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REVIEW ARTICLE

DISPERSIBLE TABLETS: AN OVERVIEW

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ABSTRACT

The new drug delivery system helps to achieve better patient compliance. Rapid dispersible tablets are one of these. Dispersible Tablets has benefits such as accurate dosing, easy transportability and fabrication, good physical and chemical stability and an ideal alternative for pediatric and geriatric patients. The oral route of drug administration remains the most ideal route because of its various advantages, including ease of ingestion, pain evasion, versatility and, above all, patient compliance. The tablets and capsules are the most common solid dosage forms. On the other hand, many elderly people will have struggles to take the conventional solid dosage forms (tablets and capsules), due to dysphasia. Swallowing complications are also common in children's because of their underdeveloped mucosal system. Other groups that may have trouble swallowing a solid dosage form are the psychologically ill, the developmentally disabled, and the non-cooperative patients. In certain circumstances, such as motion sickness, the sudden episode of an allergic attack or cough and the lack of water availability, the ingestion of tablets can be difficult. To meet these medicinal requirements, the pharmaceutical scientist has devoted significant effort to the development of a new type of dosage form for oral administration, the fast dispersible/ rapid dispersible tablets, and a tablet that disintegrates and dissolves rapidly in saliva without the requirement of water.

INTRODUCTION

Tablets that contain a special formulation, which quickly disintegrates in water to form a drinkable suspension. It provides the ease of swallowing and the enhanced bioavailability of most drug formulations are administered orally in the form of capsules, tablets or fluids. The basic requirement of any drug delivery system is to perform the effective absorption and release of the drug at its absorption site in the gastrointestinal tract (GIT). After the absorption of the drug at its site of absorption, the permeation or transport of the drug from an oral dosage form to the blood flow. Tablets continue to be the most common and acknowledged dosage forms due to their incessant improvement and employment of inventive ideas to overcome the fundamental disadvantages of existing formulations [(1)].

Dispersible tablets are defined as uncoated or film-coated tablets intended to be dispersed in water prior to administration, which provides homogeneous dispersion. Usually, a dispersible tablet is dispersed in water and the subsequent dispersion is given to the patient. Dispersible tablets are a substitute to conventional a formulation with precise dosing. Pharmaceutical active compounds which are not stable in aqueous solution may be stable as a dispersible tablet. The dispersible tablet offers a useful dosage form, decreasing the need for multiple formulations of the same medicine. . The innovative concept of a rapidly dispersible drug delivery system stems from the aspiration to provide the patient with a conventional means of taking the drug. In recent times, oral administration of the formulation has become the most popular route of administration due to its comfort of consumption, painlessness, versatility and above all patient compliance [(2)(3)].

A. Ideal Properties of Dispersible Tablets[(4)]

- It should be Cost-effective.
- Preferably dispersible tablets don't need water or require a smaller quantity of water for oral administration; the formulation must easily dissolve or disintegrate in the oral cavity within seconds
- The formulation must have sufficient hardness and be free from any friability problems to meet the strictness of the production process and the handling of the finished product by the target patient.
- It should be stable with a low manufacturing mold and the process should be subject to the existing processing and packaging mechanisms.

- The drug loading capacity of the dispersible tablets must be high.
- The formulation should disintegrate or dissolve quickly after oral administration in the oral cavity for quick action.
- Evade the first pass effect which increases the bioavailability of the fast dispersible tablets.

B. Advantages of Fast Dissolving Tablets[5]

- Rapid disintegration tablets are intended for patients who cannot swallow, such as the bed-ridden patients, elderly, stroke victims, patients with renal impairment, and patients who decline to swallow, such as geriatric, pediatric, and psychiatric patients.
- Through the use of RDT, it is possible to obtain a rapid drug therapy, obtaining greater bioavailability / rapid absorption through the pre-gastric absorption of drugs from the mouth, esophagus and pharynx as the saliva passes.
- Pre-gastric absorption may result in better bioavailability and, as a result of reduced dose, improve clinical performance by reducing unwanted effects.
- RDTs are suitable for administration and meet the needs of disabled patients, bed ridden patients and those people who do not always have access to water.
- The risk of asphyxiation in the course of oral administration of traditional formulations due to physical hitch is avoided, which provides greater safety.

C. Limitation Rapid Dispersible or Fast Dissolving Tablets[6],[7]

- Drugs with moderately larger doses are hard to formulate in the FDT.
- The hygroscopic properties of the formulation require additional moisture protection with a special packaging for the stability and adequate safety of the products.
- These tablets show low hardness and high friability, than conventional tablets, which make fragile tablets, which are difficult to handle, often require special packs in peel-able blisters.
- Drugs absorbed at a specific site cannot be administered in these dosage forms.
- Patients taking anticholinergic medicines at the same time may not be the best candidates for RDT.
- For freeze-dried dosage forms, the dose of the drug product must be less than 60 mg for soluble drugs and less than 400mg for Insoluble drugs.

D. Mechanism of drug release[8-10]

Disintegration take place when a tablet breaks into fragments when comes in contact with the fluid. This is followed by de-aggregation, disintegration beyond the original granule size into the primary particles. Dissolution occurs more rapidly from primary particles since the available surface area is large, but to a limited extent from the intact tablet, and the aggregates generated during tablet disintegration. The RDT should be disperses or disintegrates in less than three minutes. The fundamental methodology used in development of RDT is the use of superdisintegrants like Carboxy methyl cellulose, Poly vinyl pyrrolidine, sodium starch glycolate.

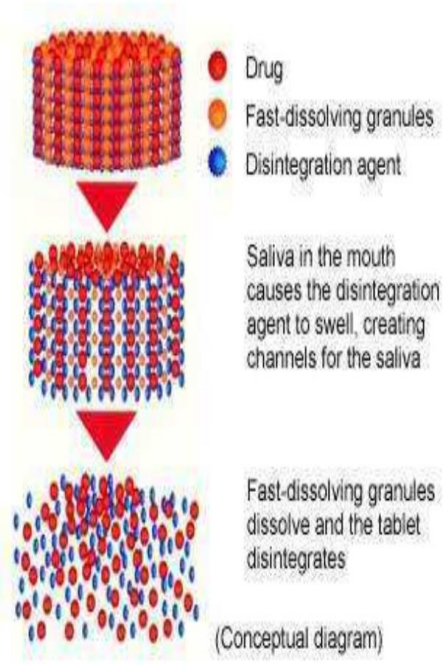

Figure – 1.1: Conceptual Diagram of Disintegration and Dissolution

E. Basic components of Rapid Dispersible Tablet Formulation[11-13]

a) Drug

High dosage, highly water soluble, poorly compressible and hygroscopic drugs represent the greatest difficulty in a dispersible compressible formulation. The excipients must be carefully selected to produce an array of tablets with high compressibility and low aqueous solubility and hygroscopicity.

b) *Disintegrates*

A Disintegrant accelerate the rate at which a tablet breaks up in water. The present study will use so-called superdisintegrants, so-called because of high disintegrant efficiency attributed to their remarkable ability to absorb water and swell. E.g. Sodium Starch Glycolate, Crospovidone, Croscarmellose.

c) *Binder*

The binder and solvent in wet granulation have a reflective effect on the disintegration properties of the tablet (Table 1.4). The aqueous solubility of the binder will affect tablet disintegration properties, and this is well documented. E.g. Hydroxy ethyl cellulose, Hydroxy propyl methyl cellulose.

d) *Diluents*

A diluent or filler facilitates the compression of a formulation and confers resistance and

acceptable appearance to the tablet. The diluents can be categorized conferring to their water solubility and the choice depends on the physical chemistry of the drug; Solubility, hygroscopicity, compression properties, instability and production method. E.g. Calcium carbonate, Calcium phosphates, microcrystalline cellulose, Starch, Mannitol, Lactose etc.

e) ***Lubricants***

Stearic acid salts, like Magnesium stearate, are potentially unsuitable in dispersible tablet formulations because they are hydrophobic, and may form a scum giving an unpleasant appearance. Paradoxically most commercial dispersible tablets are lubricated using magnesium stearate. E.g. Magnesium Stearate, Polyethylene Glycol.

Challenges in Formulation of Rapid Dispersible Tablets[14-20)]

The basic challenge during formulation design of dispersible Tablets or Fast dissolving tablets is the quick disintegration and release of active to make more bioavailability of active in to systemic circulation.

a) Enhancement of Release Profile

Solubility of drug is the basic factor which controls the release profile of the finished product. There are several techniques available for the improvement of solubility and release profile of formulations. Particle size reduction or Micronization (e.g. by high pressure homogenization) might also increase the saturation solubility of a drug, further enhancing the dissolution rate. Dissolution rate of drug can be modified by modification of the solid state (polymorphs, pseudo polymorphs) of the active. Dissolution advantage due to different lattice energies of drug physical forms can be achieved by pseudo polymorphs. Dissolution modification can also achieve by modification of the solid state (amorphous forms) of active.

b) Organoleptic Properties

Many drug substances are unattractive and unpleasant in their natural state. It is widely recognized that if a dosage form is unpalatable, patient compliance may be reduced, especially for long term treatment. Therefore, in dispersible tablet development, organoleptic properties are vital. Flavors and sweeteners may be added to modify and mask taste. The dispersion produced by a tablet must have an acceptable mouth feel and this is related to the particle size and viscosity.

c) **Hygroscopicity:**

Various dosage forms of oral disintegration are hygroscopic and cannot retain their physical integrity under normal temperature and humidity conditions. Therefore, they need moisture protection, which requires packs of special products packaging.

Technologies Used to Manufacture Rapid Dissolving Tablet

I. Conventional Techniques

1. Lyophilization:

Freeze drying is also commonly known as lyophilization. Lyophilization is a method in which water is sublimated from the product after freezing. It involves of three phases-

- Freezing the material to bring below its eutectic zone.
- Drying by Sublimation or primary drying to decrease moisture content to about 4% w/w of dry product.
- Secondary drying or Desorption to decrease moisture to the essential final value.

The ideal characteristics of the drug for this method are the relative insolubility in water with a fine particle size and a good stability of the aqueous suspension. This technique allows the drying of drugs and biological products that are sensitive to heat at low temperatures, thus eliminating the adverse thermal effects and can be kept dry in a relatively new shelf life. The lyophilized forms offer a faster dissolution time as compared to other solid formulations as this technique offers a very porous powder with a high specific surface area[(21)(22)].

***2. Cotton candy process*:**

This method is so called because it uses a distinctive rotating mechanism to create a crystalline structure similar to floss-like, which mimics cotton candy. This method includes the formation of a matrix of saccharides or polysaccharides by the concurrent action of instant melting and spinning. The shape of the matrix is moderately recrystallized to have enhanced flow and compressibility properties. This candy floss matrix is grounded and diversified with active ingredients which are then compressed to form rapidly dissolving tablets. This process can accommodate high doses of drugs and offers better mechanical strength. However, the high process temperature limits the use of this process [(23)(24)].

***3. Direct compression*:**

Conventional methods in manufacturing tablets like dry granulation, wet granulation

and direct compression method have been adapted to produce RDT's. All of these techniques, simplest method to formulate tablets is direct compression. Low manufacturing cost, traditional equipment, normally available diluents and a little number of processing steps lead this technique to be a preferred one. The disintegration and Solubilization of directly compressed tablets depends on the simple or combined action of Disintegrant, water-soluble excipients and effervescent agent. Superdisintegrants play a most important role in the disintegration and dissolution of fast dissolving tablets made by direct compression. To ensure a high disintegration rate along with good mouth feel, choice of suitable type and an optimal amount of Disintegrant is important[(21)(22)].

***4. Mass extrusion*:**

This technique includes softening of the active mixture using the water soluble polyethylene glycol solvent mixture using methanol and the subsequent ejection of the softened mass through the extruder or syringe to obtain a product cylinder in uniform segments using hot sheets to form the tablet. The dried cylinder can be used to coat granules of bitter tasting drugs and thereby masking the bitter taste [(21) (22)].

***5. Spray drying*:**

Extremely porous, fine powders are obtained by this method. The fast dispersible tablet formulations comprised of hydrolyzed/ un hydrolyzed gelatin as supportive agents for matrix, Mannitol as bulk forming agent and Croscarmellose sodium or sodium starch glycolate as disintegrating agent. Dissolution and disintegration are further enhanced by adding effervescent constituents, i.e. sodium bicarbonate (an alkali) and citric acid (an acid). The formulations were spray dried to produce a porous powder. The fast dissolving tablets through this method disintegrated within a minute [(23)(24)].

***6. Sublimation*:**

This method includes the addition of certain inert volatile substances such as camphor, urethane, urethane, urea, naphthalene, etc. to other excipients and to the compression of the mixture into tablets. The removal of volatile constituents by sublimation method generates pores in the tablet structure, because of which the tablet dissolves when it comes into contact with saliva. In addition, various solvents such as cyclohexane, benzene, etc. they can also be used as pore formation agents. With this method, rapidly dissolving tablets were

developed with a highly porous structure and of good mechanical strength [21][22].

***7. Tablet molding*:**

The molding method comprises wetting, dispersing or dissolving the drug with a solvent and then molding the wet mixture into tablets (compression molding with a lower pressure than the conventional compression of the tablet), causing the solvent to evaporate from the drug solution or suspension at room pressure (without vacuum freeze drying), respectively. The pressed tablets made by compression molding were air-dried. Since the compressive strength used is lower than the conventional tablets, the molded tablet results in a highly porous structure, which increases the disintegration and the dissolution rate of the product. Though, to further increase the dissolution rate of the powder mixture, the product must be sieved through a very thin screen [21][22].

II. Novel Technologies

***1. Zydis technology*:**

The Zydis technology is patented by R.P. Scherer. Zydis, the best known of the fast-dissolving/disintegrating tablet preparations, was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placement on the tongue. A Zydis tablet is produce by lyophilizing or freeze-drying the drug in a matrix usually consists of gelatin. The product is very light weight and fragile and must be dispensed in a special blister packaging. The Zydis product is made to dissolve on the tongue in 2 to 3s. The Zydis formulation is also self-preserving because the final water concentration in the freeze-dried product is too low to allow for microbial growth. The Zydis formulation utilizes flavors and sweeteners to optimize the taste of the dosage form. In addition, it utilized micro-encapsulation with specialized polymers or complexation with ion exchange resins to mask the bitter taste of drug [25][27].

***2. Orasolv technology*:**

This technology is introduced by CIMA Lab's. Herein this technology, the tablets are produced using a direct compression technique with low compressive strength to reduce oral dissolution time. The Orasolv technology is a case of a somewhat effervescent tablet that quickly dissolves in the oral cavity. In this system, the taste of the drug is masked and dispersed in saliva because of the effervescent disintegrating agent action. The concentration of the effervescent mixture generally used is 18-27% w/w of the tablet weight. The tablets

thus produced are soft and fragile and are packaged in containers specially designed for collection and placement [25].

3. Durasolv technology:

Durasolv is the second-generation rapid-dissolve / disintegration tablet formulation technique of CIMA Lab, produced similar to Orasolv. Durasolv has a much greater mechanical strength than its ancestor because of the use of high compaction pressures during the formulation of the tablet. The Durasolv product is produced more quickly and inexpensively. Durasolv is so hard-wearing that it can be packaged in traditional blisters or glass vials. The drawback of Durasolv is that the technology is not well-suited for high doses of active component, since the formulation is subject to such high pressures on compaction [25].

4. Wow tab technology:

Yamanouchi Pharmaceutical Co. patented the Wow tab technology. 'WOW' means 'without water'. Active ingredients can constitute up to 50% w/w of the tablet weight. In this technology high and low moldable saccharides are used to formulate the granules. The highly formable substance has a high compressibility and, therefore, shows a slow dissolution. The blend of high and low moldable is used to yield tablets of suitable hardness. The active constituents are mixed with low moldable saccharides and then are granulated with high moldable saccharides and then compacted into tablets. The wow board product quickly dissolves in 13s or less. The Wow tab tablets can be packaged either in conventional vials or in blisters [5].

5. Flashtab technology:

The Prographarm laboratories had patented the Flashtab technology. This technology involves the granulation of the excipients with the dry or wet granulation method and is then compressed into tablets. The diluents used in this technology are of two types: disintegrating and swelling agent. Disintegration agents comprise carboxy methyl cellulose (CMC) or cross-linked poly vinyl pyrrolidine (PVP). The swelling agents include starch, modified starch, carboxy methyl cellulose, microcrystalline cellulose, carboxy methylated starch, etc. These tablets have an adequate physical resistance. These tablets disintegrate within one minute in the oral cavity [25].

6. Flash dose technology:

Fuisz Corporation had patented the Flash dose technology. Flash dose tablets consist of a self-powered cut-shaped matrix called "dental floss". The Flash dose technology

uses a unique spinning mechanism to produce a crystalline structure similar to the sugar thread, just like cotton candy. The active drug is also merged into the crystalline sugar and compacted into a tablet. The final product has a very high dissolution surface area. It disintegrates and dissolves rapidly when placed on the tongue. By altering the temperature and other conditions during manufacturing, the characteristics of the product can be strongly modified. Instead of the silk-like material, small saccharide spheres can be produced to transport the drug [25].

7. Oraquick

This technology has been patented by K.V Pharmaceuticals. It uses a microspheres technology to mask the flavor called a micro mask, which provides a superior oral sensation, a significant mechanical strength and a rapid disintegration / dissolution of the product. This process includes preparation of micro particles in the form of matrix that protects drug, which can be compressed with sufficient mechanical strength. Preparation of the Oraquick rapid dispersible tablet employs a patented taste masking technology. Furthermore, the lower production heat compared to alternative dissolving/dissolving technologies makes Oraquick suitable for heat-sensitive drugs [26].

8. Nano Crystal technology

Elan's patented Nano Crystal technology (Nanomelt ™) can improve compound action and final product characteristics. The decrease in particle size increases the surface area, which leads to an increase in the dissolution rate. This can be achieved efficiently and predictably by using Nano Crystal technology. Nano Crystal particles are small particles of pharmacological material, usually not more than 1000 nm in diameter, which are formed by grinding the drug substance using a patented wet grinding technique [25].

9. Pharmaburst technology

SPI Pharma, New Castle, had patented this technology. Pharma burst ODT utilizes a patented disintegrated product (Pharmaburst) based on Mannitol mixed with traditional tablet manufacturing aids. It uses the co-processed excipients to formulate ODT, which dissolves in 30-40 s. This technology involves the dry mixing of drugs, lubricant and flavor, followed by compression of the tablet [2][32].

10. Frosta technology

Akina patents this technology. The frosta technology is based on the compression of

highly plastic granules at low pressure to prepare fast melting tablets. The highly plastic granules are composed of three components: a plastic material, (Maltrin QD M580 and MaltrinM180 are malt dextrin and corn syrup solids) a water- penetration enhancer (Mannogem EZ Spray) and a wet binder (sucrose, poly vinyl pyrrolidine and Hydroxy propyl methylcellulose). Each of the three components plays an essential role in obtaining tablets with higher strengthened faster disintegration time [21].

Advatab

The Adva Tab tablets disintegrate quickly within 30 seconds. These tablets are manufactured by using polymer-coated drug particles which are evenly dispersed in a low water ultra-thin matrix, which rapidly disintegrates with superior organoleptic properties. Adva Tab tablets are compacted using a patented exterior lubricating system in which the lubricant is applied only on the tablet surface, resulting in strong tablets that are hard and less brittle and can be packaged in bottles or blisters [21].

Tablet thickness:

Tablet thickness can be measured using a simple procedure. Five tablets are taken and their thickness is measured using Vernier Caliper [27].

f) Evaluation Of Dispersible Tablets

Evaluation of the dispersible tablets is done by tests similar to the other conventional tablets. Additional testing of the drug release is done. The mixture of powder is evaluated for bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose. The tablets are evaluated for thickness, friability, hardness, weight variation test, drug content and In-Vitro release rate studies [14][26].

General Appearance:

The general appearance of a tablet, its visual character and above all elegance which are important for consumer acceptance and for size, shape, color, presence or absence of smell, taste, surface consistency, physical defects and consistency and readability of any identifying marks on the tablet. The size and shape of the tablet can be described dimensionally, observed and controlled [31].

Weight variation:

20 random tablets are selected from the lot and weighted separately to check for the weight variation. Mean of the weight is calculated and deviation from the mean weight is calculated for each tablets. Weight variation specification as per I.P [28].

Table 1: Weight variation specification as per I.P

Average Weight of Tablet	%Deviation
80 mgor less	±10
80 mgto 250 mg	±7.5
250 mg or more	±5

Hardness:

The hardness of the tablet (tablet crushing strength) is defined as the force required to break a tablet in a diametric compression test. The tablets required a certain quantity of hardness or strength to bear mechanical shocks due to production, packaging and shipping. It is expressed in kg/cm^2 [29].

Friability:

The friability test is performed to evaluate the effect of friction and shock, which can often cause the tablet to break or break. It was anticipated to determine mass loss under defined conditions. The friability of the uncoated rapid disintegrating tablets was determined by using an Electro Lab friability Apparatus. The 20 pre-weighed tablets were placed in a friability apparatus and the effects of abrasion and impact were tested using a rotating plastic chamber at 25 rpm, dropping the tablets at a distance of six inches with each operation for 100 revolutions. The tablets were then removed from the chamber and extra powder was removed. Then the tablets were re-weighed [30]. The proportion (percentage) for friability was than calculated using following formula:

$$\text{Friability (\%)} = \frac{\text{Initial weight of Tablets} - \text{Final weight of Tablets}}{\text{Initial weight of Tablets}} \times 100$$

Wetting time:

Wetting time of dosage form is correlated to the contact angle. It should be evaluated to give an idea of the disintegration properties of the tablets; A shorter wetting time means a faster disintegration of the tablet. For this purpose, one tablet is placed on a piece of tissue paper twice folded and stored in a small Petri dish containing 5 ml of water and the complete wetting time is measured[27].

Disintegration Time:

Disintegration is defined as time required by tablet to completely disintegrate and disappear from the basket. The disintegration time of the tablets was evaluated based on the disintegration time-specificity of dispersible tablets. The disintegrating test device contains 6 glass tubes which are 3 inches long, open at the top and held against a 10 mesh screen at the

lower end of the basket frame assembly. To evaluate the disintegration time, a tablet is placed in each tube and the rack is placed in a 1 liter beaker of water, a glycine buffer of pH 3 at body temperature, so that the tablet remains 2.5 cm below the surface of the liquid in its upward movement and descend to less than 2.5 cm from the bottom of the beaker. A standard motor device is used to move the basket assembly containing the tablet up and down a distance of 5-6 cm at a frequency of 28 to 32 cycles per minute. To comply with USP standards, tablets must disintegrate and all particles must pass through a 10 mesh screen at the specified time [(28)].

Dissolution test:

The expansion of dissolution methods for ODT is similar to the approach implemented for traditional tablets and is practically same. The dissolution conditions of the drugs registered in a Pharmacopoeia monograph, is a noble place to start the investigation runs for a bioequivalent ODT. It has been recommended that USP type 2 (paddle type) apparatus is the most suitable and common option for oral disintegration tablets, with a commonly used 50-rpm paddle speed [(22)].

Accelerated stability study:

The dispersible tablets are packed in appropriate packing and kept under the following condition for a period as prescribed by ICH guideline for accelerated studies: 40±2°C, 50±2°C, 37 ± 2°C and Relative Humidity = 75%± 5% .

The tablets are withdrawn after a period of specified time and analyzed for physical characterization (Friability, Hardness, Dissolution Disintegration and other Visual defects) and drug content. The data obtained is fitted into first order equation to determine the kinetics of degradation [(33)(34)].

g) Future Directions

The studies conducted in this thesis have introduced two new concepts for the development of effective rapid dispersion tablets. The studies conducted in this thesis reveal that further progress can be made in the development of rapidly dispersed tablets through the exploration of new materials, innovative formulation processes and noel applications. The future perspectives of this dosage form will depend on:

- The development of a moisture protective novel RDT formulation with a promising stability comparable to the conventional compressed tablet and, consequently, avoids the need for

specialized packaging. This is a challenging task because of the highly porous nature of the rapid dispersible tablets.

- There are several methods and studies already performed, such as the use of the analyzer. But none of these has been officially recognized by regulatory authorities such as the British Pharmacopoeia and the European Pharmacopoeia.
- The use of co-processed excipients and the new concept of producing rapidly dispersible tablets to further improve the wetting and release profile of tablets. The use of multifunctional excipients in the co-processing of the excipients also reduces the existing drawbacks of the tablets (Saha & Shahiwala, 2009). Basically, the co-processed excipients must be rapidly dissolved in water to allow an easy formulation, possess a high wettability in a aqueous medium to allow rapid disintegration and form elegant tablets with adequate mechanical strength.

CONCLUSIONS

At the present time these tablets are gaining more significance in pharmaceutical industry directing especially pediatrics, geriatrics and all age groups. Dispersible tablets have potential advantages over conventional dosage forms, with better patient compliance; convenience, bioavailability and speed of action have attracted the attention of many manufacturers for a decade. Although extensive research has been conducted on the development of the formulation and technologies for dispersible tablets, in this promising area, more intensive research will be conducted to obtain more profitable technologies and better products. The basic method followed by all available dispersible tablets technologies is to capitalize on the porous structure of tablet matrix to attain disintegration of the tablet in the oral cavity together with good mechanical strength and excellent taste masking properties.

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