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ORAL DISINTEGRATION TABLETS – AN UPDATED REVIEW

[1]Swarupa Arvapalli[*], [2]D. Swamy, [3]Shyamala

[1]Joginpally B.R Pharmacy College, Moinabad, Hyderabad.

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Abstract:

The purpose of writing this review is Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance. It is leads to development of orally disintegrating tablets. This disintegrates in the mouth in seconds without chewing and the need of water which is advantageous mainly for pediatrics, geriatrics and patients having difficulty in swallowing tablets and capsules. The prepared tablets were evaluated for hardness, friability, disintegration time and in vitro drug release ODTs are solid dosage forms containing medicinal substances which disintegrate rapidly, usually in a matter of seconds, when placed on the tongue. The aim of this article is to review the development of ODTs, challenges in formulation, new ODT technologies and evaluation methodologies, suitability of drug candidates, and future prospects.

Key words: *Orally disintegrating tablet, Oral route, Excipients.*

Corresponding author:

Swarupa Arvapalli,

Joginpally B.R Pharmacy College, Moinabad, Hyderabad.

Email: rupa03arvapalli@gmail.com

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INTRODUCTION [1]

Oral drug delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, the most convenient and most economical method of drug delivery with the highest patient compliance.

Oral route is the most preferred route of administration and tablet and capsules are the most preferred dosage forms, but several limitations of that kind of dosage forms like chocking and swelling discomfort in geriatric and pediatric patients. Orally disintegrating tablets have been developed and new ODT technologies compensate many pharmaceuticals and patients' needs, ranging from enhanced life-cycle management to convenient dosing for pediatric, geriatric, and psychiatric patients with dysphasia .Over the past three decades, orally disintegrating tablets (ODTs) have gained considerable attention as a preferred alternative to conventional tablets and capsules due to better patient compliance . ODTs are being named as orodispersible, rapid-dissolving, mouth-dissolving, rapid-disintegrating tablets. There are some definitions that made by pharmacopeias and agency as follows: Orodispersible tablets have been placed in the mouth where they disperse fast before being swallowed and they are uncoated tablets. Orodispersible tablets disintegrate within 180 seconds when the disintegration tests have been conducted up to the test for disintegration of tablets.

For most therapeutic agents used to produce systemic effects, the oral route still represents the preferred way of administration, owing to its several advantages and high patient compliance compared to many other routes2 . Tablets and hard gelatin capsules constitute a major portion of drug delivery systems that are currently available. However, many patient groups such as the elderly, children, and patients who are mentally retarded, uncooperative, nauseated, or on reduced liquid-intake/diets have difficulties swallowing these dosage forms.

Although chewable tablets have been on the market for some time, they are not the same as the new ODTs. Patients for whom chewing is difficult or painful can use these new tablets easily. ODTs can be used easily in children who have lost their primary teeth but do not have full use of their permanent teeth.

Recent market studies indicate that more than half of the patient population prefers ODTs to other dosage forms10 and most consumers would ask their doctors for ODTs (70%), purchase ODTs (70%), or prefer ODTs to regular tablets or liquids (>80%)

MECHANISMS OF ODTs [2]

ODTs involve the following mechanisms to achieve the desired fast dissolving characteristics:

1. Water must quickly enter into the tablet matrix to cause rapid disintegration and instantaneous dissolution of the tablet.
2. Incorporation of an appropriate disintegrating agent or highly water soluble excipients in the tablet formulation.
3. There are some under mentioned mechanisms by which the tablet is broken down into the smaller particles and then subsequently result a solution or suspension of the drug. The mechanisms are-

- High swellability of disintegration
- Chemical reaction
- Capillary action

Advantages of ODTs[3]

- No need of water to swallow the tablet.
- Compatible with taste masking and have a pleasing mouth feel.
- Can be easily administered to paediatric,
- elderly and mentally disabled patients.
- No residue in the oral cavity after administration.
- Manufacturing of the tablets can be done using conventional processing and packaging equipments at minimum cost.
- Allow high drug loading.
- Accurate dose can be given as compared to liquids.
- Dissolution and absorption of the drug is fast, offering a rapid onset of action.
- Advantageous over liquid medication in terms of administration as well as transportation.

Disadvantages of ODTs[3]

- ODT is hygroscopic in nature so must be keep in dry place
- Some time it possesses mouth feeling.
- It is also shows the fragile, effervescence granules property.
- ODT requires special packaging for properly stabilization &
- safety of stable product.

Significance of ODTs [6],[10],[28]

ODTs offer dual advantages of solid dosage forms and liquid dosage forms along with special features which include:

- Accurate dosing: Being unit solid dosage forms, provide luxury of accurate dosing, easy portability and manufacturing, good physical and

chemical stability and an ideal alternative for pediatric and geriatric patients.

- Enhanced bioavailability: Bioavailability of drugs is enhanced due to absorption from mouth, pharynx and esophagus.
- Rapid action: Fast onset of therapeutic action as tablet gets disintegrated rapidly along with quick dissolution and absorption in oral cavity.
- Patient compliance: No need of water to swallow the dosage form. Hence, it is convenient for patients who are traveling and do not have immediate access to water. • Ease of administration: Convenient to administer specially for geriatric, pediatric, mentally disabled and bed ridden patients who have difficulty in swallowing.
- Obstruction free: No risk of suffocation in airways due to physical obstruction when swallowed, thus providing improved safety and compliance.
- Enhanced palatability: Good mouth feel, especially for pediatric patients as taste masking technique is used to avoid the bitter taste of drug.

Ideal characteristics of ODTs[25],[26]

ODTs should depict some ideal characteristics to distinguish them from traditional conventional dosage forms. Important desirable characteristics of these dosage forms include:

- No water requirement for swallowing purpose but it should dissolve or disintegrate in the mouth usually within fraction of seconds.
- Provide pleasant feeling in the mouth.
- Be compatible with taste masking.

Limitations of ODTs[4]

- The tablets commonly have insufficient mechanical strength. Hence, conscientious handling is necessary.
- The tablets may leave an unpalatable taste and grittiness in the oral cavity if not formulated properly.
- Drugs which have large doses, can cause problems to formulate them into ODTs.
- Patients who simultaneously take anticholinergic drugs are not suitable candidates for ODTs

Bioequivalence[5],[6]

Bioequivalence of ODTs has some challenges but in this part basic solutions to overcome these challenges were given. Active pharmaceutical ingredients that are formulated as ODTs should be dispersed or dissolved in the saliva, then directly absorbed via oral mucosa and/or absorbed through the gastrointestinal system. When defining the dissolution test conditions to prove both of the in-vitro and in-vivo bioequivalence of two formulations, the physiological conditions of the mouth should be considered. pH, flow rate, volume of the saliva and targeted population are the important factors that should be considered.

There are several in-vivo studies for ODTs that conducted to prove bioequivalence of the ODTs, nevertheless BCS based biowaiver is also being considered for especially the active pharmaceutical ingredients are not absorbed via oral mucosa, but must be absorbed through the gastrointestinal system. But if this cannot be demonstrated, bioequivalence must be evaluated via in-vivo studies

If the ODT is a generic/hybrid to an approved ODT reference medicinal product, the following recommendations regarding study design apply:

- If the reference medicinal product can be taken with or without water, bioequivalence should be demonstrated without water as this condition best resembles the intended use of the formulation. This is especially important if the substance may be dissolved and partly absorbed in the oral cavity. If bioequivalence is demonstrated when taken without water, also bioequivalence can be assumed with ODT taken with water.
- If the reference medicinal product is taken only in one way (e.g. only with water), bioequivalence should be shown in this condition (in a conventional two-way crossover design).
- If the reference medicinal product is taken only in one way (e.g. only with water), and the test product is intended for additional ways of administration (e.g. without water), the conventional and the new method should be compared with the reference in the conventional way of administration (3 treatment, 3 period, 6 sequence design). In studies evaluating ODTs without water, it is recommended to wet the mouth by swallowing 20 ml of water directly before applying the ODT on the tongue. It is recommended not to allow fluid intake earlier than 1 hour after administration

Formulation Development of ODTs[7],[19]

Selection of active pharmaceutical ingredient is one of the most important parameters to formulate ODTs. It should be dissolved in the oral cavity and absorbed. Also it shouldn't have bitter taste. It is better if it is in low dose, small to moderate molecular weight, good solubility in water and/or saliva, non-ionized property in pH 5.5-7.4 and ability to be absorbed via oral mucosa.

Excipient selection is important for disintegrating the tablet immediately and also important for masking bitter taste. Main excipient groups are diluents; disintegrants that have different disintegrate mechanisms, flavors, and taste masking agents, sweeteners, binders, lyoprotectants, glidants and lubricants. To accomplish the challenges, specific excipients can be used in different ranges.

TECHNIQUES FOR PREPARATION OF ODTs[7]

The fast dissolving property of the ODTs requires quick ingress of water into tablet matrix thus requires some basic approaches such as maximizing the porous structure of the tablet, incorporation of suitable disintegrating agent and use of highly water-soluble excipients in the formulation. Excipients use in ODTs contain at least one superdisintegrant (having mechanism of wicking, swelling or both), a diluent, a lubricant and optionally a swelling agent, a permeabilizing agent, sweeteners and flavorings.

Various preparation techniques have been developed on the basis of different principles, thus present different properties of ODTs by means of mechanical strength, stability, mouth feel, taste, swallowability, dissolution profile and bioavailability.

Freeze drying/ Lyophilization [9]

This process is based on solvent removal from a frozen drug solution or suspension which contains structure forming excipients. The process generally resulted as very light and highly porous form in nature.

Spray drying[8]

This process is based upon to use of a particulate support matrix prepared by spray drying. Support matrix and other components containing aqueous composition form a highly porous and fine powder, then disintegration and dissolution improve by adding effervescent components and finally spray dried to yield a porous powder.

Molding [9]

This process is achieved by using water soluble ingredients mostly sugars. Drug and excipients powder blend is pushed through a very fine screen then moistened with a hydroalcoholic solvent and moulded into tablets under pressure, the process ended by evaporating of the solvent by air drying.

Phase transition process [8]

In this process, tablets which contain sugar alcohols having high and low melting points are prepared by compressing; following heating to enhance bonding among particles resulted as sufficient hardness of tablets.

Melt granulation[10]

In this process powders are efficiently agglomerated by the use of binder which can be liquid or melting during the process by using high shear mixers, and temperature is raised above the melting point of the binder.

Sublimation[11]

For accomplishing this process some inert volatile substances like urea, camphor etc. is added to other tablet excipients and blend is compressed into tablet. Subsequently removal of volatile substances by sublimation generates a porous structure.

Mass extrusion[11]

This process based on softening of the active blend by using a solvent mixture of water soluble polyethylene glycol and methanol. Following expulsion of softened mass through the extruder or syringe to get a cylindrical shaped, they cut into segments by using heated blade to form tablets.

Patented technologies for orally disintegrating drug delivery system[12]

The various technologies are developed for the preparation of Orally Disintegrating Drug Delivery System that are:

- Zydis
- Lyoc
- Wowtab
- Flashtab
- Durasolv
- Orasolv
- Frosta
- AdvaTab
- Flashdose
- OraQuick
- Nanocrystal Technology
- Quick-Dis Technology
- EFVDAS
- Fast Melt
- Multiflash

Zydis® (Cardinal Health Inc.) [12]

Zydis® was first marketed technology and introduced by R. P. Scherer Corporation (Cardinal Health, Inc.) in 1986. Zydis tablet is produced by lyophilizing the drug in a matrix usually consisting of gelatin. The product is very lightweight and fragile and must be dispensed in a special blister pack. Zydis formulation is also self-preserving because the final water concentration in the

freeze-dried product is too low to allow for microbial growth

Disadvantages to the Zydis® technology-

- Relatively expensive & time consuming manufacturing process.
- Formulation is very lightweight and fragile.
- Poor stability at higher temperatures and humidity & stress conditions.
- A water insoluble drug can be incorporated only upto 400 mg per tablet or less. On the other hand water soluble drug can be incorporated only upto 60 mg.

The preferred drugs are water insoluble, low dose, chemically stable, small particle size and tasteless. The two most commonly used structural additives are gelatin and mannitol. Some other structural additives (e.g., starches, gums etc.) may be used depending on the properties of the active ingredient. The best physical characteristics are achieved by using a mixture of a water-soluble polymer and a crystalline sugar alcohol or amino acid. The polymer gives the strength and resilience while the crystalline component gives the hardness and texture. Polymers such as gelatin, dextran or alginates are added to impart strength during handling. These form a glossy and amorphous structure. Mannitol or sorbitol is added to impart crystallinity, elegance and hardness. Various gums may be added to prevent sedimentation of dispersed drug particles. Water is used as a medium to ensure the formation of a porous dosage form. Collapse protectants like glycine may be used to prevent shrinkage of dosage form during freeze drying and long-term storage. If necessary, suspending agents and pH adjusting agents may be used.

Lyoc (Cephalon Corporation)[12]

Lyoc technique was owned by Cephalon Corporation. Lyoc utilizes a freeze drying process but differ from Zydis in that the product is frozen on the freeze dryer shelves. The liquid solution or suspension preparation evolves fillers, thickening agents, surfactant, non-volatile flavoring agents and sweeteners along with drug. This homogeneous liquid is placed in blister cavities and subjected to freeze drying. To prevent inhomogeneity by sedimentation during this process, these formulations require a large proportion of undissolved inert filler (mannitol), to increase the viscosity of the inprocess suspension. The high proportion of filler reduces the potential porosity of the dried dosage form and results in denser tablets with disintegration rates are comparable to loosely compressed fast melt formulations.

Wowtab (Yamanouchi Pharma Technologies, Inc.) [12]

Wowtab technology was developed by Yamanouchi Pharma Technologies. 'Wow' means ' without water'. The active ingredients may constitute upto 50% w/w of the tablet. Here, saccharides of both low and high Moldability are used to prepare the granules. Moldability is the capacity of a compound to be compressed. Highly Moldable substance has high compressibility and thus slow dissolution. The combination of high and low Moldability is used to produce tablets of adequate hardness & a rapidly melting strong tablet. Active ingredients are mixed with low Moldability saccharides and then granulated.

Wowtab product can be packed in both into conventional bottle and blister packs. This technology utilizes conventional granulation and tableting methods and used for both water-soluble and insoluble drugs. The manufacturing process involves granulating low-moldable sugars (e.g.mannitol, lactose, glucose, sucrose, and erythritol) that show quick dissolution characteristics with high moldable sugars (e.g. maltose, maltitol, and sorbitol). The result is a mixture of excipients that have fast-dissolving and highly moldable characteristics.

Flashtab (Prographarm) [12],[15]

Flashtab was developed by Prographarm. A disintegrating agent and a swelling agent are used in combination with coated taste-masked microgranules of drug. FlashTab involves coating a drug with a Eudragit polymer to provide rapid release of the drug in the stomach, and formulating this microencapsulated drug with an effervescent couple to produce a flash dispersal tablet. This technology includes granulation of excipients by wet or dry granulation method followed by compression into tablets. Disintegrating agents include polyvinylpyrrolidine or carboxy methyl cellulose and Swelling agents include carboxymethylcellulose, starch, modified starch, microcrystalline cellulose, carboxy methylated starch etc. These tablets have satisfactory physical resistance. Tablets containing hygroscopic materials can also be blister packed using high quality polyvinyl chloride or aluminum foils for providing the higher degree of moisture protection than normal polyvinyl chloride or polypropylene foils.

Durasolv (Cima Labs, Inc.)[12]

DuraSolv is Cima's second-generation fast-dissolving/disintegrating tablet formulation. DuraSolv has much higher mechanical strength than Orasolv due to the use of higher compaction pressures during tableting. DuraSolv product is thus produced in a

faster and more cost-effective manner. DuraSolv is so durable that it can be packaged in either traditional blister packaging or vials. This technology is not compatible with larger doses of active ingredients, because the formulation is subjected to such high pressures on compaction. Unlike OraSolv, the structural integrity of any taste masking may be compromised with high drug doses. The drug powder coating in DuraSolv may become fractured during compaction, exposing the bitter-tasting drug to a patient's taste buds. Therefore, DuraSolv technology is best suited for formulations including relatively small doses of active compound. The tablets made by this technology consist of a drug, fillers and a lubricant and prepared by using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Due to higher force of compaction used, tablets prepared are rigid.

Orasolv (Cima Labs, Inc.) [17]

Orasolv® is Cima's first orally disintegrating dosage form. It based on direct compression of an effervescent agent and taste masked drug. The use of effervescence causes a tablet to disintegrate rapidly in less than 1 min on contact with water or saliva leaving coated drug powder. This technique is frequently used to develop over the counter formulations. This technology can accommodate a wide range of active ingredient from 1 mg to 500 mg. The effervescence occurs due to chemical reaction between organic acid such as citric acid, fumaric acid or maleic acid and a base such as sodium bicarbonate, potassium bicarbonate, magnesium bicarbonate, which result in generation of CO2.

Effervescent disintegration agents evolve gas by means of chemical reaction called effervescent couple. Carbonates such as sodium bicarbonate, sodium carbonate, potassium bicarbonate and potassium carbonate, magnesium carbonate, and acids like citric, tartaric, fumaric, adipic and succinic are used. Microparticles, effervescent agents and other ingredient such as flavors, sweeteners, colorants and lubricants are blended and compressed at a low degree of compaction.

Frosta (Akina) [19]

It utilizes the concept of formulating plastic granules and compressing them at low pressure to produce strong tablets with high porosity. Plastic granules composed of porous and plastic material, water penetration enhancer, and binder. The process involves mixing the porous plastic material with water penetration enhancer followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30 sec depending on size of tablet.

Flashdose (Fuisz Technologies, Ltd.)[13].[14]

This technology is patented by Fuisz. This uses the combination of Shearform and Ceform technologies in order to mask the bitter taste of the drug.

A sugar based matrix, called 'Floss', which is made up of a combination of crystalline sugars alone or in combination with drugs, is used. Floss is self binding shearform matrix, which is prepared by flash heat processing. FlashDose technology utilizes a unique spinning mechanism to produce a floss-like crystalline structure, much like cotton candy. This crystalline sugar can then incorporate the active drug and be compressed into a tablet. This procedure has been patented by Fuisz and is known as Shearform. It disperses and dissolves quickly. The method has certain drawbacks like the dosage form can accommodate only up to 600 mg of drug and tablets required specialized packing as highly friable, soft and moisture sensitive nature.

Instead of a floss-like material, small spheres of saccharides can be produced to carry the drug. The process of making microspheres has been patented by Fuisz, and is known as Ceform and serves as an alternative method of taste masking. Ceform technology involves preparation of microspheres of the active drug. Drug material alone or in combination with other pharmaceutical substances, and excipients is placed into a rapidly spinning machine. The centrifugal force comes into action, which throws the dry drug blend at high speed through small heated openings. Due to the heat provided by carefully controlled temperature, drug blend liquefies to form a sphere, without affecting the drug stability. The formed microspheres are compressed into tablet. This technique effectively masked the taste of product.

OraQuick (KV Pharmaceutical Co., Inc.) [20]

OraQuick utilizes its own patented taste masking technology i.e. MicroMask®. In MicroMask® technology, taste masking process is done by incorporating drug into matrix microsphere. In this technique, tablet is prepared by dissolving the sugar (sucrose, mannitol, sorbitol, xylose, dextrose, fructose or mannose) and protein (albumin or gelatin) in a suitable solvent such as water, ethanol, isoproryl alcohol and ethanol-water mixture. The solution of matrix is then spray dried, yielding highly porous granules. Also, utilization of lower heat of production is advantageous for heat-sensitive drugs. Granules

formed then mixed with drug and other excipients and compressed at low compression force. KV pharmaceuticals claimed that matrix formed protects and surrounds the drug powder in microencapsulated particles is more reliable during this step.

Nanocrystal Technology (Elan corporation) [(21), (23)]
This technology is based on concept that decreasing particle size increases the surface area, which leads to an increase in dissolution rate. NanoCrystal particles are small particles of drug substance, typically less than 1000 nm in diameter, which are produced by wet milling the drug.

NanoCrystal™ fast dissolving technology provides for:

- Pharmacokinetic benefits of orally administered nanoparticles (<2 microns) in the form of a rapidly disintegrating tablet matrix.
- Product differentiation based upon a combination of proprietary and patent-protected technology elements.
- Cost-effective manufacturing processes that utilize conventional, scalable unit operations.
- Exceptional durability, enabling use of conventional packaging equipment and formats (i.e., bottles and/or blisters).
- Wide range of doses (up to 200mg of API per unit).
- Utilization of non-moisture sensitive inactives.

Quick-Dis Technology (Lavipharm) [(24)]
Lavipharm Laboratories Inc. has invented an ideal intraoral fast-dissolving drug delivery system called as Quick-Dis™. This is a thin, flexible, and quick-dissolving film. The film is placed on the top or the floor of the tongue. It is retained at the site of application and rapidly releases the active agent for local and/or systemic absorption. The Quick-Dis™ drug delivery system can be provided in various packaging configurations, ranging from unit-dose pouches to multiple-dose blister packages. Disintegration time is only 5 to 10 seconds for the Quick-Dis™ film with a thickness of 2 mm. The dissolving time, which is defined as the time at which not less than 80% of the tested film is dissolved in aqueous media, is around 30 seconds for Quick Dis™ film with a thickness of 2 mm. The typical release profile of an active ingredient exhibited by a Quick-Dis™ drug delivery system is 50% released within 30 seconds and 95% within 1 minute [46].

EFVDAS (Elan Corporation) [(23)]
EFVDAS or Effervescent Drug Absorption System is a drug delivery technology that has been used in the development of a number of both OTC and prescription medications. This is particularly advantageous for conditions such as colds and flu, for which Elan has modified its EFVDAS technology to develop hot drink sachet products that combine medicines and vitamins for OTC use. The granular contents of the sachets can be added to boiling water to produce pleasant-flavored solutions. In these cases the effervescence of the granulate mixture is modified to accommodate the use of heated water. Examples of products that Elan has developed include effervescent ibuprofen, acetaminophen, cimetidine, naproxen, and acetaminophen and codeine combination product.

Fast Melt (Elan Corporation) [(16),(15)]
It is a highly porous, microfine matrix tablet. Once placed on the tongue, this matrix rapidly absorbs liquid and disintegrates. The drug, in a stabilized, size-reduced form to ensure optimal solubility, dissolves rapidly. The combination of a mild effervescent base and drug processing ensures that the dosage form goes into solution in approximately 15 to 30 seconds. The drug is released rapidly within the oral cavity, where it dissolves to form a drug solution that is then swallowed. This is particularly advantageous in cases like migraine where a fast onset of clinical effect is required. A portion of the drug solution may be absorbed locally in the oral cavity and therefore may avoid first-pass metabolism in the liver that limits the bioavailability of many drugs. The fast-melt system rapidly disintegrates in the oral cavity; hence, patients do not have to swallow a large cumbersome dosage form, which discourages many from taking their medication. Thus, the fast-melt dosage form combines the benefits of liquid formulations with those of a solid oral dosage form.

Multiflash (Prographarm) [(18)]
Multiflash is a multi-unit tablet composed of coated microgranules and fast-disintegrating excipients. This multiparticulate tablet quickly disintegrates in the esophagus after being swallowed with a minimum amount of water. This tablet avoids mucosal adhesion, and coated pellets can match various dissolution rates.

Cotton candy process[(21)]
This process based on formation of matrix of polysaccharides or saccharides which are partially recrystallized and attain better flow properties and compressibility by concurrent action of flash melting and spinning. Then matrix is milled and blended with active ingredients and excipients, soon after compressed to form tablets.

Direct compression [20]

The basic principle of this technique is addition of superdisintegrants in optimum concentrations to tablet formulation in which powdered blend compress directly to form tablets.

CONCLUSION:

As a conclusion orally disintegrating tablets have many advantages compared with the other oral dosage forms, such as better bioavailability, better patient compliance, and improved efficacy. Nevertheless formulation challenges such as limited tablet weight, disintegration time, friability, manufacturing technology, and packaging should be considered. Orally disintegrating tablets may be evaluated as a first choice for pediatrics and geriatrics –situations that parenteral cannot be used especially for central nervous system, gastrointestinal system disorders and pain.

This dosage form has been formulated for existing drugs for extending the patent life of the drug and also for granting the new patent. Majority of drugs can be formulated as orodispersible tablets. The safety and efficacy profile of drugs in orodispersible tablet is same like their conventional tablet dosage form. Based on conventional techniques, new techniques are developed like Zydis, WowTab, Orasolv and many more, which leads to getting a patent and new market strategy for orodispersible tablets. This dosage form are gaining market share day by day and becoming a better choice of acceptance.

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