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A REVIEW ON ORO-DISPERSIBLE TABLETS AND PATENTED TECHNOLOGY

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ABSTRACT

ODT's are known by various names such as "fast-melting, fast-dissolving, mouth dissolving tablets, or orodisperse". The European pharmacopoeia defines the term "orodisperse" as a tablet that can be placed in the mouth where it disperses rapidly before swallowing. Suitable drug candidates for such systems include neuroleptics, cardiovascular agents, analgesics, antiallergics and drugs for erectile dysfunction. Mouth dissolving of tablet results in quick dissolution and rapid absorption which provide rapid onset of action. The concept of orally disintegrating tablets (ODT's) emerged with an objective to improve patient's compliance. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus obviating the need for water during administration, an attribute that makes them highly attractive for pediatric and geriatric patients. Several Patented technologies are available for preparing mouth dissolving tablets.

KEYWORDS: Oro- dispersible, Disintegration, Patent Technology.

INTRODUCTION

Mouth dissolving of tablet results in quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pre-gastric absorption when formulated as ODTs may show increased oral bioavailability. It provides good stability, accurate dosing, and easy manufacturing.

1. Oral dispersible tablets[1,2,3,4]

The concept of Orally Disintegrating tablets (ODTs) emerged with an objective to improve patient's compliance. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus obviating the need for water during administration, an attribute that makes them highly attractive for pediatric and geriatric patients. Difficulty in swallowing conventional tablets and capsules is common among all age groups, especially in elderly and dysphagic patient.

1.1 Characteristics and formulation challenges of ODTs[7,18]

The key properties of the tablets are fast absorption or wetting of water into the tablets and disintegration of associated particles into individual components for fast dissolution. This requires that excipients should have high wettability, and the tablet structure should also have a highly porous network hence for components see Figure 2.

1.2 Ideal properties[5,6,18]

- Allow high drug loading.
- Be compatible with taste masking and other Excipient.
- Have a pleasing mouth feels.
- Leave minimal or no residue in the mouth after oral administration
- Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling.
- Exhibit low sensitivity to environmental conditions such as humidity and temperature

1.3 Advantages of ODTs[8,9,10,18]

Achieve increased bioavailability/rapid absorption through pre-gastric absorption of drugs from mouth, pharynx and esophagus as saliva passes down. Apart from it the drug is protected from degradation due to pH and GIT enzymes. It improves patient compliance due to the elimination of associated pain with injections.

1.4 Disadvantages of ODTs[11,12,18]

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.

2. Patented Technologies for Preparation of ODTs

Several technologies are available for preparing Mouth dissolving tablets. But some commercially useful technologies see Figure 2.

2.1 Zydis technology[13,14,18]

'Zydis' is the first mouth dissolving dosage form in the market. It is a unique freeze-dried tablet in which the active drug is incorporated in a water-soluble matrix, which is then transformed into blister pockets and freeze dried to remove water by sublimation. Zydis matrix is made up of a number of ingredients in order to obtain different objectives. 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. Preservatives may also be added to prevent microbial growth. Zydis products are packed in blister packs to protect the formulation from environmental moisture. A secondary moisture proof foil punch is often required as this dosage form is very moisture sensitive. When putted into the mouth, Zydis unit quickly disintegrates and dissolves in saliva.

2.1.1 Drawbacks

- 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 up to 60 mg.
- Fragility and poor stability of dosage form during storage under stressful conditions.

2.2 Orasolv technology[13,15,18]

Orasolv formulation has been developed by CIMA labs. In this system, active medicament is taste masked in two-fold. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique, low compression force in order to minimize oral dissolution time. Soft and friable tablets produced by Conventional blenders and tablet machine, and the tablet matrix dissolve in less than one minute. The advantage of Orasolv Technology is that the formulations are not very hygroscopic, and it also provides a distinct, pleasant sensation

of effervescence in the mouth. The major disadvantage of the Orasolv formulations is its Poor mechanical strength.

2.3 Durasolv technology[15,18]

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and a lubricant. In this system, active medicament is taste masked. It also contains effervescent disintegrating agent. DuraSolv has much higher mechanical strength than its predecessor due to the use of higher compaction pressures during tableting. Durasolv tablets are prepared by using conventional tableting equipment and have good rigidity (friability less than that 2%). The DuraSolv product is thus produced in a faster and more cost-effective manner. One disadvantage of DuraSolv is that the technology is not compatible with larger doses of active ingredients, because the formulation is subjected to such high pressures on compaction.

2.4 Flash Dose Technology[16,18]

Flash dose technology has been patented by Fuisz. Nurofen meltlet, a new form of ibuprofen as melt-in mouth tablets, prepared using flash dose technology which is the first commercial product launched by Biovail Corporation. Flash dose tablets consist of self binding shear form matrix termed as "floss". Shear form matrices are prepared by flash heat process.

2.5 Wow tab Technology[16,18]

Wow tab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water ". In this process, combination of low mould ability saccharides and high mould ability saccharides are used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mould ability saccharide and granulated with a high mould ability saccharide and compressed into tablet.

2.6 Oraquick Technology[16,18]

The Oraquick oral disintegrating tablet formulation utilizes a patented taste masking technology. KV Pharmaceutical claims its microsphere technology, known as Micro Mask, has superior mouth feel over taste-masking alternatives. The taste masking process does not utilize solvents of any kind, and therefore leads to faster and more efficient production. Also, lower heat of production than alternative oral disintegrating technologies makes OraQuick appropriate for heat-sensitive drugs. KV Pharmaceutical also claims that the matrix that surrounds and protects the drug powder in microencapsulated particles is more pliable,

meaning tablets can be compressed to achieve significant mechanical strength without disrupting taste masking. OraQuick claims quick dissolution in a matter of seconds, with good taste-masking. There are no products using the OraQuick technology currently on the market, but KV Pharmaceutical has products in development such as analgesics, scheduled drugs, cough and cold, psychotropics, and anti-infectives.

2.7 Nano crystal technology[17,18]

This is patented by Elan, king of Prussia. Nanocrystal technology includes lyophilization of colloidal dispersions of drug substance and water soluble ingredients filled into blister pockets. This method avoids manufacturing process such as granulation, blending and tableting, which is more advantageous for highly potent and hazardous drugs. As manufacturing losses are negligible, this process is useful for small quantities of drug.

2.8 Ceform technology[17,18]

In ceform technology microspheres containing ceform active drug ingredient are prepared. The essence of ceform microsphere manufacturing process involves placing a dry powder, containing substantially pure drug material or a special blend of drug materials plus other pharmaceutical compounds, and excipients into a precision engineered and rapidly spinning machine. The centrifugal force of the rotating head of ceform machine throws the dry drug blend at high speed through small, heated openings. The carefully controlled temperature of the resultant microburst of heat liquefies the drug blend to form a sphere without adversely affecting drug stability. The microspheres are then blended and/ or compressed into the pre-selected oral delivery dosage format. The ability to simultaneously process both drug and excipients generates a unique microenvironment in which materials can be incorporated into the microspheres that can alter the characteristics of the drug substance, such as enhancing solubility and stability.

2.9 Pharmaburst technology[17,18]

SPI Pharma, New Castle, patents this technology. It utilizes the co processed excipients to develop ODT's which dissolves within 30 – 40s. This technology involves dry blending of drug, flavour and lubricant followed by compression into tablets. Tablets obtained have sufficient strength so they can be packed in blister packs and bottles.

2.10 Frosta technology[17,18]

This technology is patented by Akina. It utilizes the concept of formulating plastic granules and compressing 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 usually mixing the porous plastic material with water penetration enhancer and followed by granulating with binder. The tablets obtained have excellent hardness and rapid disintegration time ranging from 15 to 30s depending on size of tablet.

3. Applications

Numerous applications have been sought in the areas of drug designing and in monitoring quality, stability, and safety of pharmaceutical compounds, whether produced synthetically, extracted from natural products or produced by recombinant methods. The applications include alkaloids, amines, amino acids, analgesics, antibacterial, anticonvulsants, antidepressant, tranquilizers, antineoplastic agents, local anesthetics, macromolecules, steroids, miscellaneous. These dosage forms rapidly disintegrate and/or dissolve to release the drug as soon as they come in contact with saliva, thus obviating the need for water during administration, an attribute that makes them highly attractive for pediatric and geriatric patients. Several Patented technologies are available for preparing mouth dissolving tablets. Some Marketed products of ODTs also available see table No. 1

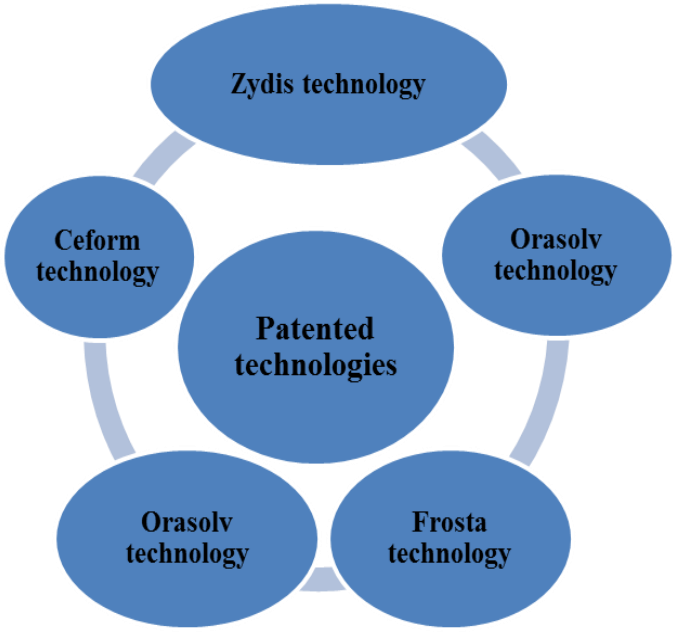

Figure 1: Patented technologies.

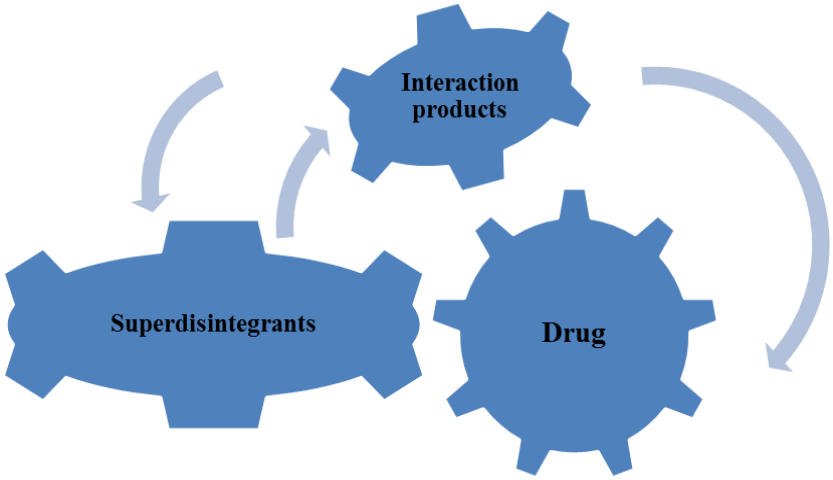

Figure 2: Components of Oro-dispersible Dosage Forms.

Table 1: Marketed Fast Disintegrating Tablets.

Sr. no.	Product Name	Active Agent	Name of Company
1	Mosid-MT	Mosapride citrate	Torrent Pharmaceutical, India
2	Torrox MT	Rofecoxib	Torrent Pharmaceutical, India
3	Romilast	Montelukast	Ranbaxy Labs Ltd. India
4	Zeplar TM	Selegilline	Amarin Corp, UK
5	Feldene Fast, Melt	Piroxicam	Pfizer, USA
6	Claritin Reditabs	Loratidine	Schering Plough Corp, USA
7	Zyprexia	Olanzapine	Eli Lilly, USA
8	Mazalit MTL	Rizatritan	Merckasnd Co. USA
9	Nimulid-MD	Nimesulide	Panacea Biotech, India
10	Pepcid RPD	Famotidine	Merck and Co., USA
11	Zopran ODT	Ondansetron	Glaxo Wellome, UK
12	Zooming –ZMT	Zolmitriptan	Astrazeneca, USA

CONCLUSION

This article provides the valuable information about the Patented Techniques and types and its classification, various techniques of Formulation and Development in Solid Orals dosage forms, Oro-dispersible or Oro-disintegrating drug delivery systems are the most preferable systems in order to deliver the drugs which have a narrow absorption window near the gastric region. Now days a number of drug delivery devices are being developed which aim at releasing the drug at gastric region. Even though these drug delivery systems have several advantages they also have disadvantages like their in-vitro and in-vivo correlation is very less.

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