidone	Astra pharma, Bangladesh
5	Feldene fast melt	Piroxicam	Pfizer Inc, NY, U.S. A
6	Febrectol	Paracetamol	Prographarm, chateauneuf, France
7	Gaster D	Famotidine	Yamanouchi
8	Impodium Istant melt	Loperamide HCL	Janssen, UK
9	Maxalt MLT	Rizatriptan	Merk and co. nj. USA
10	Nasea OD	Ramosetoron HCL	Yamanouchi

Frosta technology (Akina)

This technology is implemented by Akina. Frosta technology uses the basic concept of molding plastic granules and compression at short pressures to produce solid tablets with high porosity. The process involves mixing a porous plastic material with a water penetration enhancer and subsequent granulation with a binder.

Nanocrystal Technology

For fast tablet melting, Elans' patented nanocrystalline technology is able to create and improve the composite activity and properties of the final product. By reducing the particle size, the surface area increases, which leads to an increase in the melting rate. This can be predicted and effectively with nanocrystalline technology. Nanocrystalline particles are easily small drug particles, typically less than 1000 nanometers (nm) in diameter, made by grinding the drug using a patented wet milling technique.

Dispersible Tablet Technology

Leak in Yugoslavia has issued patents for dihydroergotoxin and cimetidine dispersible tablets, which are said to dissolve in less than 1 minute upon contact with water at room temperature. In its basic form, dihydroergotoxin is poorly soluble in water. Better degradation of this dihydroergotoxin methane sulfonate was observed for dispersible tablets containing 0.8 to 10%, preferably about 4% by weight of organic acids. One of the main excipients of cimetidine is the formation of ions, which is a disintegrant. It causes rapid swelling and / or a good ability to read tablets and thus rapid disintegration. Disintegrants include starch such as modified starch, microcrystalline cellulose, alginic acid, cross linked sodium carboxymethylcellulose, and cyclodextrin polymers. The combination of two or more disintegrants provides better disintegration results.

Table 05: Work which is done on fast Dissolving drug delivery system or FDTs

Sr.No	Author	Drug	Method/polymer	Interference
1	Lee etal (2013)	megestrol	Spray drying	Quicker dissolve and mask the taste of drug.
2	Szamost etal (2013)	Phenyl propanolamine Lamina HCL	Direct compression	melt at 37.c and low compression force.
3	Constantine (2011)	Ondasetron	Polyethylene glycol	Used of the bioactive agent and treatment of dysphagia.
4	Singh etal (2006)	Nimesulide	Sodium starch glycolate	Dissolve or disintegrate in digestive organ.
5	Aggarwal etal (2005)	Galanthamine	Direct compression	Used in Alzheimer disease.
6	Callihan etal (2005)	Aspirine	Direct compression	Mannose provide rapid disintegration and dissolution.
7	Szamost etal (2013)	Ibuprofen	Direct compression	Provide excellent mouth feel.
8	Khawla etal (2013)	Ibuprofen	Melt extrusion	Very low compression force.
9	Callihan etal (2013)	Caffeine	Direct compression	Rapid dissolution.
10	John etal (2013)	Active substance	Freeze drying	Rapid disintegration.
11	Abu-Izzakawla etal (2013)	Iboprofen	Direct compression	Low melting point of compound use.
12	William etal (2013)	efavirenz	Wet granulation	Used in HIV.
13	Gilis etal (2013)	Galanthamine HBr	Direct compression	Used in treatment of Alzheimer dementia.
14	Warner Lambert Co. etal (2012)	Active substance	Direct compression	Used low density granules.
15	Makino etal (2012)	Active substance	Compression molding	High adequate strength disintegration and Dissolving rate.

Wow Tab Technology

This tablet technology is patented by Yamanouchi Pharmaceutical Co. WOW means "no water". In this process, a combination of low formability carbohydrates and high formability carbohydrates is used to obtain a fast-melting solid tablet. The combination of their high and low ductility is used to produce boards with sufficient hardness.

Preformulation studies

1. Bulk Density (Db): It is a ratio of the total weight of the powder to the maximum volume of powder. Measured by pouring weight powder (exceeded by standard filter # 20) in the measuring cylinder and initial weight was detected. It is expressed in g / ml and is given

by Db = M/ Vb Where, M is the mass of powder; Vb is the bulk volume of the powder.

2. Tapped Density (Dt): It is a measure of the total weight of the powder in a concentrated dose of powder. Volume was measured by tapping the flour 750 times and the taped volume was detected if the difference between the two categories was less than 2%.

It is expressed in g / ml and is given by Dt = M / Vt

Where, M is the mass of powder Vt is the tapped volume of the powder.

3. Angle of Repose (q): The friction forces in a loose powder can be measured by the angle of repose (q). It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane tan (q) = h / r q = tan-1 (h / r) Where, q is the angle of repose. h is the height in cms r is the radius in cms.

4. Carr's index (or) % compressibility: It indicates powder flow properties. It is expressed in percentage and is give Dt – Db I = 100

Dt Where, Dt is the tapped density of the powder and Db is the bulk density of the powder.

Evaluation of mouth dissolving tablets:

Weight variation: 20 tablets were selected randomly from the lot and weighted individually to check for weight variation.

5. Hardness: Hardness or tablet crushing strength (fc), the force required to break a tablet in a diametric compression was measured using Monsanto tablet hardness tester.

6. Friability (F): Friability of the tablet determined using Roche friabilator or Electro lab friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at I height of 6 inches in each revolution. Preweighted sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula.

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} \times 100$$

7. Mechanical Strength: Tablets should possess adequate strength to withstand mechanical shocks of handling in manufacturing, packaging and shipping. Crushing strength and friability are two important parameter to evaluate a tablet for its mechanical strength.

8. Crushing Strength: It is the force required to break the tablet by pressing on the spreading side, it is an important parameter in the formation of oral tablets because the force of excessive crushing greatly reduces the dispersion time.

9. Wetting time: Wetting time is closely related to the inner structure of the tablets and to the hydrophilicity of the excipient. According to the following equation proposed by Washburn E.W (1921), the water penetration rate into the powder bed is proportional to the pore radius and is affected by the hydrophilicity of the powders. dl/dt = r¡cosq/(4hl)

10. In vitro dispersion time: Tablet was placed in 10 ml phosphate buffer solution, pH 6.8±0.5°C. Time required for complete dispersion of a tablet was measured. In-vitro disintegration time The process of dividing a tablet into smaller particles is called dispersing. The duration of the in-vitro segmentation of the tablet was determined using the diagnostic testing tools according to I.P statistics.

11. Thickness Variation: Ten tablets from each formulation were taken randomly and their thickness was measured with a digital screw gauge micrometer. The mean SD values were calculated.

Conclusion

Fast dissolving tablets emerge as one of the popular and widely accepted dosage forms, especially for pediatric patients because of incomplete development of the muscular and nervous system and a case of geriatric patients suffering from Parkinson's disorder or hand tremors. Few solid dosage forms like capsules and tablets are present days facing the problems like difficulty in swallowing (dysphagia), resulting in many incidences of non-compliance and making the therapy ineffective. Oral dosage form and oral route are the most preferred route of administration for various drugs has limitations like first-pass metabolism, psychiatric patients, bedridden and uncooperative patients.

Author Contributions

All authors are contributed equally

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Declaration of Competing Interest

The Authors have no Conflicts of Interest to Declare.

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