ORODISPERSIBLE TABLETS AND IT’S TECHNOLOGIES: A REVIEW

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ABSTRACT
Recent development in the oral administration of medicinal substances comprises of various technologies, many of which may be classified as oral dispersible tablets for the past few years, oral dispersible tablets have become popular than conventional tablets and capsules as well as acknowledge as new drug delivery system due to better patient compliance. ODTs are oral solid dosage forms that quickly disintegrates inside the mouth and thus swallowed easily without the intake of water. ODTs are useful for elderly, pediatric, geriatric patients who have difficulty in swallowing conventional solid dosage forms. A large number of companies prefer ODTs over other delivery technologies because it is less risky delivery option to formulate. The present review is focused on new ODTs technologies, suitability of drug candidates and overview of formulations.

KEYWORDS: orodispersible tablets, direct compression, spray drying, patented technologies, conventional technologies.

INTRODUCTION
Drug delivery system is process or method of pharmaceutical compound administration for achieving therapeutic effects in humans and animals. Oral drug delivery system consists of the steady delivery of measurable and reproducible amount of drug to the target site over a prolonged period Consists mostly solids and based on dissolution, diffusion or combination
of both mechanisms in the control of release rate of drugs. The most popular solid dosage forms are being tablets and capsules; one important drawback of this dosage forms for some patients, is the difficulty to swallow. Drinking water plays an important role in the swallowing of oral dosage forms. Often times people experience inconvenience in swallowing conventional dosage forms such as tablet when water is not available, in the case of the motion sickness (kinetics) and sudden episodes of coughing during the common cold, allergic condition and bronchitis.¹

For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Oro dispersible tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people. Orodispersible tablets are also called as melt-in mouth tablets, fast dissolving tablets, fast melting tablets, mouth-dissolving tablets, rapimelts, porous tablets, quick dissolving, rapid disintegrating tablets etc. Orodispersible tablets (ODTs) are those when put on tongue disintegrate instantaneously releasing the drug which dissolve or disperses in the saliva.²

Their growing importance was underlined recently when European pharmacopoeia adopted the term “Oro dispersible tablet” as a tablet that to be placed in the mouth where it disperses rapidly before swallowing. According to European pharmacopoeia, the ODT should disperse disintegrate in less than three minutes.³

United States food and drug administration (FDA) Center of drug evaluation and research (CDER) defines orodisinterating tablets in the orange book as A solid dosage form which contains a medicinal substance or active ingredients which disintegrates quickly within a matter of seconds when put on the tongue. The faster the drug into solution, quicker the absorption and onset of clinical effect some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablets dosage form. The advantage of mouth dissolving dosage forms is increasingly being recognized in both, industry and academics.⁴

As a result of increased life expectancy, the elderly now make up a significant portion of the global population. The physiological and physical capacities of these individuals can deteriorate over time. The bioavailability of some drugs may be increased due to absorption of drug in oral cavity and also due to pre-gastric absorption of saliva containing dispersed
drugs that pass down into the stomach additionally, the amount of drug that is subjected to first pass metabolism is decreased as compared to standard tablet

Criteria for Fast dissolving Drug Delivery System
The tablets can dissolve or disintegrate in the mouth in a matter of seconds without the need for water. Compatibility with taste masking is a must. Be compact without being fragile. Get a good taste in your mouth. After oral administration, there should be little to no residue in the mouth. High sensitivity to environmental factors including temperature and humidity. Allow for low-cost tablet production using traditional processing and packaging equipment.

Advantages of ODTs
1. Improved patient compliances.
2. No water needed for swallowing.
3. No Chewing needed.
4. Superior therapeutic benefit.
5. It allows high drug loading.
7. Better taste obtained by the taste masking.
8. Ease of administration by patients.

First generation ODTs
While first-generation ODT technologies produce tablets that dissolve quickly in the mouth, provide convenience and ease of swallowing, and have had market success, some of them fall short in terms of taste masking and the ability to accommodate high doses. Additionally, because most first-generation technologies can only handle small amounts of APIs, their therapeutic applications are limited and are only used in applications that require immediate release. High porosity, low density, and low hardness are common characteristics of first-generation ODTs, making them brittle and difficult to handle. As a result, blister packaging is frequently required, which is less convenient for patients than bottles and comes with high production costs. Freeze-dried ODTs are particularly brittle, making conventional packaging difficult and raising concerns about storage stability.

Furthermore, with first-generation ODTs, it is difficult to mask bad-tasting APIs with traditional flavours and sugars, limiting their application to non-bitter APIs. Instead of neutralising the taste, flavouring and sweetening agents are commonly used to overpower it.
Only a few technologies on the market today provide effective taste masking, which necessitates a physical barrier between the API and the taste buds. Coacervation (encapsulation) is one of these techniques. Pharmaceutical companies are looking for more capabilities from ODTs as the market matures. Higher API loading, more effective taste masking, controlled release capability, low friability, cost-effective development, and more packaging options are some of these benefits.

**New generation of ODTs**

A new generation of ODTs is now available that can be combined with a proprietary process to improve taste masking, allow for a modified release profile, and increase bioavailability. As a result, formulators can mask even the most unpleasant-tasting drugs, use high API doses, and broaden the range of therapeutic applications.

These ODTs are made up of microgranules that disperse quickly, a direct compression blend, and an external tablet lubrication method. As a result, an ODT with outstanding mouthfeel, physical robustness, and disintegration properties has been created. The tablets dissolve in 15 to 30 seconds (depending on dosage strength) and produce a smooth, pleasant-tasting API granule-carrier mixture that is easy to swallow. The tablets are printed on both sides and can be packaged in bottles or blister packs. They are made on standard presses and have a friability of less than 0.5 percent. Microencapsulation in combination with ODT technology effectively masks bitter APIs and can be used on soluble and poorly soluble substances, as well as high-dose products.

Coacervation, a coating technique that completely encapsulates individual drug particles and provides superior taste masking, is one of the technologies used. The coacervation process coats dry crystals or granules with a uniform coating of polymeric membranes of varying thicknesses and porosities, resulting in particles that are typically 150 to 300 microns in size. Between the API and the taste buds, the membranes create an inert barrier, as well as a stabilisation barrier between the API and the tablet excipients.

This coacervation technique has been used to mask the taste of a variety of extremely unpleasant drugs, including ranitidine (for gastroesophageal reflux disease), cetirizine (for allergic rhinitis), zolpidem (for insomnia) and sumatriptan (for migraines).
Controlled release ODTs with sustained, modified, and customised release profiles can be created by combining ODTs with specialised functional polymers and coating processes. Even multiple release profiles can be combined in a single dose. Micro-encapsulation and multiparticulate coating technologies are examples of these approaches, which allow formulators to create modified release polymer layers around API particles. These particles are small enough to provide good mouthfeel while remaining flexible enough to withstand compression without breaking or losing their modified release properties. The desired plasma profile is changed by adjusting the coating parameters (thickness, composition, porosity, pH modifying agents, and number of layers).[5,6,7,8]

Conventional Technologies for Oro-Dispersible Tablets

Spray drying
In this technique, gelatine can be used as a supporting agent and as a matrix, Mannitol as a bulking agent and sodium starch Glycolate or Crosspovidone are used as Superdisintegrants. In an aqueous medium, tablets made from spray-dried powder disintegrated in less than 20 seconds. The formulation included bulking agents such as mannitol and lactose, as well as superdisintegrants such as sodium starch glycolate and croscarmellose sodium, as well as acidic and/or alkaline components (citric acid) (e.g. sodium bicarbonate) This spray-dried powder demonstrated accelerated disintegration and improved dissolution when compressed into tablets.

Nanonization
A new advanced Nano melt technology consists of milling the drug using a patented wet-milling process to reduce the particle size to Nano size. Surface adsorption on chosen stabilisers prevents agglomeration of the drug's nanocrystals, which are then inserted into FDTs. This method is particularly useful for medicines that are poorly water soluble. Quick disintegration/breakdown of Nanoparticles leads to greater absorption and hence higher bioavailability and dosage reduction, cost-effective production operation, traditional packaging due to exceptional longevity, and a wide variety of doses (up to 200 mg of drug per unit) are some of the other benefits of this technology.[9]

Lyophilization or Freeze-drying
The formation of porous products during the freeze-drying process is used to formulate ODTs. Lyophilization is a procedure that involves the following steps-solvent removal from a frozen suspension or drug solution with structure-forming additives The combination of
freeze-drying the drug and adding additives results in a shiny amorphous structure that is highly porous and lightweight. When put on the tongue, the resulting tablet has rapid disintegration and dissolution, and the freeze-dried product dissolves instantly to release the drug. The ODTs generated by lyophilization, on the other hand, have low mechanical strength, temperature stability, and humidity stability.\textsuperscript{[10]}

**Molding**

Molded tablets are made up of solid dispersion. Because the dispersion matrix is usually made of water soluble sugars, moulded tablets disintegrate faster and have a better taste. In most cases, the active ingredient is absorbed through the mucosal lining of the mouth. Molding tablets involves moistening the powder blend with a hydroalcoholic solvent before pressing it into mould plates to form a wetted mass (compressing molding) after that, the solvent is removed by air drying. As a result, the procedure is similar to that used in the production of tablet triturates. Compressed tablets with a porous structure that speeds up dissolution are less compact than these tablets. A heat moulding process is also used to create moulded forms, which involves forming a molten mass containing a dispersed drug. To make tablets, the heat-molding process uses an agar solution as a binder and blister packaging as a mould. Preparing a suspension containing a drug, agar, and a sugar (e.g., mannitol or lactose), pouring the suspension into the blister packaging well, and allowing the agar solution to solidify at room temperature to form a jelly, and drying at -300C under vacuum are all steps in the process. No-vacuum lyophilisation, which involves evaporating a solvent from a drug solution or suspension at standard pressure, is another method used. In a tablet-shaped mould, Pebley et al. evaporated a frozen gum mixture (e.g., acacia, carageenan, guar, tragacanth, or xanthan), a carbohydrate (e.g., dextrose, lactose, maltose, mannitol, or maltodextrin), and a solvent. The mechanical strength of moulded tablets is usually low. During the handling and opening of blister packs, the moulded tablet is frequently eroded and broken.\textsuperscript{[11]}

**Sublimation**

The presence of a porous structure in the tablet matrix is essential for rapid disintegration of mouth dissolving tablets. Because of the low porosity of the matrix, traditional compressed tablets containing highly water soluble ingredients frequently fail to dissolve quickly. As a result, volatile ingredients are used to create porous matrix, which are then subjected to a sublimation process. In this method, a subliming material such as camphor is removed from compressed tablets by sublimation, the formation of many pores where camphor particles
previously existed in compressed tablets prior to camphor sublimation results in high porosity. These compressed tablets dissolved in saliva in 15 seconds due to their high porosity (approximately 30%). Wet granulation was used to create granules containing nimusulide, camphor, crospovidone, and lactose. Vacuum exposure was used to sublime camphor from dried granules. Dry granulation, wet granulation, and direct compression with highly soluble excipients, super disintegrants, and/or effervescent systems are some of the other methods that can be used.\[12\]

Cotton candy process
This process gets its name from the fact that it uses a special spinning mechanism to create floss-like crystalline structures that look like cotton candy. The simultaneous action of flash melting and spinning results in the formation of a matrix of polysaccharides or saccharides in the cotton candy process. To improve flow properties and compressibility, the matrix is partially re-crystallized. After milling and blending with active ingredients and excipients, the candy floss matrix is compressed into ODTs.\[13\]

Mass extrusion
This technology involves softening the active blend with a solvent mixture of water soluble polyethylene glycol and methanol, then, using a heated blade, extruding or syringing the softened mass through an extruder or syringe into even segments to form tablets. The dried cylinder can also be used to coat bitter-tasting drug granules, enhancing their bitterness.\[14\]

Direct compression
It is the easiest method of producing tablets. Direct compression uses standard equipment, widely available excipients, and a small number of processing steps. In addition, high doses can be accommodated, and the final weight of the tablet can easily exceed that of other methods of production. Because of the availability of improved tablet excipients, such as Tablet disintegrants and sugar-based excipients, this technique can now be applied to fast dissolving tablets. The addition of disintegrants to fast-dissolving tablets causes rapid disintegration and thus improves dissolution. The rate of disintegration and thus the dissolution are primarily affected by the disintegrants in many fast dissolving tablet technologies based on direct compression. The popularity of this technology has grown due to the introduction of superdisintegrants and a better understanding of their properties. The time it takes for a tablet to disintegrate can be accelerated by concentrating the disintegrants. Tablet disintegration time is inversely proportional to disintegrants concentration below
critical concentration. However, above the critical concentration level, disintegration time remains nearly constant, if not increasing. Although water insoluble, microcrystalline cellulose, cross linked carboxymethyl cellulose sodium, cross linked polyvinyl pyrrolidone, and partially substituted hydroxypropyl cellulose absorb water and swell due to capillary action, making them effective disintegrants in the preparation of first dissolving tablets.

Sugar-based excipients (e.g., dextrose, fructose, isomalt, maltose, mannitol, sorbitol, starch hydrolyse, polydextrose, and xylitol), which have high aqueous solubility and sweetness and thus impart taste masking and a pleasing mouthfeel, are another approach to fast dissolving tablets by direct compression.\[15, 6,17,18\]

**Patented Technologies for Oro-Dispersible Tablets**

**Zydis Technology**

Zydis was first introduced in Sweden in 1986 by R. P. Scherer Corporation (cardinal health, inc). According to the Zydis process, the active ingredient is dissolved or suspended in an aqueous solution of water-soluble structure forming additives, then poured into preformed blister pockets of a laminate film and freeze-dried. The active ingredient must be dissolved or suspended in an aqueous solution of water-soluble structure forming additives before being poured into preformed blister pockets of a laminate film and freeze-dried, according to the Zydis process. This produces a tablet-shaped dosage form that dissolves in seconds in the mouth. The two most commonly used structural additives are gelatine and mannitol although some other (e.g., starches, gums, etc.) may be used depending on the properties of the active ingredient.

In general, the best physical characteristics are obtained by combining a water-soluble polymer with a crystalline sugar alcohol or amino acid in the matrix solution at a typical combined concentration of 10% w/w. The crystalline component provides hardness and texture, while the polymer provides strength and resilience.

When compared to traditional tablets, the Zydis product claims to have higher bioavailability. Because of its dispersion and dissolution in saliva while still in the oral cavity, this formulation has the potential to cause significant pregastric absorption. The Zydis formulation is absorbed in the buccal, pharyngeal, and gastric regions. Any pregastric absorption avoids first-pass metabolism, which is advantageous for drugs with a high hepatic metabolism. However, if the amount of drug swallowed varies, there is a chance that bioavailability will be inconsistent. While the claimed increase in bioavailability is debatable, it is clear that the Zydis formulation has a significant advantage in terms of convenience. For
soluble drugs, the amount of drug that can be incorporated should be less than 60 mg. To avoid sedimentation during processing, insoluble drugs should have a particle size of less than 50mm and no more than 200mm. The Zydis technology does have a few drawbacks. Freeze drying is a relatively costly manufacturing process. As previously stated, the Zydis formulation is very light and fragile, so it should not be kept in backpacks or at the bottom of purses.[26,27]

**Orasolv Technology**

Orasolv Technology was developed in the United States by CIMA labs. The taste of the active medication is masked in this system. It also includes an effervescent disintegrating agent. To reduce the time it takes for a tablet to dissolve in the mouth, it is made using a direct compression technique with a low compression force. The tablets are made using traditional blenders and a tablet machine. The resulting tablets are soft and pliable.[19]

**Ora Quick**

KV Pharmaceutical Co., Inc claims that its Micro Mask microsphere technology has a better mouth feel than other taste masking options. Because the taste masking process does not use any solvents, it allows for faster and more efficient production. Also, because Ora Quick produces less heat than other fast-dissolving/disintegrating technologies, it is suitable for heat-sensitive drugs. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable, allowing tablets to be compressed to achieve significant mechanical strength while maintaining taste masking. Ora Quick claims to dissolve in a matter of seconds and to mask unpleasant tastes. There are currently no Ora Quick-based products on the market, but KV Pharmaceutical is working on analgesics, scheduled drugs, cough and cold, psychotropic, and anti-infective products.[20]

**Quick-Dis Technology**

Lavipharm Laboratories Inc. has developed an ideal intraoral fast-dissolving drug delivery system that addresses market gaps. Quick-Dis is a thin, flexible, and quick-dissolving intraoral drug delivery system developed by Lavipharm. On the top or bottom of the tongue, the film is applied. It sticks to the application site and releases the active agent quickly for local and/or systemic absorption. The Quick-Dis drug delivery system is available in a variety of packaging options, from single-dose pouches to multi-dose blister packages. For the Quick-DisTM film with a thickness of 2 mm, the typical disintegration time, which is defined as the time at which the film begins to break when brought into contact with water, is only 5
to 10 seconds. For Quick DisTM film with a thickness of 2 mm, the dissolving time, which is defined as the time it takes for not less than 80% of the tested film to dissolve in aqueous media, is around 30 seconds. A Quick-DisTM drug delivery system's typical release profile for an active ingredient is 50 percent released in 30 seconds and 95 percent released in 1 minute.\textsuperscript{[21]}

**Durasolv Technology**

Dura Solv is Cima’s second-generation fast-dissolving/disintegrating tablet formulation. Dura Solv, which is made in the same way as Ora Solv but with higher compaction pressures during tabletting, has a much higher mechanical strength than its predecessor. Dura Solv tablets are prepared by using conventional tabletting equipment and have good rigidity (friability less than that 2%). The Dura Solv product is thus produced in a faster and more cost-effective manner. Dura Solv is such durable that it can be packaged in blister packs, pouches, or vials. One disadvantage of Dura Solv is that the technology is not compatible with larger doses of active ingredients, because the formulation is subjected to such high pressures on compaction. Unlike Ora Solv, the structural integrity of any taste masking may be compromised with high drug doses. The drug powder coating in Dura Solv may become fractured during compaction, exposing the bitter-tasting drug to a patient’s taste buds. Therefore, the Dura Solv technology is best suited for formulations including relatively small doses of active compound.\textsuperscript{[22]}

**Flash Dose Technology**

Fuisz Technologies uses this technique. This technology utilizes a special spinning mechanism to originate a floss like composition much like a cotton candy. This sugar based matrix known as floss which made from combination of excipients is then merged with the active drug either alone or in combination of drugs and compressed in tablets this mechanism is patented by Fuisz and acknowledged as Shearform. A very high area of dissolution is found in the final product which when kept on tongue disperses and dissolve quickly Nurofen mettle, a new form of ibuprofen is based on same technology.

**Flash tab technology**

Prographarm laboratories patented this technology in which tablet consists of active ingredients in form of microcrystals. The drug microgranules were prepared by techniques like coacervation, micro encapsulation, normal pan coating, extrusion-spheronization. The microcrystals of microgranules of the active pharmaceutical ingredients are added to the
mixture of excipients by conventional technology i.e dry and wet granulation and compressed in the form of tablets. The tablets formed found to have disintegration time less then one minute and also show good mechanical strength.

**Wowtab Technology**

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. Wowtab fast dissolving tablets has been in the Japanese market over a couple of years. In wowtab the word WOW means “Without Water “. In this process, combination of low mouldability saccharides for rapid dissolution and high mouldability saccharides for good binding property, are used. API constitute the 50%-w/w are mixed with low mouldability saccharides and then granulated with high mouldability saccharides to form tablet of adequate hardness and fast disintegration rate. Wowtab technology is little more stable then the Orasolv and Zydis due to its greater stability in environment caused by its expressive hardness.

**Lyoc tech**

Laboratories L. Lafon, Maisons Alfort, France, has patented this technology. It uses the freeze-drying method, but unlike Zydis, the product is frozen on the freeze-dryer shelves. These formulations require a large proportion of undissolved inert filler (mannitol) to increase the viscosity of the in-process suspension to prevent inhomogeneity due to sedimentation during this process. The high filler content reduces the dried dosage form's potential porosity, resulting in denser tablets with disintegration rates comparable to loosely compressed fast melt formulations.[23]

**Pharma burst technology**

Pharma burst is a patented SPI Pharma "Quick Dissolve" delivery system. Pharma burst is a co-processed excipient system with specific excipients that allows for quick disintegration and low punch face adhesion. Saccharine with moulding ability is used to make a strong tablet that melts quickly. The active ingredient combines with saccharine, which has a low Mould resistance.[24]

**Frosta technology**

This technology is patented by Akina. It works by forming plastic granules and compressing them under low pressure to create strong tablets with high porosity. Porous and plastic granules, as well as a water penetration enhancer and a binder, make up plastic granules. The porous plastic material is mixed with a water penetration enhancer before being granulated
with a binder. The tablets obtained have a high hardness and a quick disintegration time of 15 to 30 seconds, depending on tablet size.\textsuperscript{[25]}

**AdvaTab Technology**

Kyowa Hakko Kogyo holds the patent. AdvaTab tablets dissolve quickly in the mouth, usually in under 30 seconds, allowing for easy oral drug administration without the use of water. These tablets are especially helpful for patients who have trouble swallowing capsules and tablets. Adva Tab is distinct from other ODT technologies as it can be combined with Eurand’s complimentary particle technologies like its world leading Microcap taste-masking technology and its Diffucaps controlled release technology. The combination of AdvaTab and Microcap results in products that have a patient-favorite dosage form as well as a superior taste and smooth mouth feel. This is a significant benefit because the unpleasant taste of drugs is a major barrier to the use of other ODT technologies.

**Table 1: Techniques Used in the Preparation of ODTs.**

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Techniques</th>
<th>Drug</th>
<th>References</th>
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<tr>
<td>1</td>
<td>Porous matrix</td>
<td>Olanzapine</td>
<td>[28]</td>
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<td>2</td>
<td>Freeze drying</td>
<td>Phloroglucinol Hydrate</td>
<td>[29]</td>
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<td>3</td>
<td>Tableting with effervescent disintegrants</td>
<td>Paracetamol</td>
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<td>4</td>
<td>Tableting with low and high moldability saccharides</td>
<td>Famotidine</td>
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<td>5</td>
<td>Microcaps and diffuscaps CR</td>
<td>Cetirizine HCl</td>
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<td>6</td>
<td>Micromask taste masking</td>
<td>Hyoscyamine Sulfate</td>
<td>[33]</td>
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<td>7</td>
<td>Lyophilisation</td>
<td>Cisapride monohydrate</td>
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<td>8</td>
<td>Tableting with disintegrants and swelling agent</td>
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<td>[35]</td>
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<td>Direct compression</td>
<td>Zolmitriptan</td>
<td>[36]</td>
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<td>Tableting with water in soluble ingredient and effective disintegrants</td>
<td>Ibuprofen</td>
<td>[37]</td>
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<td>Cotton Candy Press</td>
<td>Tramadol HCl</td>
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Future Perspective

In the pharmaceutical industry, oral administration is currently the gold standard, as it is the safest, most convenient, and cost-effective method of drug administration with the highest patient compliance. The tablet is the most common oral dosage format. The ODT is a novel tablet design that allows for easy oral administration and improved patient compliance. This tablet format was created to allow for the administration of an oral solid dose form without the use of water or fluids. In most cases, such tablets dissolve or disintegrate in the saliva within 60 seconds. Pharmaceutical companies such as Cardinal Healthcare, Jannsen Pharmaceutical, Bioavail, and Eurand, Yamanouchi have developed technologies that have made a number of ODT commercially available for human use. These technologies, on the other hand, either use expensive processing technology to produce fragile tablets that require expensive specialised packaging, or they use traditional tableting procedures that result in slower disintegration than desired and still necessitate specialised packaging.

CONCLUSION

Forthcoming challenges for various ODT manufacture include cost effective methods to manufacture ODT with conventional equipment using versatile packaging and effective taste
masking capabilities. ODT need to be manufactured for pediatric, geriatric, psychiatric patients or those who have difficulty in swallowing traditional tablets and capsules or has no access to water. Due to vast significance of ODT, thus drug delivery system may lead to improved patient compliance and acceptance the introduction of new pharmaceutical excipients leads to the emergence of novel technologies for the ODTs in the days to come.

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