



INTERNATIONAL JOURNAL OF ADVANCE RESEARCH, IDEAS AND INNOVATIONS IN TECHNOLOGY

ISSN: 2454-132X

Impact factor: 4.295

(Volume 5, Issue 3)

Available online at: www.ijariit.com

A review on mouth dissolving tablets of Glimepiride

Bobina Arora

arorabobina09@gmail.com

Swami Vivekanand College of Pharmacy, Banur, Punjab

Perna Sarup

psarup_pu@hotmail.com

Swami Vivekanand College of Pharmacy, Banur, Punjab

Sonia Pahuja

pharmsoniapahuja@gmail.com

Swami Vivekanand College of Pharmacy, Banur, Punjab

Navneet Kaur

nkgill1115443@gmail.com

Swami Vivekanand College of Pharmacy, Banur, Punjab

ABSTRACT

The oral route is considered as the most common and preferred technique for drug administration because it is considered as the easiest and simplest method. The route provides the simplicity of drug administration in a handy way and individuals tend to be more knowledgeable about this particular route. The latest developments in Novel Drug Delivery System (NDDS) seeks for improving effectiveness and molecules security that was used previously by preparing suitable dosage forms for administration. Nowadays the problems such as dysphagia are faced by the conventional dosage forms like capsules and tablets, which results in ineffective therapy because of the high incidence of non-compliance. Mouth dissolving tablets (MDTs) were developed to prevent the above issues in conventional dosage forms. These MDTs have easy administration, dose uniformity, and good hardness as well as are the first preference for travelling, geriatric, and pediatric patients. This paper provides a review for MDT because of its wide significance, as well as such a drug delivery system may help for better compliance of patient along with ultimate clinical output.

Keywords— Mouth Dissolving Tablets (MDT), Orally disintegrating tablets, Super-disintegrate

1. INTRODUCTION

In today's existing dosage form these tablets are mostly used form due to manufacturing ease, compactness and self-administration. Nevertheless, mental, pediatric and geriatrically ill individuals' encounters trouble in swallowing traditional capsules that is normal amongst most age groups, particularly in aged that results to bad patient conformity (Gosh et al., 2011). In order to conquer these issues, scientists have created a revolutionary medication distribution process referred to as mouth disintegrating or dissolving pills. This particular doses disintegrates and dissolves in the mouth in just a few minutes without any chewing or even water. This particular invention is helpful in medication administration of geriatric and pediatric patients (Kumar et al., 2011).

1.1 Advantages of mouth dissolving tablets

- Geriatric, pediatric, as well as institutionalized patients (especially psychiatric or mentally retarded patients), can administrate easily.
- Easier handling by patients, small packaging size, easy manufacturing, accurate dosing and good stability is provided by the MDT as they are unit solid dosage forms.
- Various sweeteners and flavors are used in MDT due to which it is easily palatable.
- The travelling patients that do not have water access are benefitted by such tablets as the dosage obstruction risk is eliminated.
- Quick onset action is provided as this tablet disintegrates quickly which results in quick absorption and dissolution.

1.2 Challenges in developing MDT

- The tablet should not disintegrate rapidly
- Tablet size should not be increased
- Mechanical strength should be sufficient
- Least or no residue in the mouth
- Moisture protection
- Not affected by drug properties (Bharadwaj et al., 2010)

1.3. Superdisintegrants

Disintegrating representatives are compounds regularly used in the formulations of the tablet to help the breakup of the compressed mass into the main particle to ease the dissolution or maybe the introduction of the effective substances when it's placed into a suitable atmosphere. Recently new information called "superdisintegrants" are prepared to enhance the processes of disintegration (Gupta and Pahwa, 2011). The various superdisintegrants mechanism used are:

- Particle repulsive forces
- Chemical reaction (Acid-Base Reaction)
- Heat of wetting
- Porosity and capillary action (wicking)
- Swelling

2. MOUTH DISSOLVING TABLETS MANUFACTURING TECHNOLOGIES

The manufacturing technology for MDT is classified into two main categories: Conventional Technologies and Patented Technologies. These two categories are further discussed in detail as follows:

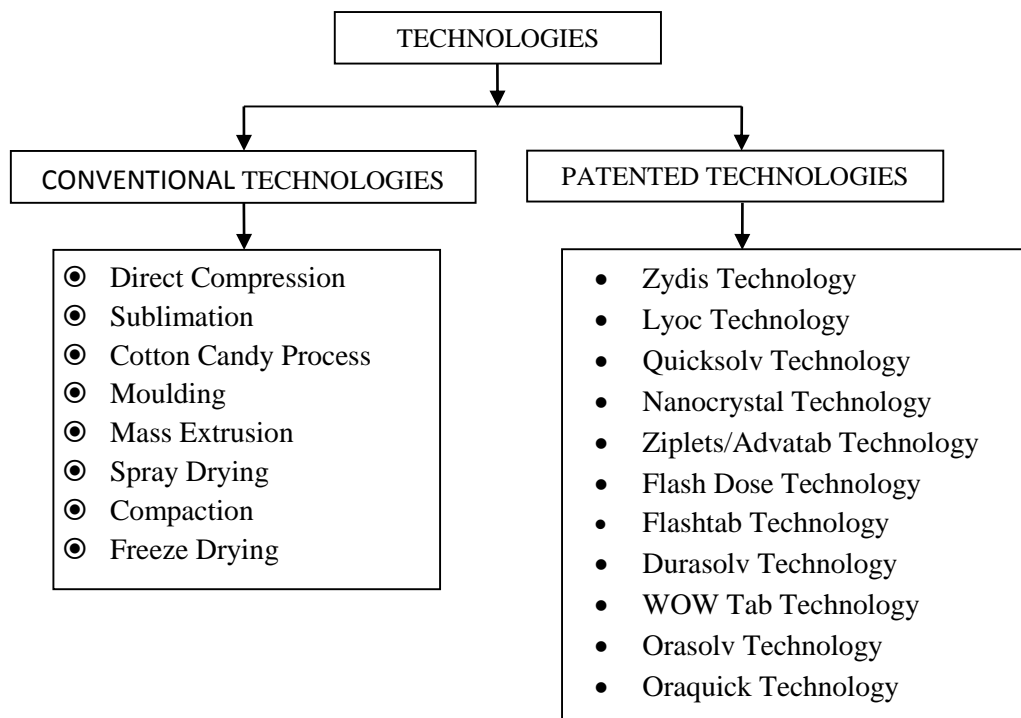


Fig. 1: Manufacturing technologies for MDTs

2.1 Conventional technologies

2.1.1 Direct compression: Standard techniques in formulating capsules for instance dried up granulation damp granulation as well as immediate compression were modified to create MDT. From all of the strategies, immediate compression is the simplest way to produce capsules. This technique is most preferable because of its limited number of processing steps, commonly available excipients, conventional equipment and low manufacturing cost.

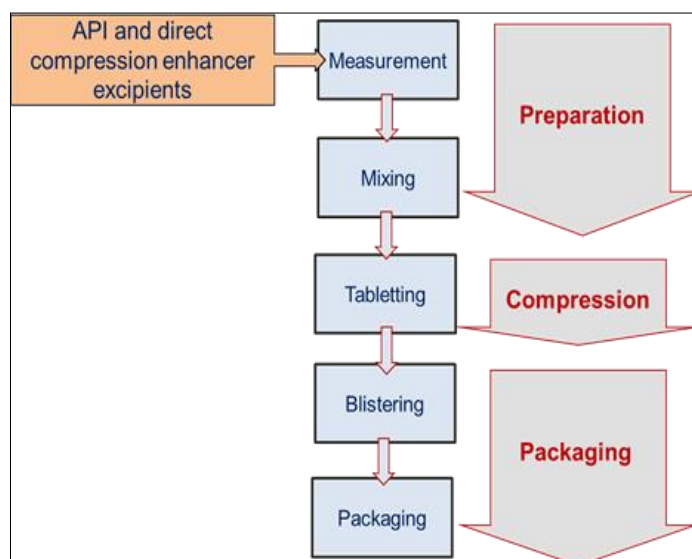


Fig. 2: Direct compression technique

2.1.2 Sublimation: The existence of a very permeable framework in the tablet matrix will be the crucial element for MDT's fast disintegration. Although the standard capsules have extremely water-soluble substances, they usually neglect to disintegrate quickly due to very low porosity. In the tableting process, inert solid volatilizable substances like urethane, urea, ammonium bicarbonate, ammonium carbonate, thymol, menthol, camphor etc. were used for improving the porosity that is subsequently transferred from a tablet that is formed.

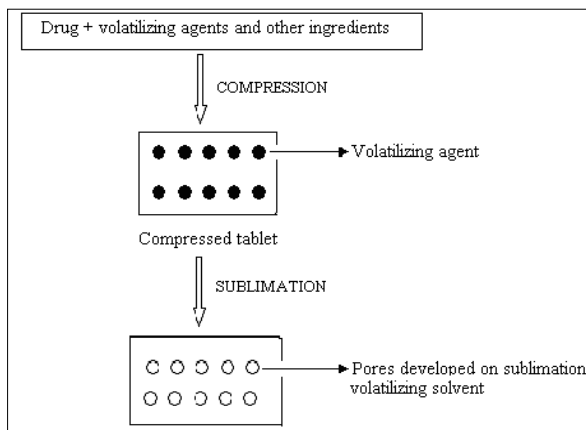


Fig. 3: Sublimation process

2.1.3 Cotton candy process: Cotton candy procedure entails matrix development of saccharides or polysaccharides by concurrent activities of flash spinning and melting. After this, the created matrix is partly recrystallised so that it would have enhanced flow qualities as well as compressibility. This candy floss matrix will be blended, also milled with established excipients as well as ingredients and consequently compressed to MDT. The particular technique is able to support higher doses of medication and provides improved physical toughness. Nevertheless, high process heat restricts the usage of the procedure.

2.1.4 Moulding: Water-soluble ingredients are used to prepare moulded tablets so that tablet disintegrates and dissolves completely and rapidly. Different techniques followed for this are:

- **Compression moulding:** A solvent like water/ethanol is used to moisten the powder mixture that is then used to form wet mass by compressing mould plates.

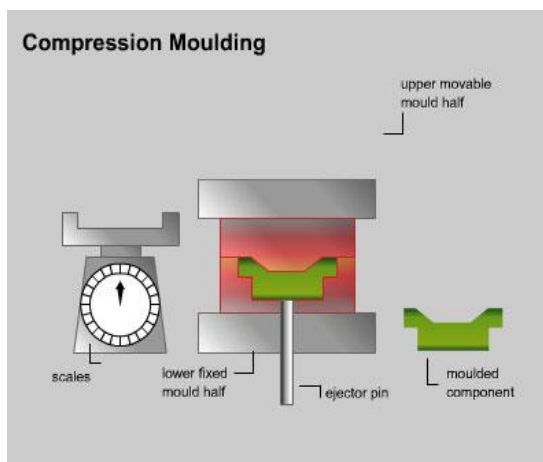


Fig. 4: Process of compression moulding

- **Heat moulding:** The moulded modes could be acquired precisely from a molten matrix which is able for dissolving or dispersing the drug.
- **Vacuum lyophilization:** In this approach at regular strain the solvent by a solution of drug or even suspension is evaporated.

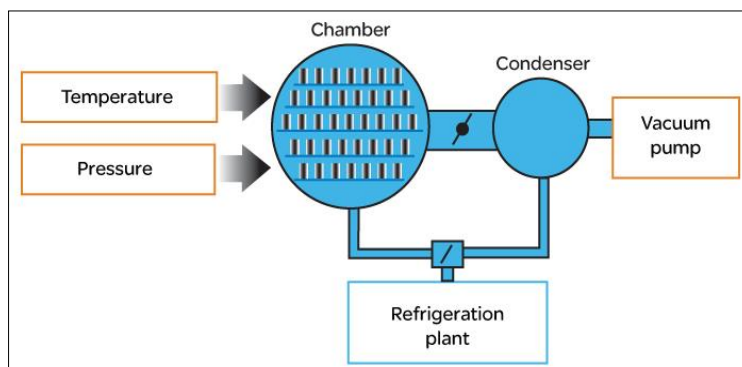


Fig. 5: Vacuum lyophilization process

- **Mass Extrusion:** This particular method entails softening the lively mixture aided by the solvent combination of water-soluble PEG, applying ensuing expulsion and methanol of softened mass with the extruder or maybe syringe to buy a cylinder of the item into actually segments utilizing warmed cutters to create the capsules. The dried out cylinder is often utilized to layer granules of sour tasting drugs and thereby covering up the sour flavour (Joshi and Biswati, 2011).

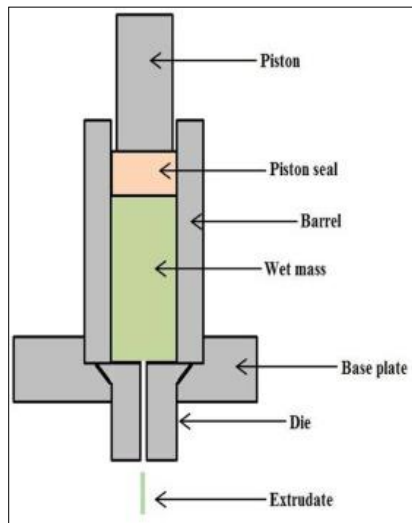


Fig. 6: Mass extrusion technique

- **Spray Drying:** This particular technique depends on a particulate assistance matrix that's prepared by spraying drying out an aqueous structure with other elements and support matrix to form a fine and porous highly powder (Asish et al., 2010).
- **Compaction:** The process of compaction takes place in two phases:
 - (a) **Melt granulation:** MDT can be prepared using hydrophilic waxy binder (super polylysate) PEG-6-stearate. MDT can be prepared by this method which includes granules formulation by using this material's molten form. Superpolylysate is a waxy material with an HLB of 9 and a melting point of 33-37°C. It can be utilized as a binder as well as for increasing the tablets' physical resistance and helps in tablets disintegration.

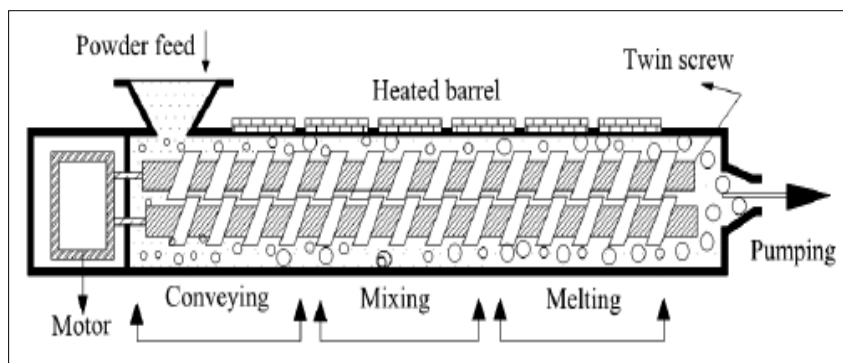


Fig. 7: Melt granulation technique

- (b) **Phase transition process:** Tablets have been created by compressing a powder with two sugar alcohols with low- and high-melting points and consequent heating in temperature between the melting points of theirs.

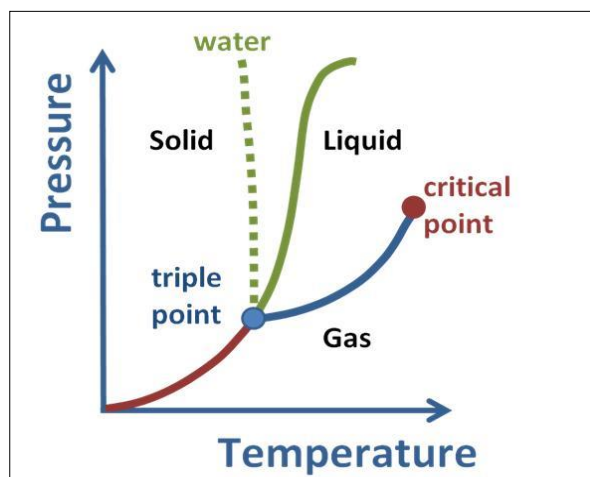


Fig. 8: Phase transition and triple point

- **Freeze Drying:** Lyophilization or Freeze drying out is among the very first model methods of making MDT that requires removal of solvent out of a frozen suspension or perhaps drug solutions with additives that can form structures. It is composed of 3 phases
 - To get the material below the eutectic zone of its freezing is used.
 - For reducing the moisture around 4% w/w of dry product primary drying or sublimation drying is used.
 - For reducing the bound moisture so that final required value is obtained secondary drying or desorption is used.

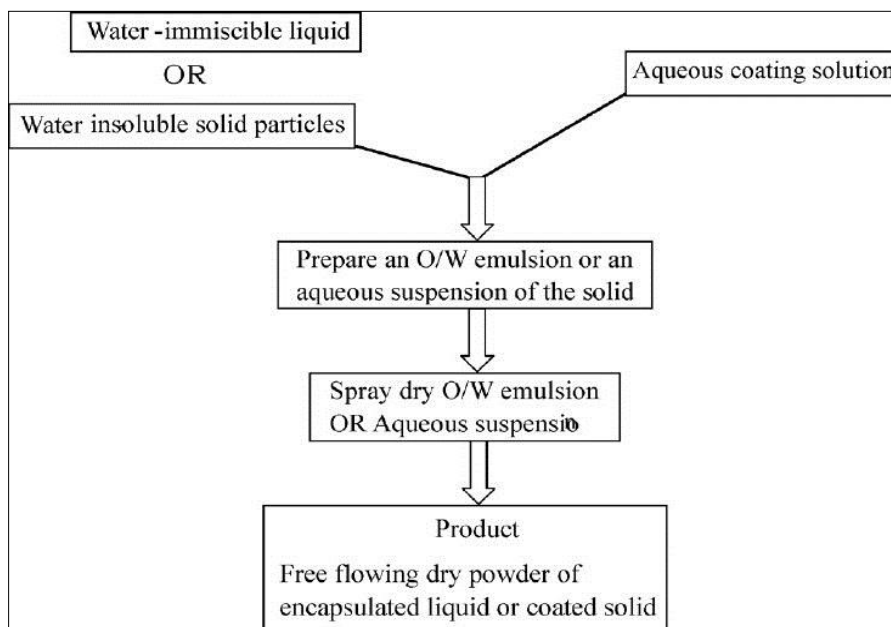


Fig. 9: Process of Freeze drying

2.2 Patented technologies

2.2.1 Zydis technology: Zydis, is considered as first marketed new technology tablet and is fast-disintegrating/ dissolving tablet. Zydis formulation is a distinctive freeze dried tablet where medication is actually trapped or perhaps dissolved within a wide open water-soluble matrix system of fast dissolving carrier materials. The strategy entails preparing dispersion or maybe alternative of filling as well as pieces into blister cavities that are frozen to a liquid nitrogen atmosphere. The frozen solvent is eliminated and sublimed to create porous wafers. When placed into the mouth, the freeze dried framework disintegrates instantly within 2-3 seconds and doesn't need to drink water to help to swallow.

2.2.2 Lyoc technology: Pharmalyoc have the patent of Lyoc technology. Oil in water emulsion is formulated as well as put straight into blister cavities accompanied by freeze drying. Non-homogeneity during freeze drying is stayed away from by integrating inert filler to boost the viscosity and lastly the sedimentation. Excessive proportion of filler decreases the porosity of capsules on account of that disintegration is decreased.

2.2.3 Quicksolv technology: Janssen Pharmaceuticals have the patent of this particular technology. Two solvents are used in matrix formulation, and that disintegrates immediately. The strategy has dissolving matrix parts in warm water and also the option or maybe dispersion so gotten will be frozen. The matrix will be dehydrated by detaching water utilizing an excess of alcoholic beverages (solvent extraction). Hence the item created has sufficient toughness and consistent porosity for managing.

2.2.4 Nanocrystal technology: Elan pharmaceuticals had the patent of Nanocrystal technology. It contains lyophilization of colloidal dispersions of water soluble elements as well as drug substances loaded into blister sections. This particular technique stays away from manufacturing method, for example, tableting, blending and granulation that is much more beneficial for extremely powerful as well as dangerous prescriptions. As producing losses are negligible, this procedure is beneficial for tiny drug quantities.

2.2.5 Zipllets/Advatab technology: Pessano Con Bornago, Italy have patented this technology. It uses a water-insoluble component coupled with one or even better disintegrants to create MDT with enhanced physical power as well as optimum disintegration period at lower compression pressure. This particular technological innovation manages excessive drug loading as well as coated particles of drugs and doesn't need specific wrapping so that they could be loaded in thrust through bottles or blisters.

2.2.6 Flash dose technology: "Fuisz" have the patent of flash dose technology. Flash dose capsules comprise of self-binding shearform matrix called as "floss". This particular technological innovation uses a distinctive spinning mechanism to create a floss-like crystalline framework, similar to as cotton candy. Shearform matrices are formulated by flash high heat processing in that the high sugar is concurrently put through temperature gradient and also to centrifugal force, and that increases the mass heat to produce an inner flow quality.

2.2.7 Flashtab technology: Flashtab technologies are patented by Prographarm laboratories. Capsules formulated by this particular method include microcrystals that act as an active component. A swelling agent along with a disintegrating agent is utilized in conjunction with coated particles of the drug in this particular formulation to develop a tablet which disintegrates in the mouth within a few minutes.

2.2.8 Durasolv technology: It is CIMA Lab's second generation disintegrating/fast-dissolving tablet formula. The production process of Durasolv is similar to as that of Orasolv, except Durasolv has a lot of higher physical toughness as compared to the predecessor of its because of the usage of increased compaction pressures during tableting. The capsules produced by this particular engineering include a lubricant, nondirect compression fillers as well as a drug.

2.2.9 WOW Tab technology: Yamanouchi Pharmaceutical Co has the patent of this particular technology. WOW means “Without Water”. Wowtab is an intra buccally soluble compressed tablet formulated by a combination of low mouldability saccharides (for rapid dissolution) and high mouldability saccharides (for good binding property) to obtain a rapidly melting strong tablet.

2.2.10 Orasolv technology: The very first fast dissolving formulation by CIMA Lab's was orasolv technology. Capsules are created by direct compression strategy at lower compression pressure to lessen oral dissolution period. In this particular method, the energetic medicament is masked taste as well as dispersed in saliva because of the activity of the effervescent disintegrating agent. Effervescent combination concentration generally used is 20-25% w/w of tablet mass.

Table 1: Patented manufacturing technologies for MDT

Name of Patented Technology	Basis of Technology	Advantages	Disadvantages	Patent Owner
FlashDose	Cotton-candy process	For dissolution, it is having a high surface area.	It is sensitive to moisture and humidity also for melting the matrix high Temperature is required due to which heat-sensitive drugs usage is limited.	Fuisz Technology Ltd
Zip lets	Molding	The high dose (450 mg) and high weight (850 mg) helps in obtaining the satisfactory properties, during the manufacturing process good mechanical strength is obtained, and also handling problems are avoided.	Due to viscous concentrated solution formation when soluble component dissolves, the decreased water diffusion rate into tablet is noticed.	Eurand
WOWTAB	Compressed Moulded Tablets	Adequate hardness and dissolution rate.	Bioavailability does not change significantly.	Yamanouchi Pharma Technologies, Inc.
RapiTab	Compressed Tablets			Schwarz Pharma
Durasolv		Proprietary taste masking and Compressed dosage form.	Having good rigidity along with higher mechanical strength than Orasolv.	Cima Labs Inc.
Orasolv	Compressed Tablets	Quick dissolution with twofold taste-masking	Less mechanical strength	Cima Labs Inc.
Flash tab	Multiparticulate Compressed Tablets	It requires only conventional tableting technology.	--	Ethypharm
Quicksolv	Lyophilization			Janseen Pharmaceutica
Zydis	Lyophilization	Increased bioavailability, self-preserving, quick dissolution	At higher humidities and temperatures it shows poor stability. It is an expensive process	R.P.Scherer Inc.

3. CONCLUSION

The improvement associated with a fast dissolving tablet additionally presents a chance for just a marketplace line extension; a broad category of medications (e.g., antihistamines, analgesics, cardiovascular drugs, neuroleptics, and medications for erectile dysfunction) could be regarded as applicants because of this dosage type. Pharmaceutical advertising is an additional reason behind the expansion in free fast dissolving/ disintegrating items. A new dosage type enables a producer to lengthen industry exclusivity while providing its affected persons with a far more handy dosage type or maybe dosing program. In such manner, quickly dissolving/ disintegrating tablet formulations are much like several continual discharge products which are right now widely offered. An extension of industry exclusivity that could be supplied by a fast dissolving/disintegrating dosage type results in better profits, whereas simultaneously focusing on under-treated and underserved affected person populations. While the price to produce these special dosage styles surpasses that of standard capsules, this extra price isn't getting handed down to the customer.

4. REFERENCES

- [1] Abdul Sayeed et al., Mouth dissolving tablets: An Overview., International Journal of Research in Pharmaceutical and Biomedical Sciences, 2011; 2(3): 959-970.
- [2] Sharma.S.et al., Pharmainfo.net, 2008; 6(5). Available at: <http://www.pharmainfo.net/reviews>.
- [3] Jagani et.al. Fast Dissolving Tablets: Present and Future Prospectus. Journal of Advances in Pharmacy and Healthcare Research. 2011; 2(1):57-70.
- [4] Bhupendra G Prajapati et al ., A Review on Recent patents on Fast Dissolving Drug Delivery System, International Journal of PharmTech Research.2009,1(3)
- [5] D Bhowmik et al., Fast Dissolving Tablet: An Overview, Journal of Chemical and Pharmaceutical Research, 2009; 1(1): 163-177
- [6] Vummaneni V. et al., Mouth Dissolving Tablets: A Review, American Journal of Pharmatech Research; 2012; 2(3).

- [7] H. Seager. , Drug-delivery Products and the Zydis Fast-dissolving Dosage Form., J. Pharm. Pharmacol. 1998; 50: 375-382.
- [8] D. Shukla et al., Mouth Dissolving Tablets I: An Overview of Formulation Technology, Scientia Pharmaceutica. 2009; 76; 309–326.
- [9] McLaughlin Rosie, Banbury Susan, Crowley Kieran., Orally Disintegrating Tablets The Effect of Recent FDA Guidance on ODT Technologies and Applications, Pharmaceutical Technology: Sep.(2009)
- [10] Kumari S., Visht S., Sharma P.K., Yadav R.K., (2010). , Fast dissolving Drug delivery system: Review Article; Journal of Pharmacy Research 3(6), 1444-1449.
- [11] Sharma S., (2008). , New generation of tablet: Fast dissolving tablet; Latest review Vol VI.
- [12] Chaudhari P.D., Chaudhari S.P., Lanke S.D. and Patel N., (2007). , Formulation and in vitro evaluation of teste masked orodispersible dosage form of Levocetirizine dihydrochloride; Indian journal of pharmaceutical Education and research 41(4)., 319-327.