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FAST DISSOLVING TABLET: A REVIEW

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ABSTRACT

Fast dissolving Tablets are disintegrating and/or dissolve rapidly in the saliva without the need for water. Some tablets are designed to dissolve in saliva remarkably fast, within a few seconds, and are true fast-dissolving tablets. Others contain agents to enhance the rate of tablet disintegration in the oral cavity, and are more appropriately termed fast-disintegrating tablets, as they may take up to a minute to completely disintegrate. 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. Paediatric, elderly and mentally handicapped patients can be readily administered. Accurate dose as compared to liquids may be provided. Advantageous in terms of administration and transportation over fluid medication. No risk of suffocation when swallowed owing to physical disturbance, thus enhancing safety. ODTs are appropriate for sustained and controlled release actives.

KEYWORDS: Super disintegrants, Disintegration, diclofenac tablet and dissolution.

INTRODUCTION

Oral routes of drug administration have wide acceptance up to 50-60% of total dosage forms. Solid dosage forms are popular because of ease of administration, accurate dosage, self medication, pain avoidance and most importantly the patient compliance. 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 (kinetosis) and sudden episodes of coughing during the common cold, allergic condition and bronchitis. For these reason, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention.

Fast dissolving tablets are also called as mouth-dissolving tablets, melt-in mouth tablets, Orodispersible tablets, rapimelts, porous tablets, quick dissolving etc. The basic approach in development of FDT is the use of superdisintegrants like cross linked carboxymethylcellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrollidone (polyplasdone) etc, which provide instantaneous disintegration of tablet after putting on tongue, their by release the drug in saliva.[1]

1.1.1 Ideal characteristics of fast disintegrating tablets[2]

- It exhibits low sensitivity to environmental conditions like humidity and temperature.
- It Should dissolve or disintegrate in the mouth rapidly without the aid of water in a matter of seconds and without swallowing.
- Must maintain physical integrity and possess no friable loss with sufficient mechanical strength.
- It should have a pleasant mouth feel.
- Leaves minimum or no residue in the mouth after oral administration.
- Allows high drug loading capacity.
- Must be adaptable and susceptible to the existing processing and packaging machinery at low costs.
- Should have Small to moderate molecular weight.
- Good solubility in water and saliva.
- Partially non-ionized at the oral cavity pH.
- Ability to diffuse and partition into the epithelium of the upper GIT [logp>1 or preferably more than 2].
- Ability to permeate oral mucosal tissue
- The excipients should have high wettability, and the tablet structure should also have a highly porous network for fast dissolution.
- The disintegrating tablet should convert to a soft paste or liquid suspension, which can provide a good mouthfeel and smooth swallowing.
- A pleasant taste inside the oral cavity becomes critical for patient acceptance. The ideal taste-

masking technology should provide drugs without grittiness and with good mouthfeel.
- The amount of taste masking materials used in the ODTs formulation should be less as possible to avoid an excessive increase in tablet size.

1.1.2 Advantages of fast disintegrating tablets[3]
- No need to swallow the tablet with water.
- Masking compatible with taste and feeling pleasant to the mouth.
- Paediatric, elderly and mentally handicapped patients can be readily administered.
- No residue after administration in the oral cavity.
- Using standard processing and packaging equipment, tablets can be delivered at minimum price.
- Allow drug loading to be high.
- Accurate dose as compared to liquids may be provided.
- The medicine is dissolved and absorbed quickly, delivering a rapid onset to action.
- Advantageous in terms of administration and transportation over fluid medication.
- Some drugs are absorbed from the mouth, pharynx and oesophagus as the saliva moves into the stomach, thereby decreasing the metabolism of the first pass, which promotes bioavailability and decreases the dose and side effects.
- No risk of suffocation when swallowed owing to physical disturbance, thus enhancing safety.
- ODTs are appropriate for sustained and controlled release actives.
- Packaging for each unit.

1.1.3 Limitations of fast disintegrating tablets
- Usually tablets have inadequate mechanical strength. It is therefore essential to handle conscientiously.
- Unless correctly formulated, tablets may leave an unpalatable flavour and gritty in the oral cavity.
- Drugs with massive doses can cause issues in the formulation of FDTs.
- Patients receiving anticholinergic drugs at the same time are not appropriate candidates for FDTs.[3]

1.2 Mechanism of disintegration by superdisintegrants[4]
- Swelling: eg: sodium starch glycolate.
- Porosity and capillary action(wicking):eg: crospovidone, crosscarmillose.
- Deformation: eg: starch grains.
- Due to disintegrating particle/particle repulsive forces.
- By enzymatic reaction.

1.3 Criteria for Fast dissolving Drug Delivery System[1]
The tablets should
- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental condition as temperature and humidity.
- Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost.

1.4 Techniques in preparation of fast disintegrating drug delivery system[4]
1. Freeze drying or Lyophilization
2. Spray drying.
3. Moulding
4. Phase transition process
5. Melt granulation
6. Sublimation
7. Mass extrusion
8. Direct compression
9. Nanonization
10. Effervescent method

1.4.1 Patented Technologies for Fast Disintegrating Tablets[5]
a) Zydis Technology

Zydis was the first marketed technology developed by R.P.Scherer, Inc. for formation of new generation tablets. Zydis tablet is produced by lyophilizing or freeze-drying the drug in a matrix usually consisting of gelatin. The product is very light weight and fragile, which is dispensed in a special blister-packing. The preparation is also self-preserving because due to freeze drying, there is very little amount of water left in the drug for the attack of the microorganisms. The disintegration time of the tablets made by Zydis technology is few seconds.

b) Durasolv technology

The tablets made by this technology which was developed by CIMA labs, consist of a drug, fillers and the lubricants. The tablets are prepared by conventional tabletting equipment and have good rigidity. They can be packed in the conventional tabletting equipment and have good rigidity. This technology is good for tablets having low amount of active ingredients.

c) Orasolv Technology

CIMA labs developed this technology where the tablets are made by direct compression but with less of the pressure than the conventional DC. The active ingredient is taste masked and it also contains the effervescent disintegrators. The tablets produced are soft and friable and packaged in specially designed pick and place system.

d) Wowtab technology

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. where the word “WOW” means “without water”. It is the combination of low mouldability saccharides and high mouldability

saccharides used to obtain a rapidly melting strong tablet. The active ingredient is mixed with a low mouldability saccharide and granulated with a high mouldability saccharide and compressed into tablet.

e) Flashtab technology

The tablet prepared by this technology was patented by Prographarm laboratories. It dconsists of active ingredient in the form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like coacervation, microencapsulation, and extrusion spheronisation. Beside these, there are some other patented technologies like Lyoc patented by Farmalyoc, Quicksolv patented by Janssen pharmaceutics, Ziplets and Advatab patented by Eurand International, Oraquick patented by KV Pharm.Co.,Inc. etc(Modi ,et al,2006;Reig, et al,2006;Ahmed,et al,2006;Cirri,et al,2006;Takagi,et al,2005)

Table No.1.1: Some of Promising Drug candidates for Fast Dissolving Tablets.[6]

Sl. No	Category	Examples
1	Antibacterial agents	Ciprofloxacin, tetracycline, erythromycin, rifampicin, penicillin, doxycycline, nalidixic acid, trimethoprim, sulphacetamide, sulphadiazine etc.
2	Anthelmintics	Albendazole, mebendazole, thiabendazole, ivermectin, praziquantal, dichlorophen etc.
3	Antideprresants	Trimipramine maleate, nortriptyline HCl, trazodone HCl, amoxapine etc.
4	Antidiabetics	Glibenclamide, glipizide, tolbutamide, tolazamide, gliclazide, chlorpropamide etc.
5	Analgesics/Anti-inflammatory agents	Diclofenac sodium, ibuprofen, ketoprofen, mefenamic acid, naproxen, oxyphenbutazone, indomethacin, piroxicam, phenylbutazone etc,
6	Antihypertensives	Amlodipine, carvedilol, diltiazem, felodipine, minoxidil, nifedipine, prazosin HCl etc.
7	Antiarrhythmics	Disopyramide, quinidine sulphate, amiodarone HCl etc.
8	Antihistamines	Acrivastine, cetirizine, cinnarizine, loratadine, fexofenadine, triprolidine etc.
9	Anxiolytics , sedatives hypnotics and neuroleptics	Alprazolam, diazepam, clozapinde, amylobarbitone, lorazepam, haloperidol, phenobarbitone, oxazepam etc.
10	Diuretics	Acetazolamide, Chlorothiazide, amiloride, furosemide, Spironolactone, bumetanide etc.
11	Gastro-intestinal agents	Cimetidine, ranitidine HCl, famotidine, domperidone, omeprazole, ondansetron HCl, granisetron HCl etc.
12	Corticosteroids	Betamethasone, beclomethasone, hydrocortisone, prednisone, prednisolone etc.
13	Antiprotozoal agents	Metronidazole, tinidazole, imidazole, benznidazole etc.

Table No. 1.2: Marketed Fast Disintegrating Tablets.[7]

Sl. No	Name of the Product	Active Ingredients	Company
1	Feldene Fast, Melt	Piroxicam	Pfizer, USA
2	Claritin Redi tabs	Loratadine	Schering plough corp, USA
3	Mazalit MTL	Rizatriptan	Merckasnd Co. USA
4	Zyprexa	Olanzapine	Eli Lilly, USA
5	Nimulid-MD	Nimesulide	Panacea Biotech, India
6	Pepcid RPD	Famotidine	Merck and Co,USA
7	Zofran ODT	Ondansetron	Glaxo Wellcome, UK
8	Zooming – ZMT	Zolmitriptan	Astra Zeneca, USA
9	Zepclo TM	Selegiline	Amarin Corp, UK
10	Torrox MT	Rofecoxib	Torrent pharmaceutical, India

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