

FAST DISSOLVING TABLET: A REVIEW**Pritam T. Kelgire*, S. B. Bothara and P. R. Mahaparle**

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ABSTRACT

Oral drug delivery is most common drug delivery and convenient drug delivery because of simplicity, economical, safest drug delivery. But there are some disadvantages of conventional tablet to overcome that modified release dosage form utilised. Fast dissolving tablet can be used in paediatric, geriatric patients, it also used during journey, and there is little or no access of water. It is best alternative for liquid formulation because of its rapid action and accuracy in dosage form. Fast dissolving tablets prepared by using different excipient along with drug. Fast dissolving tablet is produced by conventional techniques and also advanced patented technologies. The prepared formulations were evaluated for pre-compressional and post-compressional parameters.

KEYWORDS: Fast dissolving tablet, Super disintegrants, patented technologies.**INTRODUCTION**

Oral drug delivery is most common drug delivery and convenient drug delivery because of simplicity, economical, safest drug delivery but there are some demerits of conventional oral drug delivery like it cannot be used in emergency condition, patient with vomiting, unconscious patient,^[1] mentally disabled patient, diarrheal patient. So, there is need of modification in oral drug delivery system and there is invention of fast dissolving tablet which overcome the above all problems. Fast dissolving drug-delivery systems were first developed in the late 1970s as an alternative to conventional dosage forms for paediatric and geriatric patient^[2] According to the United States Food and Drug Administration defines ODT as "a solid dosage form containing medicinal substance or active ingredient which disintegrates rapidly usually within a matter of seconds when placed upon the tongue"^[3] The disintegration time for ODTs generally ranges from several seconds to about a minute. European Pharmacopoeia (EP), which states Mouth Dissolving Tablets as "uncoated tablets intended to be placed in the mouth where they may disperse or disappear rapidly before being swallowed". EP also specifies that the Mouth Dissolving Tablets should disintegrate within 30sec - 3 minutes when subjected to common disintegration test used for tablets and capsules^[4] Fast dissolving tablet are also called as orodispersible tablets, quick-disintegrating tablets, oral disintegrating tablet, mouth-dissolving tablets, fast-disintegrating tablets, fast dissolving tablets, rapid-dissolving tablets, porous tablets, and rapimelts^[5] There is some important benefit of fast dissolving tablet is it can be used with little amount of water or without water so this benefit during

travelling there is no access of water. it provide combine effect of liquid dosage form and conventional tablet formulation.^[6] It is a best alternative for liquid formulation because its rapid action and accuracy in dosage form. Yet, dysphagia is the most common disadvantage of conventional tablets. FDTs overcome the disadvantages of conventional dosage form especially dysphagia.^[7] Fast dissolving tablet when put into mouth it readily disintegrates on come in contact with saliva and result into pre-gastric absorption through mouth and then pass into stomach this result into improved bioavailability of dosage form and reduced chances of toxicity of metabolite formed after passes to the liver.

❖ Advantages of fast dissolving tablet

Following are the advantage of fast dissolving tablet:

- Simplicity in the administration of patient who show difficulty in swallowing like paediatric, geriatric, psychiatric patient.
- There is little requirement of water or no need of water which is very convenient to traveling patient and who do not have access water.
- It provides patient compliance by rapid absorption through GIT.
- It can be used in emergency condition by rapid onset of action.
- It provides drug and dosage stability.
- Provide the accuracy in dosage form.
- Free from risk of suffocation.

❖ **Disadvantages of fast dissolving tablet**

Following are the disadvantage of fast dissolving tablet:

- The tablet gives the unpleasant taste if not formulated properly.
- The fast dissolving tablet shows low mechanical strength as compare to traditional tablet.
- Fast dissolving tablet are sensitive to environmental condition like temperature, humidity so this tablet dispensed in stock bottle.
- Drug with larger dose difficult to formulate in fast dissolving tablet.
- Patient with Sjogren's syndrome or dryness of the mouth due to decreased saliva production may not be good candidate for these tablet formulations.^[8,9]

❖ **Ideal requirements for fast dissolving tablet**

- It should give pleasing mouth fill.
- It should leave no or minimal residue in mouth after oral administration.
- It does not require water to swallow and dissolve and disperse in mouth within matter of second.
- It should have sufficient mechanical strength.
- It should exhibit low environmental sensitivity.^[10,11]

❖ **Need for fast dissolving tablets**

Patient factor: Conventional tablet has certain limitations so as to overcome that limitations there is need of fast dissolving tablet,

- ✓ Some patients unable to take tablet with 8oz water.
- ✓ There is risk of choking.
- ✓ Elderly patients have problem of swallowing tablet.
- ✓ Psychotic patients hide the tablet under tongue which result into patient noncompliance.
- ✓ During journey and when there is little or no access to water that time this dosage form can take.

Effectiveness factor: fast dissolving tablet when put on the tongue results into suspension or dispersion of tablet and dissolves on contact with saliva and pre-gastric absorption through buccal, pharyngeal, GIT. This ultimately increase the bioavailability of dosage form and avoid the first pass metabolism.

Marketing factor: Development of new or improved dosage form is simple and cheaper as compared to development of new API. When API near to the end life of patent, the pharmaceutical manufacturer developed the new or improved dosage form with same API. A new dosage form allows manufacturer to extend the product utility in market, unique product in market, extend product patent.^[12]

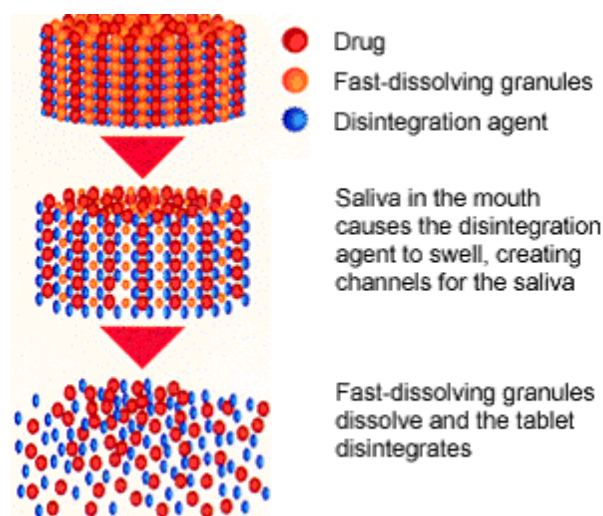
❖ **Mechanism of fast dissolving tablet^[13]**

Fig. 1: Mechanism of the fast dissolving tablets.

❖ **Composition of fast dissolving tablet^[14,15]**

Following components are used in the formulation of fast dissolving tablet

- ✓ Diluent
- ✓ Binding agent
- ✓ Super-disintegrants
- ✓ Surfactant
- ✓ Saliva stimulating agent
- ✓ Lubricant
- ✓ Sweetening agent
- ✓ Flavouring agent and colouring agent

Diluent: There are some drugs have high potency so used in low concentration therefore to increase the bulkiness of tablet diluents are used. Most commonly used diluents are Mannitol, Sorbitol, xylitol, calcium carbonate, magnesium carbonate, calcium phosphate, calcium sulphate, pregelatinized starch, magnesium trisilicate, aluminium hydroxide.

Binding agent: Binder is used to form coherent mass of powder so upon compression that leads to form a tablet. Commonly used binder are cellulose derivatives that is ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose used alone or in combination. Povidone, polyvinyl alcohol.

Super-disintegrants: Disintegrants are the agent used in tablet formulation to break or disintegrate the compacted mass into fine particle when come in contact with fluid environment. Super disintegrants are effective in small amount. The common most super disintegrants are Sodium starch glycolate, Croscarmellose, Cross povidone, Microcrystalline cellulose.

Surfactant: surfactant increases solubility drug by reducing surface tension and also aids to the super-disintegrants. Common surfactants used in fast

dissolving tablet are sodium dodecyl sulphate, sodium lauryl sulphate, Tween, Span.

Saliva stimulating agent: These agents increases the production of saliva so helps in disintegration of fast dissolving tablet. Common saliva stimulating agents are citric acid, malic acid, lactic acid, ascorbic acid and tartaric acid.

Lubricants: These agents reduced the friction between powder particles or powder and die wall. Commonly used lubricants are magnesium stearate, talc.

Sweeteners: To give sweet taste to the formulation sweeteners are used. Common sweeteners are aspartame, saccharin, sucrose.

Flavours and colorants: Flavours are used to mask the bitter taste of drug. Commonly used flavours are peppermint oil, cinnamon oil, oil of nutmeg, eucalyptus oil, anise oil, thyme oil. another examples vanilla, raspberry. Colorants used in formulation to give colour to formulation. Commonly used colorants including FD& C colours, EU colours, natural colouring agents, and natural juice concentrates, pigments such as titanium oxide, silicon dioxide and zinc dioxide and custom pantone-matched colours.

Common techniques for preparation of fast dissolving tablet:

Common techniques for preparation of fast dissolving tablet are follows:

1. Direct compression
2. Freeze drying or lyophilization
3. Tablet molding
4. Mass extrusion
5. Spray drying

1. Direct compression

This is most common technique for preparation of tablet and this is very convenient technique. In this method, tablets are compressed directly from the mixture of the drug and excipients without any preliminary treatment. The mixture to be compressed must have adequate flow properties and cohere under pressure thus making pre-treatment as wet granulation unnecessary. Few drugs can be directly compressed into tablets of acceptable quality. The disintegrants addition technology is cost effective and easy to implement at industrial level^{[16],[17]}.

2. Tablet molding

a. Solvent method: In this method, powder mixture is moistening with the hydro alcoholic solvent and then mass pressure is applied which is lower than conventional tablet and the solvent is removed by air drying method.

b. Heat method: In this method the mixture drug, agar, sugar and other excipient are heated which form the suspension and this suspension placed into blister wall

and solidified agar converted into gelly form at room temperature and is dried at 30°C under vacuum.^[18]

3. Mass-extrusion: In this method in active drug and solvent system such as combination polyethylene glycol and methanol and subsequent soften mass is passes through extruder or syringe which produces cylinder of even segment and cut by heating blade to produce tablet.

4. Spray drying: This is common method of preparation fast dissolving tablet. In this the aqueous composition of active ingredient and other substance passing through the spray dryer which result into powder with porous structure and this powder is directly compress to form tablet. due to porous nature increases solubility and rapid onset of action produces.^[19]

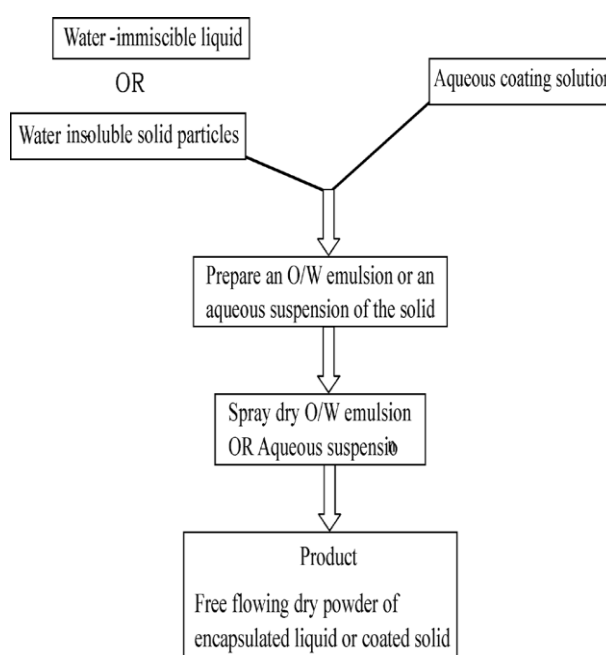


Fig. 2 : Flow chart for spray- dry process of coating liquid or solid particles.^[20]

5. Sublimation^[21]: In this method, the mixture of active ingredient and excipient and sublimating agent are mixed and triturated in mortar and pestle²¹. Then most common sublimating agent are urea, ammonium bicarbonate, camphor, ammonium carbonate, benzoic acid, naphthalene. Then powder is pass through 100 sieves. Then powder is mixed with binder (10%PVP in alcohol). Then wet mass is screen to form granules. Then granules are dried by vacuum drying this drying also remove sublimating agent. Dried granules further screen and then mixed with lubricant and directly compressed to form the tablet with porous structure.

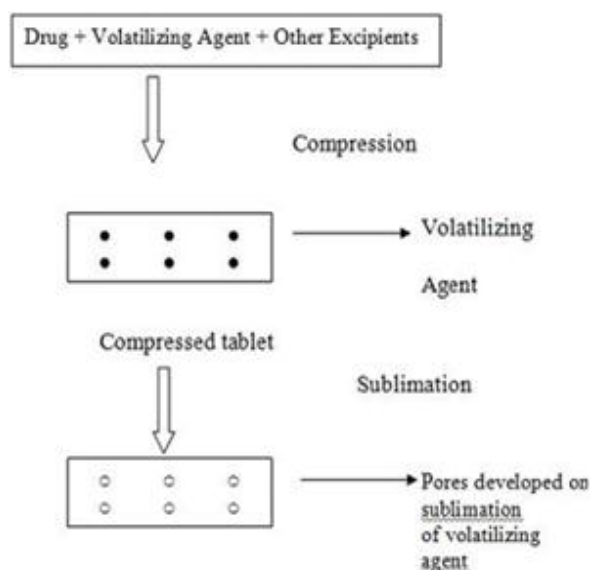


Fig. 3: sublimation process

6. Lyophilization^[22]: The process of freeze-drying was invented in 1906 by Arsène d'Arsonval. In this method gelatine, sugar like mannitol and another excipient used. In this active ingredient and water is stirred for sufficient period of time and then gelatine, mannitol and other excipient were added and stirred for sufficient period of time. Then this suspension placed in blister strip and kept into lyophilization chamber. The water is removed in freeze drying and result into highly porous structure, hygroscopic and soft solid. Then obtained solid is directly compress to form the tablet. When these tablets placed on the tongue which readily dissolve within matter of second.

Phase transition^[23]: It is one of the method of formulating fast dissolving tablet. In this method two different range of melting point sugar alcohol are utilised one having high melting point and another having low melting point. Drug is incorporated into mixture of two different sugar alcohol having high and low melting point. Then this blend is heated between the ranges of sugar alcohol. This results in tight bonding of these blend having sufficient hardness which is compress to form a tablet. Erythritol having high melting point and xylitol having low melting point are most commonly used sugar alcohols.

❖ Patented technology

- ✓ Zydis
- ✓ Orasolv
- ✓ Durasolv
- ✓ Quicksolv
- ✓ Lyoc
- ✓ Wowtab
- ✓ Flashtab
- ✓ Flashdose
- ✓ Frosta
- ✓ Pharmabrust
- ✓ Advatab

Zydis^[24,25,26]: Zydis technology is the first patented technology. Zydis dosage form is a freeze-dried product which is developed by R.P. Scherer in 1986 and which is currently owned by Catalent pharma. Currently 13 products of zydis are available in U.S. market. This technology consists of API that are dissolved in the water-soluble carrier matrix made up of gelatine. Gelatine and mannitol are key components of zydis technology. Gelatine gives the strength to the formulation while mannitol gives hardness to the formulation. Variety of gums used as suspending agent and glycine used as a lyoprotectant. Disintegration time of zydis formulation is less than 10s. Zydis formulation is very fragile and very sensitive to environment to overcome this issue it is packed in blister.

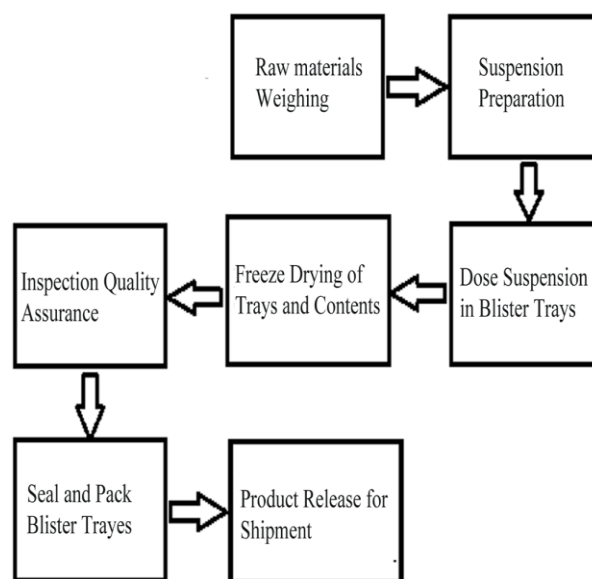


Fig. 4: Zydis® tablet manufacturing process.^[27]

Orasolv^[28]: The patent of Orasolv technology belongs to CIMA lab. In this technology, various excipients are used along with API. In Orasolv effervescent disintegrating agent are releases the CO₂ upon contact with the water. Release of CO₂ helpful in the masking of taste and stimulate the saliva. In this method compression of powder on requires less pressure than the conventional tablet. In Orasolv technology tablet is break by disintegration upon contact with saliva. Disintegration time of Orasolv formulation is 6-40s. and in this about 1-750mg of drug can be incorporated. This formulation is packed into blister card.

Durasolv: It is a second-generation technology for fast dissolving tablet. This technology is developed by CIMA lab. This technology is very similar to the Orasolv technology. In this various excipient are used with or without effervescent disintegrating agent which is directly compressed to form tablet. In this wicking agent are used that's why tablet is break via wicking rather than disintegrating. The disintegrating time is 10-50s and dose strength is 125mcg-500mg. This formulation is packed in blister or bottle.

Quicksolv^[29]: Janssen Pharmaceutica have a patent of Quicksolv technology. In this technology water, soluble matrix containing drug dissolves in the water. Then formulation frozen to form a solid form of solvent. Then this solid solvent comes in contact with other organic solvents like acetone, ethanol, methanol which result into evaporation first solvent and ultimately other solvent also evaporated to form a porous mass which is directly compressed to form tablet. This formulation packs in the blister pack.

Lyoc^[30]: CIMA lab have a patent of Lyoc technology. Lyoc technique is owned by Cephalon Corporation. Lyoc is a freeze-drying technology which is differ from zydis technology. In zydis freeze drying done on shelve. In Lyoc there is incorporated large amount of insoluble diluent to prevent the inhomogeneity in suspension by increase the viscosity of formulation. This also denser the formulation this directly compress to form tablet. Then this packed into blister.

Wowtab^[31]: Yamanouchi Pharmaceutical Co. was developed the Wowtab technology. Wowtab means "without water". In this technology uses two types different sugar that is one is high molding ability another one is low molding ability. Combination of two sugar result into fast dissolving tablet with sufficient hardness. Disintegration time of tablet is 1-40s. It is less sensitive to the environment so it can be packs into conventional bottle.

Flashtab^[32]: Flashtab technology was developed by prographarm. In this technology disintegrating agent and swelling agent are mixed with the active coated drug. Which is then directly compressed to form tablet. Crospovidone, croscarmellose which is used as disintegrants and starch used as a swelling agent. This can be packed into blister.

Flashdose: Fuisz technology was the innovator of this technology. Now Biovail is owned the Flashdose technology. This technology utilise unique spinning mechanism to produce the micro-crystalline structure like cotton candy process. In this self-binding sugar matrix used which called as 'floss'. This technology also called as shear form technology which uses the combinations of sugar. Shear form matrix produced by shear heat method.

Frosta^{[33],[34]}: Akina have a patent over the Frosta technology. Fast dissolving tablet by this technology uses a wet granulation method. In this technology plastic granules are compress at low pressure than conventional tablet to form the tablet. Plastic granules are made up of three components i.e a plastic material, a water-penetration enhancer and a wet binder. Each ingredient has role in the development of fast dissolving tablet. Disintegration time of this tablet 5-40s.

Pharmaburst: SPI Pharma have patent of Pharmaburst technology. It is utilise direct compression method. In this method drug with excipients are blended in dry form and then directly compress to form tablet. Disintegrating time of this tablet is 30-40s.

Advatab: Advatab technology consist of coated drug particle that are placed into fast disintegrating matrix. It is a taste masking technology having disintegrating time 30s.

Promising drugs to be incorporated in fast dissolving tablet

1. Analgesic and Anti-inflammatory agents
2. Anthelminitics
3. Anti-arrythmic agents
4. Anti-bacterial agents
5. Anti-coagulants
6. Anti-depressant
7. Anti-epiletics
8. Anti-fungal agents
9. Anti-gout agents
10. Anti-hypertensive agents
11. Anti-migraneAgents
12. H1 antagonist^[35]

Evaluation of fast dissolving tablets

These tests are as following: -

1. Appearance
2. Thickness
3. Hardness
4. Weight variation
5. Friability
6. Disintegration
7. Uniformity of dispersion
8. Wetting Time
9. Water absorption ratio
10. Drug content
11. In vitro Dissolution
12. Stability studies

Uniformity of dispersion^[36]

Two tablets placed into 100ml of water and slowly stirred for 2min. Then solution is passed through 22 mesh and then all tablet must pass and no residue should remain for compliance of test.

Wetting time^[37,38]

Five circular tissue papers of 10cm diameter were placed in a Petri dish containing 0.2% w/v solution of amaranth of volume 10ml. one tablet placed on the surface of tissue paper. Time required to develop colour on top surface of tablet is a wetting time

Water absorption ratio^[39,40,41,42]

A small piece of tissue paper folded twice was placed in a small petridish containing 6ml of water. A tablet was put on the paper. The wetted tablet was then weighed. Water absorption ratio, R was determined by using following formula.

$$R = \frac{w_a - w_b}{w_b} \times 100$$

Here,

R = Water absorption ratio

W_b = Weight of tablet before water absorption

W_a = Weight of tablet after water absorption

Disintegrating test^[43]: This is the most important test for fast dissolving tablet. This is done in disintegrator consist of basket in which beaker consisting of 6 tubes are present which is open at top and at the bottom 10 number screen present. In beaker, one litter distilled water is placed at 37⁰c ± 2⁰C. 6 tablets placed into 6 tubes and the tube movement started in upward and downward direction descending not closer than 2.5cm from the bottom of the beaker. Fast dissolving tablet should be disintegrated within 1minute but actual patient shows 20 to 30s disintegration time.

In vitro dissolution: This test is performed in dissolution apparatus type 2(paddle type) consist of beaker in which bowl are present containing 900ml of 0.1N HCL or 6.8PH phosphate buffer are present. Outside bowl in beaker containing water at temperature 37⁰±0.5⁰C. Tablet placed into bowl containing buffer with paddle rotating at 100 rpm for 30 min. periodically sample (5,10,15,20,25,30min) taken from bowl and same quantity of buffer added to the bowl into this for maintaining sink condition. Sample is filtered and take 1ml and diluted with 10ml buffer and analysed by spectrophotometer and further calculation carried out for determining drug release.

CONCLUSION

Fast dissolving tablet is a novel drug delivery system that is very convenient because of its simplicity. new trend in tablet formulation is created by using different excipients. Fast dissolving tablet have much more advantage over the conventional tablet that it is utilised in patient showing problem in swallowing like paediatric and geriatric patient. It is used with little or no access of water. It provides patient compliance by producing rapid onset of action. Fast dissolving tablet have both advantages as well as disadvantages. Fast dissolving tablet in which super disintegrants are the main component which is used in optimum concentration that increases suitability of fast dissolving tablet.

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