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RECENT PATENTS ON FAST DISSOLVING TABLETS - A REVIEW

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ABSTRACT

Fast dissolving drug delivery system are the fast rising and highly usual drug delivery system aims to enhance safety and efficacy of drug molecule by formulate a convenient dosage form for administration and to achieve better patient compliance. Fast dissolving tablets (FDT) are those solid dosage forms which put on tongue, disintegrate or dissolve instantaneously, releasing the drug, within one minute without the need of water. These dosage forms are placed in the mouth, allowed to disperse or dissolve in the saliva. Fast dissolving tablets have number of advantages over conventional dosage forms like- ease of administration, enhanced bioavailability etc and due to these advantages the fast dissolving tablets have emerged as an alternative to conventional dosage forms. There are many techniques used in fabrication of FDT such as direct compression, tablet moulding, freeze drying, spray drying, mass extrusion, sublimation etc. Many patented technologies have been developed such as Zydis, Orasolv, Durasolv, Quicksolv, WOWTAB, FlashDose, Lyoc technology etc. The objective of present article is to describe the recent patents on fast dissolving drug delivery system.

Keywords*: Fast dissolving drug delivery system, Patents*

INTRODUCTION

Fast dissolving drug delivery system is a delivery system which engage solid dosage forms which put on tongue, disintegrate or dissolve immediately, releasing the drug, within one minute without the need of water. These tablets, when taken orally, disintegrate or dissolve rapidly such that active agent included in the tablets is absorbed in the buccal cavity. When this type of tablet is placed into the mouth, the saliva will serve to rapidly disintegrate the tablet. The faster the release of drug into solution quicker the absorption and show clinical effect [1]. Szamosi et al (2011) claimed processes for the preparation of tablets which dissolve rapidly in the mouth and provide an excellent mouthfeel. The tablets of the invention comprise a compound which melts at about 37° C or lower, have a low hardness, high stability and generally contain few insoluble disintegrants which may cause a gritty or chalky sensation in the mouth [2]. A characteristic that makes FDTs highly attractive for paediatric and geriatric patients are dissolving them to release the drug as soon as they come in contact with saliva, therefore avoiding the need for water during administration. Skulj et al (2012) claimed the rapidly disintegrating tablets intended to be used as dispersible tablets, ingested either by dispersing directly in the mouth. These tablets are also suitable for use in pediatric patients in the age above 3 years and can be used as dispersible tablets for pediatric patients below 3 years. Rapidly disintegrating tablets which contain amoxicillin and clavulanic acid are also described [3]. Difficulty in swallowing predictable tablets and capsules is common among all age groups, specially in elderly and dysphagic patients. This disorder of dysphagia is interrelated with many medical conditions including stroke, Parkinson's disease, AIDS, thyroidectomy, head and neck radiation therapy and other neurological disorders including cerebral palsy [4].

Costantini et al (2011) claimed the invention related to the administration of bioactive agents through oral fast dispersing/dissolving drug delivery systems for treating illnesses of patient with critical buccal condition, leading to difficulties in swallowing oral medicine forms and thus difficulties in treating said illnesses. Particularly, the invention disclose the administration of bioactive agents via oral fast dispersing/dissolving drug delivery systems for treating illnesses of patient with dysphagia and/or odynophagia and/or aspiration risk [5]. Fu et al (2006) claimed a fast-dissolving pharmaceutical tablet comprise a dissolution-effective amount of mannose, which tablet has a hardness of at least about 20 newtons and disintegrates within about 30 seconds in being there of an amount of water sufficient to soak the tablet. The mannose component imparts two properties to the tablets like- structure-forming and fast dissolution properties. The granulation and humidification of tablet components forms strong liquid bridges at the surface interfaces of mannose particles, which leads to strengthened tablets. However, the mannose particles remain porous following compression, so that contact with moisture e.g., saliva in the mouth, leads rapidly to tablet disintegration and dissolution [6]. Pruss et al (2003) claimed a rapidly disintegrating solid dosage form having opposed major face surfaces comprising: (a) at least one active agent; and (b) at least one pharmaceutically acceptable water-disintegrable or water soluble excipient, wherein the dosage form: (i) substantially disintegrates or dissolves upon contact with an aqueous medium in less than about 3 minutes; (ii) has a friability of less than about 2%; and (iii) wherein each of the major face surfaces forms a double-convex shape [7]. A List of various patents on fast dissolving delivery has been summerized in table 1.

Salient Features of Fast Dissolving Drug Delivery System [8]

- Ease of administration to patients who snub to swallow a tablet, such as paediatric, geriatric and psychiatric patients.
- Convenience of administration.
- Accurate dosing as compared to liquids.
- No need of water to swallow the dosage from, which is greatly suitable feature for patients who are travelling and do not have immediate access to water.
- Good mouth feels property of FDDS helps to change the basic view of medication as "bitter pill", particularly for paediatric patients.
- Produce rapid onset of action due to rapid dissolution and absorption of drug.
- Some drugs are absorbed from the month, pharynx and oesophagus as the saliva passes down into the stomach, and in such cases bioavailability of drugs is increased.
- Pre-gastric absorption can result in improved bioavailability
- Ability to provide advantages of liquid medication in the form of solid preparation.
- As a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.

ADVANTAGES [9]

- Easy administration to the patients who cannot swallow, such as the elderly, bedridden patients, patients affected by renal failure and patients who refuse to swallow such as paediatric, geriatric and psychiatric patients.
- Rapid drug therapy intervention.
- Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx & oesophagus as saliva passes down into the stomach. Dong et al (2010) claimed an orodispersable tablets and methods of preparation for the identical. The tablets and methods are useful, for example, for reducing first pass

metabolism and enhancing bioavailability of orally active agents, and/or reducing the time it takes for an active agent to achieve maximum therapeutic effect in a subject [10].

- Convenient for administration and patient compliance for disabled, bedridden patients, travellers and busy peoples, who do not always have access to water.
- Good mouth feel property helps to change the sensitivity of medication as bitter pill, particularly in paediatric patients.
- Providing improved safety by avoiding the risk of chocking or suffocation due to physical obstruction during oral administration of conventional formulations.
- New business opportunity like product differentiation.

DISADVANTAGES

- The tablets usually have insufficient mechanical strength so, careful handling is required.
- The tablets may leave unpleasant taste and/or grittiness in mouth if not formulate properly.

METHODS OF PREPARATION

1. **Freeze drying / lyophilisation**: 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 and has verified improved absorption and increase in bioavailability. The major disadvantages of lyophillization technique are that it is expensive, time consuming; brittleness makes conventional packaging unsuitable for these products and shows poor stability under stressed conditions. Do et al (2004) claimed a method for the fabrication of a fast dissolving tablet that includes: blending of highly-compactable filler with a highly water-absorbing material and adding purified water to the mixture until granules are formed thus creating the cushioning component; and this component is milled to a particle size of between 10-325 mesh (2000-45 micron); and adding active-loaded beads to the milled cushioning component to create a mixture followed by an optional step of extrusion and spheronization and freeze-drying of the mixture of active-loaded beads and milled cushioning component with or without said extrusion and spheronization to create the Cushioning Beads™; and compressing the Cushioning Beads™ into a fast dissolve tablet for treatment of a patient in need of said treatment [11].

2. **Tablet Moulding**: Tablets produced by moulding are solid dispersions. Physical form of the drug in the tablets depends whether and to what extent, it dissolves in the molten carrier. Wang et al (2010) claimed a method for preparing a fast dissolving tablet, comprising: preparing first a powdery solution comprises a hydrophilic polymer and a starch; and second solution which comprises a pharmaceutically active ingredient and a surfactant; blending the both first and second solutions to form a plurality of granule powders by a granulating process then mixing the granule powders at least with an excipient; and applying a compression-moulding process to form the fast dissolving tablet; wherein the compression-moulding process applies a pressure, porosity and disintegration time of about 800˜1200 lb/cm^2, 30˜70% and less than 1 minute respectively [12]. Bauer et al (2007) claimed a method of manufacture of fast-disintegrating tablets obtained comprising chemicals, oral drug components and foodstuff. The method is characterized in that the components in pulverized form are contacted with a pressurized liquefied gas or gas mixture, homogenized, introduced into moulds under pressure, and decompressed. The pressurized liquefied gas or gas mixture may further comprise a low-boiling solvent [13].

3. **Cotton candy process**: The floss-like crystalline structure is produced by unique spinning mechanism, which mimics cotton candy, so this process is known as cotton candy process. Cotton candy process involves formation of matrix of polysaccharides or saccharides by simultaneous action of flash melting and spinning. The matrix formed is moderately recrystallized to have improved flow properties and compressibility. This candy floss matrix is then pulverized and blended with active ingredients and excipients and afterwards compressed to FDT.

4. **Spray drying**: The highly porous, fine powders can be produced by a process known as Spray drying. It contains a bulking agent (mannitol and lactose), a disintegrant (sodium starch glycolate and croscarmellose sodium), an acidic ingredient (citric acid) and/ or alkaline ingredients (sodium bicarbonate), which compressed into tablets having fast disintegration and enhanced dissolution. Lee et al (2011) claimed that fast oral tablets produced by using a method comprising: produce the tablets by tableting the mixture containing active ingredients, pharmaceutically acceptable additives, and supercritical fluid-soluble substances; and forming fine pores in the tablets by extracting the supercritical fluid-soluble substances by contacting the tablets with the supercritical fluid. When a technique developed that is called as Zydis as a trade name produced by freeze-drying from R.P. Scherer company for the first time, after this technique that is called as Fast-dissolving began to receive attention and the development of the technique has become faster as launching the product applied with Zydis technique [14]. Grimshaw et al (2007) claimed a rapidly disintegrating tablet comprising a compressed granulate containing: hyoscyamine, directly compressible spray-dried mannitol and directly compressible microcrystalline cellulose, in which the tablet has a friability of not more than about 1.5% and a porosity of from about 15% to 45%, wherein the tablet disintegrates rapidly in an aqueous media [15].

5. **Sublimation**: This method includes the addition of a sublime salt to the tableting components, compressing the blend and removing the salt by the process of sublimation. The tablets are prepared using active pharmaceutical ingredient, diluent, sublime salt (camphor/ammonium bicarbonate), binder and other excipients, then blended and compressed. The tablets dissolve within 10-20 seconds and show sufficient mechanical strength. Rao et al (2010) prepared the fast dissolving tablets by using different concentrations of superdisintegrants like indion-414, crospovidone, sodium starch glycolate, croscarmellose sodium using sublimation method. The blend was examined for the pre-compressional and post-compressional parameters. The different formulations F1, F8, F9 shows less *in vitro* dispersion time 18, 25, 19 sec respectively with rapid *in vitro* dissolution within 5 min. *In vitro* dispersion time decreases with increases in concentration of indion 414 up to 3% then dispersion time increases, where as *in vitro* dispersion time decreases with increase in the concentration of croscarmellose sodium [16]. Gaur et al (2011) prepared fast disintegrating tablets of Aceclofenac by subliming method using two super-disintegrants, such as crospovidone and sodium starch glycolate were used in different ratio (2-8 % w/w) with camphor (30 % w/w) as subliming agent and prepared batches of tablets were evaluated for thickness, weigh variation, hardness, friability, drug content uniformity, wetting time, water absorption ratio, *in-vitro* disintegration time and *in-vitro* drug release. Three formulations were tested for the *in-vitro* drug release pattern (in pH 7.4 phosphate buffer) based on disintegration time (approximately 21 second) [17]. Gupta et al (2011) formulated mouth-dissolving tablet of Cetirizine dihydrochloride (non-sedative antihistamine with potent antiallergic action) using Cetirizine diHCl E.P, D-Mannitol, DL-Camphor was used in various ratios and provide advantages like quick onset of action, no need of water for swallowing of tablet, less disintegration and dissolution time, thus providing faster relief to the patient. Tablets prepared with drug, mannitol and camphor in ratio 1:16:3 showed least disintegration time (less than 1min. without

shaking), maximum *in vitro* dissolution rate (T50%=4.75 min., T90% = 13.75min.) and least *in vivo* mouth disintegration time (17.58 sec) [18].

6. **Direct compression**: Direct compression represents the simplest and most cost effective tablet manufacturing technique. Mezaache et al (2012) claimed a direct compression quick dissolve oral dosage form comprising: a drug-containing microparticle, and an excipient mass comprising: (i) at least one of a directly compressible inorganic salt, a cellulose derivative, and a mixture thereof; and (ii) at least one directly compressible filler; manufactured by direct compression process wherein said oral dosage form is a fast dissolving oral dosage form that have dissolution time less than about 40 seconds and friability of less than about 1% [19]. Nayak et al (2011) prepared orodispersible tablets of Lornoxicam using superdisintegrants viz; crospovidone, croscarmellose sodium and sodium starch glycolate using the direct compression method. The different formulations showed disintegration time between 18 to 75 sec and drug release showed time between the ranges of 10 to 12 min. Among all the formulations, F3 (containing 4% of crospovidone) showed 99% drug release within 12 min and it showed least disintegration time (18 sec) due to this reason F3 formulation considered best among the other formulations. The stability study was conducted as per the ICH guidelines and the optimized formulation (F3) was found to be stable [20].

The direct compression technique can now be applied to preparation of FDT because of the availability of improved excipients especially superdisintegrants and sugar based excipients.

6.1) **Superdisintegrants:** Many orally disintegrating tablet technologies based on direct compression, the addition of superdisintegrants predominantly affects the rate of disintegration, dissolution and hence the bioavailability. The presence of other formulation ingredients such as water-soluble excipients and effervescent agents further hastens the process of disintegration. Makooi et al (2001) claimed a capsule or a compressed tablet pharmaceutical dosage form comprising a therapeutically effective amount of efavirenz and greater than about 10% by weight of a disintegrant relative to the total dry weight of the pharmaceutical dosage form [21]. Alur et al (2009) claimed a pharmaceutical composition in which the intragranular disintegrating agent comprises a super disintegrant selected from sodium starch glycolate, the sodium salt of carboxymethyl starch, cross-linked polyvinyl pyrrolidone, croscarmellose and the sodium salt of carboxymethyl cellulose [22].

6.2) **Sugar Based Excipients**: This is another approach to manufacture FDT by direct compression. The use of sugar based excipients especially bulking agents such as dextrose, fructose, isomalt, lactilol, maltilol, maltose, mannitol, sorbitol, starch hydrolysate, polydextrose and xylitol, which display high aqueous solubility and sweetness, and hence provide a pleasing mouth feel. Ramtoola et al (2012) claimed a directly compressed orodispersible tablet comprises 0.1 to 50% of an ungranulated active agent (w/w), 10 to 80% of a sugar-based direct compression base, and 10 to 80% of a microcrystalline cellulose (MCC) direct compression base. The formulation has a hardness and disintegration time of at least 60N and less than 40 seconds respectively. The sugar-based direct compression base is a DC sugar alcohol, especially direct compression mannitol, and the MCC base is a silicified MCC, especially a Prosolv. The active agent is a hydrophobic active, typically a high-dose active. An orodispersible tablet prepared using the mixture of components comprises 0.1 to 50% of an active agent (w/w), 10 to 80% of a sugar-based direct compression base (w/w); and 10 to 80% of a microcrystalline cellulose (MCC) direct compression base (w/w) by comprising the steps of directly compressing a mixture of components at a compression force of at least 5 k N to form the tablet [23].

7. **Mass extrusion**: This technology involves softening the active blend using the solvent, mixture of water soluble polyethylene glycol using methanol and ejection of softened mass through the extruder or syringe to get a cylinder of the product and cutting into even segments upon heated blade to form tablets.

APPLICATIONS

Champion et al (2008) claimed a quick-dissolve flavour tablet for flavouring a beverage comprising a flavour component and a quick-dissolve carrier component in a container, wherein the tablet is capable of dissolving leading placement in the beverage container with minimal residue. The tablet dissolves significantly completely upon placement in the beverage container in a time period selected from the group consisting of less than about 1 minute, 45 seconds, 30 seconds, 15 seconds, 10 seconds, 5 seconds, 3 seconds, 1 second [24].

Rawas et al (2007) claimed a pharmaceutical tablet for buccal or sublingual administration comprising: (a) about 0.5% to 90% epinephrine; (b) about 7.5% to 95% filler; and (c) about 2.5% to 10.5% disintegrant, wherein administration of supposed pharmaceutical tablet provides a multi-phasic pharmacokinetic release profile of said epinephrine [25].

Ramalho et al (2006) claimed fast water-dispersible tablets containing domperidone for oral administration in an amount by means of therapeutic efficacy, comprising pharmaceutically acceptable salts, characterised in that they contain about 60-80% (w/w) of an "secondary" granulate, about 10-30% (w/w) of disintegrating agent, sweetener, flavouring agent and lubricant. The formulations which have an enhanced structural integrity, having a friability lower than 1.0% and are able to disperse in water within 3 minutes, to provide a dispersion all components passes through a 710 μm diameter mesh size sieve, that provides a pleasant taste and make absence of traceable granules in the mouth [26].

Jeong et al (2006) claimed a fast-melting tablet containing a plurality of compressed granules, each comprising an effective amount of particles of at least one active ingredient/ion-exchange resin complex, dry binder, and bulk diluent, wherein the active ingredient/ion-exchange resin complex comprises an active ingredient ionically bound to an ion-exchange resin further comprising a substance coating or microencapsulating the particles of active ingredient/ion-exchange resin complex. Wherein the active ingredient is an acidic, basic, or amphoteric pharmaceutical, nutritional, vitamin, mineral or dietary supplement [27].

Murpani et al (2003) claimed the invention relates to fast dissolving tablets for oral administration comprising a therapeutically effective amount of drug(s) that acts selectively as a cyclooxygenase-2 (COX-2) enzyme inhibitor, which disintegrate quickly in mouth. The tablets are particularly suitable for patients who have difficulty in swallowing [28].

Gilis et al (2002) claimed a method of treating a disorder selected from dementia, mania or nicotine dependence in a patient in need thereof a tablet comprising as an active ingredient, therapeutically effective amount of galanthamine hydrobromide (1:1) and pharmaceutically acceptable carrier, in which supposed carrier comprises a spray-dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluents, and an insoluble or poorly soluble cross-linked polymer disintegrant [29].

CONCLUSION

Fast dissolving drug delivery system deliver the drug faster than other conventional dosage forms and have better patient compliance. By using different method of preparation of FDTs we can improve its disintegration and dissolution time. In present time there are many patented technologies used to formulate the different formulation of FDTs.

Table 1: List of various patents on fast dissolving delivery

Patent No.	Contents	Ref. No.
US20120082729 (2012)	Quick dissolve compositions and tablets based thereon	19
US20120028949 (2012)	Rapidly disintegrating tablet	3
US20120077888 (2012)	Orodispersible tablets	23
US20110217372 (2011)	Fast dissolving oral tablets and method for production thereof	14
US20110237563 (2011)	Fast dissolving drug delivery systems	5
US20110288135 (2011)	Fast dissolving tablet	2
US7709023 (2010)	Quick dissolve compositions and tablets based thereon	30
US20100029691 (2010)	Fast onset orodispersable tablets	10
US7771745 (2010)	Fast dissolving tablet and method of preparing the same	12
US20100074948 (2010)	Method of producing fast dissolving tablets	31
US7695735 (2010)	Fast disintegrating tablet	32
US20100255091 (2010)	Oral fast disintegrating tablets	33
US20090170955 (2009)	Fast release paracetamol tablets	22
US20080187628 (2008)	Water-soluble, quick-dissolve flavour tablets	24
US20070202163 (2007)	Fast-disintegrating epinephrine tablets for buccal or sublingual administration	25
US7282217 (2007)	Rapidly disintegrable tablets	15
US20070148231 (2007)	Fast-disintegrating tablets	13
US7067149 (2006)	Fast disintegrating tablet	34
US20060134195 (2006)	Mannose-based fast dissolving tablets	6
US20060051414 (2006)	Fast water-dispersible domperidone tablets	26
US20060115529 (2006)	Fast-melting tablets having taste-masking and sustained release properties	27
US20050196438 (2005)	Fast dissolving tablet and method of preparing the same	35
US6733781 (2004)	Fast dissolving tablet	36
US20040037878 (2004)	Fast dissolving tablet	37
US20040161459 (2004)	Fast dissolve tablet technology	11
US20030161875 (2003)	Fast dissolving tablets of cyclooxygenase-2 enzyme inhibitors	28
US20030215502 (2003)	Fast dissolving dosage forms having reduced friability	7

US6358527 (2002)	Fast-dissolving galanthamine hydrobromide tablet	29
US6238695 (2001)	Formulation of fast-dissolving efavirenz capsules or tablets using super-disintegrants	21

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