

FAST DISSOLVING TABLET

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Received: 30 July 2010, Revised and Accepted: 05 Oct 2010

ABSTRACT

Tablet is the most popular among all dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing; however hand tremors, dysphasia in case of geriatric patients, the underdeveloped muscular and nervous systems in young individuals and in case of uncooperative patients, the problem of swallowing is common phenomenon which leads to poor patient compliance. To overcome these drawbacks, mouth dissolving tablets (MDT) or orally disintegrating tablets, (ODT) has emerged as alternative oral dosage forms. These are novel types; of tablets that disintegrate/dissolve/ disperse in saliva within few seconds'. According to European Pharmacopoeia, the ODT should disperse/disintegrate in less than three minutes. The basic approach used in development of MDT is the use of super disintegrants like Cross linked carboxymethyl cellulose (Croscarmellose), Sodium starch glycolate (Primogel, Explotab). Polyvinylpyrrolidone (Polyplasdone) etc. which provide instantaneous disintegration of tablet after putting on tongue, thereby releasing the drug in saliva. The bioavailability of some drugs may be increased due to absorption of drugs in oral cavity and also due to pregastric absorption of saliva containing dispersed drugs that pass down into the stomach. Moreover, the amount of drug that is subject to first pass metabolism is reduced as compared to standard tablets.

Keywords: Fast Dissolving Tablet, Drug delivery system

INTRODUCTION

Definition

A fast-dissolving drug delivery system, in most cases, is a tablet that dissolves or disintegrates in the oral cavity without the need of water or chewing. Most fast-dissolving delivery system films must include substances to mask the taste of the active ingredient. This masked active ingredient is then swallowed by the patient's saliva along with the soluble and insoluble excipients. 4-5 These are also called melt-in-mouth tablets, porous tablets, oro-dispersible, quick dissolving or rapid disintegrating tablets.

Ideal Properties of Fast Dissolving Tablet

Require no water for oral administration, yet dissolve /disperse/ disintegrate in mouth in a matter of seconds. Have a pleasing mouth feel. Have an acceptable taste masking property. Be harder and less friable. Leaves minimal or no residue in mouth after administration

Advantages of Fast Dissolving Tablet

Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure & patients who refuse to swallow such as pediatric, geriatric & psychiatric patients. Rapid drug therapy intervention achieves increased bioavailability/rapid absorption through pregastric absorption of drugs from mouth, pharynx & oesophagus as saliva passes down. Convenient for administration and patient compliant for disabled, bedridden patients and for travelers and busy people, who do not always have access to water. Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients. The lower risk of choking or suffocation during oral administration.

Salient Features of Fast Dissolving Drug Delivery

System

Ease of administration to patients who refuse to swallow a tablet, such as pediatric and geriatric patients and, psychiatric patients. Convenience of administration and accurate dosing as compared to liquids. No need of water to swallow the dosage form, which is highly convenient feature for patients who are traveling and do not have immediate access to water. Good mouth feels properly of MDDS helps to change the basic view of medication as "bitter pill", particularly for patients. Rapid dissolution of drug and absorption which may produce rapid, onset of action. Some drugs are absorbed from the mouth pharynx and oesophagus as the saliva passes down

into the stomach, In such cases bioavailability of drugs is increased. Ability to provide advantages of liquid medication in the form of solid preparation. Pregastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects.

Conventional Techniques used for preparation of FDDDS

Disintegrant Addition

Disintegrant addition technique is one popular technique for formulating Fast-dissolving tablets because of its easy implementation and cost-effectiveness. The basic principle involved in formulating Fast-dissolving tablets by disintegrant addition technique is addition of superdisintegrants in optimum concentration so as to achieve rapid disintegration along with the good mouth feel. Microcrystalline cellulose and low substituted hydroxypropyl cellulose were used as disintegrating agents' in the range of 8:2 – 9:1 to prepare fast dissolving tablet. Agar powder is used as disintegrant for the development of rapidly disintegrating tablets by enhancing the porosity of agar by water treatment. Rapidly disintegrating tablets of bitter drug *oxycodone* & *pirozepine* were prepared by using the taste masked granules and the mixture of excipients consisting of crystalline cellulose (Avicel PH 02) and low-substituted hydroxypropyl cellulose HPC, LH-11), Ishikawa et al. prepared rapidly disintegrating tablets using microcrystalline cellulose (Avicel PH-M series) that was spherical and had a very small particle size (7-32 μm). Instead of conventional microcrystalline cellulose (PH 102). Tablets prepared using microcrystalline cellulose; PH-M06 and L-HPC in the ratio of 9:1 were very rapidly disintegrating in saliva. They concluded that Avicel PH-M06 was superior to Avicel PH102 in terms of the feeling of roughness in the mouth. Fast dissolving tablet of *efavirenz* (anti HIV agent) were formulated by using combination of microcrystalline cellulose and sodium starch glycolate as super disintegrant. Prepared a fast-dissolving tablet of *galanthamine hydro bromide* which comprises of spray dried mixture of lactose monohydrate and microcrystalline cellulose (75:25) as a diluent, a cross linked polymeric disintegrant such as cross povidone and with a direct compression process of preparing such fast-dissolving tablets. Fast-dissolving tablets having analgesic activity was formulated using a combination of superdisintegrants. Rapid oral disintegration tablets were developed by direct compression using co-ground mixture of D-mannitol and crospovidone. CIMA labs patented Orasolv technology by employing the evolution of carbon dioxide or the effervescence as disintegration

mechanism in the formulation of fast-dissolving tablets. The Orasolv technology is an oral dosage form, which combines taste-masked drug ingredients with a quick dissolving effervescent excipients system. Taste masking is achieved through a process of microencapsulation, which coats and traps the active compound in an immediate release matrix. The effervescent excipients system aids in rapid disintegration of the tablet, permitting swallowing of pharmaceutical ingredients before they come in contact with the taste bud. The Orasolv tablet dissolves quickly without chewing or without water and allows for effective taste masking of a

wide variety of active drug ingredients, both prescription and nonprescription. Flashtab technology™ is a patented technology of Prographarm, which employ combination of taste-masked multiparticulate active drug substances, a disintegrating agent, a swelling agent and other excipients to form a multiparticulate tablet that disintegrates rapidly. Rapidly disintegrating multiparticulate tablet was prepared by using taste-masked microcrystals of drugs, crosslinked disintegrating agent and soluble diluent with binding properties.

Table 1: List of super disintegrants

Superdisintegrants	Example	Mechanism Of action	Special comment
Crosscarmellose® Ac-Di-Sol® Nymce ZSX® Primellose®Solutab® Vivasol®L-HPC Crosspovidone Crosspovidone M® Kollidon® Polyplasdone®	Crosslinked Cellulose Cross linked PVP	-Swells 4-8 folds in < 10 seconds. -Swelling and wicking both -Swells very little and returns to original size after compression but act by capillary action -Swells 7-12 folds in < 30 seconds	Swells in two dimensions. -Direct compression or granulation -Starch free -Water insoluble and spongy in nature so get porous tablet
Sodium starch glycolate Explotab® Primogel®	Cross linked Starch		Swells in three dimensions and high level serve as sustain release matrix
Alginic acid NF Satialgine®	Cross linked alginic acid	-Rapid swelling in aqueous medium or wicking action	-Promote disintegration in both dry or wet granulation
Soy polysaccharides Emcosoy®	Natural super disintegrate		-Does not contain any starch or sugar. Used in nutritional products.
Calcium silicate		-Wicking action	Highly porous, Optimum concentration is between 20-40%.

Freeze Drying

A process in which water is sublimated from the product after freezing. Lyophilization is a pharmaceutical technology which allows drying of heat sensitive drugs and biological at low temperature under conditions that allow removal of water by sublimation. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability.

Moulding

In this method, molded tablets are prepared by using water soluble ingredients so that the tablets dissolve completely

and rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded into tablets under pressure lower than that used in conventional tablet compression. The solvent is then removed by air-drying. Molded tablets are very less compact than compressed tablets. These possess porous structure that enhances dissolution. Sublimation The slow dissolution of the compressed tablet containing even highly water-soluble ingredients is due to the low porosity of the tablets. Inert solid ingredients that volatilize readily (e. g. urea, ammonium carbonate, ammonium bicarbonate, hexamethylenetetramine, camphor etc.) are added to the other tablet ingredients and the mixture is compressed into tablets. The volatile materials are then removed via sublimation, which generates porous structures. Additionally, several solvents (e. g. cyclohexane, benzene) can be also used as pore forming agents.

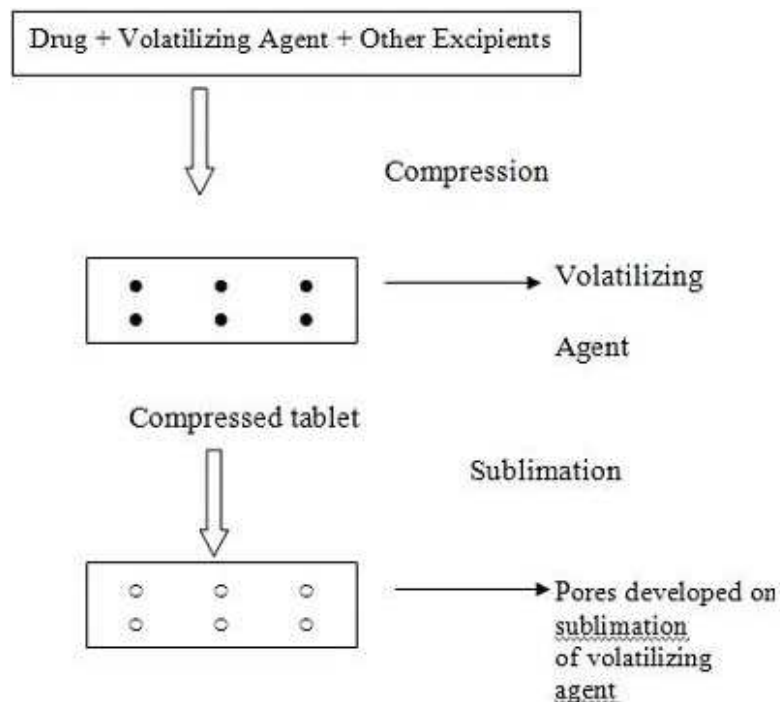


Fig. 1: Steps Involved in sublimation

Spray-Drying

Spray drying can produce highly porous and fine powder that dissolve rapidly. The formulations are incorporated by hydrolyzed and non hydrolyzed gelatins as supporting agents, mannitol as bulking agent, sodium starch glycolate or crosscarmellose sodium as disintegrating and an acidic material (e. g. citric acid) and / or alkali material (e. g. sodium bicarbonate) to enhance disintegration and dissolution. Tablet compressed from the spray dried powder disintegrated within 20 seconds when immersed in an aqueous medium.

Mass-Extrusion

This technology involves softening the active blend using the solvent mixture of water soluble polyethylene glycol, using methanol and expulsion of softened mass through the extruder or syringe to get a cylinder of the product into even segments using heated blade to form tablets. The dried cylinder can also be used to coat granules of bitter tasting drugs and thereby masking their bitter taste.

Direct Compression

It is the easiest way to manufacture tablets. Conventional equipment, commonly available excipients and a limited number of processing steps are involved in direct compression. Also high doses can be accommodated and final weight of tablet can easily exceed that of other production methods. Compressed tablet's disintegration and solubilization depends on single or combined action of disintegrants, water soluble excipients and effervescent agent.

Patented Technologies For Fast Dissolving Tablets

Zydis Technology

Zydis, the best known of the fast-dissolving/disintegrating tablet preparations was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placing on the tongue. A Zydis tablet is produced by lyophilizing or freeze-drying 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. Patients should be advised not to push the tablets through the foil film, but instead peel the film back to release the tablet. The Zydis product is made to dissolve on the tongue in 2 to 3 seconds.

The Zydis formulation is also self-preserving because the final water concentration in the freeze-dried product is too low to allow for microbial growth.

Durasolv Technology

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Orasolv Technology

Orasolv Technology has been developed by CIMA labs. In this system active medicament is taste masked. It also contains effervescent disintegrating agent. Tablets are made by direct compression technique at low compression force in order to minimize oral dissolution time. Conventional blenders and tablet machine is used to produce the tablets. The tablets produced are soft and friable and packaged in specially designed pick and place system.

Flash Dose Technology

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 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 processing.

Wowtab Technology

Wowtab Technology is patented by Yamanouchi Pharmaceutical Co. WOW means "Without Water". In this process, combination of low mouldability saccharides and high mouldability saccharides is 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.

Flashtab Technology

Prographarm laboratories have patented the Flashtab technology. Tablets prepared by this system consist of an active ingredient in the

form of micro crystals. Drug micro granules may be prepared by using the conventional techniques like Coacervation, microencapsulation, and extrusion spherulisation. All the processing utilized conventional tableting technology.

Promising Drugs to be incorporated In Fast Dissolving Tablets

There are no particular limitations as long as it is a substance which is used as a pharmaceutical active ingredient.

Analgesics and Anti-inflammatory Agents

Aloxiprin, Auranofin, Azapropazone, Benorylate, Diflunisal, Etodolac, Fenbufen, Fenoprofen Calcium, Flurbiprofen, Ibuprofen, Indomethacin, Ketoprofen, Meclofenamic Acid,

Mefenamic Acid, Nabumetone, Naproxen, Oxaprozin, Oxyphenbutazone, Phenylbutazone, Piroxicam, Sulindac.

Anthelmintics

Albendazole, Bephenium Hydroxynaphthoate, Cambendazole, Dichlorophen, Ivermectin, Mebendazole, Oxarniquine, Oxfendazole, Oxantel Embonate, Praziquantel, Pyrantel Embonate, Thiabendazole.

Anti-Arrhythmic Agents

Amiodarone, Disopyramide, Flecainide Acetate, Quinidine Sulphate,

Anti-bacterial Agents

Benethamine Penicillin, Cinoxacin, Ciprofloxacin, Clarithromycin, Clofazimine, Cloxacillin, Demeclocycline, Doxycycline, Erythromycin, Ethionamide, Imipenem, Nalidixic Acid, Nitrofurantoin, Rifampicin, Spiramycin, Sulphabenzamide, Sulphadoxine, Sulphamerazine, Sulphacetamide, Sulphadiazine, Sulphafurazole, Sulphamethoxazole, Sulphapyridine, Tetracycline, Trimethoprim.

Anti-coagulants

Dicoumarol, Dipyridamole, Nicoumalone, Phenindione.

Anti-Depressants

Amoxapine, Ciclazindol, Maprotiline, Mianserin, Nortriptyline, Trazodone, Trimipramine Maleate, Acetohexamide, Chlorpropamide, Glibenclamide, Gliclazide, Glipizide, Tolazamide,

Anti-Epileptics

Beclamide, Carbamazepine, Clonazepam, Ethotoin, Methoin, Methsuximide, Methylphenobarbitone, Oxcarbazepine, Paramethadione, Phenacemide, Phenobarbitone, Phenytoin, Valproic Acid.

Anti-Fungal Agents

Amphotericin, Butoconazole Nitrate, Clotrimazole, Econazole Nitrate, Fluconazole, Flucytosine, Griseofulvin, Itraconazole, Ketoconazole, Miconazole, Natamycin, Nystatin, Sulconazole

Nitrate, Terbinafine, Terconazole, Tioconazole, Undecenoic Acid.

Anti-Gout Agents

Allopurinol, Probenecid, Sulphinpyrazone.

Anti-Hypertensive Agents

Amlodipine, Carvedilol, Benidipine, Darodipine, Diltiazem, Diazoxide, Felodipine, Guanabenz Acetate, Indoramin, Isradipine, Minoxidil, Nicardipine, Nifedipine, Nimodipine, Phenoxybenzamine, Prazosin, Reserpine, Terazosin.

Anti-Malarials

Amodiaquine, Chloroquine, Chlorproguanil, Halofantrine, Mefloquine, Proguanil, Pyrimethamine, Quinine Sulphate.

Anti-Migraine Agents

Dihydroergotamine Mesylate, Ergotamine Tartrate, Methysergide Maleate, Pizotifen Maleate, Sumatriptan Succinate.

Anti-Muscarinic Agents

Atropine, Benzhexol, Biperiden, Ethopropazine, Hyoscine Butyl Bromide, Hyoscyamine, Mepenzolate Bromide, Orphenadrine, Oxyphencyclimine, Tropicamide.

Anti-Neoplastic Agents And Immunosuppressants

Aminoglutethimide, Amsacrine, Azathioprine, Busulphan, Chlorambucil, Cyclosporin, Dacarbazine, Estramustine, Etoposide, Lomustine, Melphalan, Mercaptopurine, Methotrexate, Mitomycin, Mitotane, Mitozantrone, Procarbazine, Tamoxifen Citrate, Testolactone.

Anti Protozoal Agents

Benznidazole, Clioquinol, Decoquinol, Diiodohydroxyquinoline, Diloxanide Furoate, Dinitolmide, Furzolidone, Metronidazole, Nimorazole, Nitrofurazone, Omidazole, Tinidazole.

Anti-Thyroid Agents

Carbimazole, Propylthiouracil.

Anxiolytic, Sedatives, Hypnotics And Neuroleptics

Alprazolam, Amyobarbitone, Barbitone, Bentazepam, Bromazepam, Bromperidol, Brotizolam, Butobarbitone, Carbromal, Chlordiazepoxide, Chlormethiazole, Chlorpromazine, Clobazam, Clotiazepam, Clozapine, Diazepam, Droperidol, Ethinamate, Flunansone, Flunitrazepam, Fluopromazine, Flupenuixol Decanoate, Fluphenazine Decanoate, Flurazepam, Haloperidol,

Lorazepam, Lormetazepam, Medazepam, Meprobamate, Methaqualone, Midazolam, Nitrazepam, Oxazepam, Pentobarbitone, Perphenazine Pimozide, Prochlorperazine, Suipiride, Temazepam, Thioridazine, Triazolam, Zopiclone.

Cardiac Inotropic Agents

Amrinone, Digitoxin, Digoxin, Enoximone, Lanatoside C, Medigoxin.

Corticosteroids

Beclomethasone, Betamethasone, Budesonide, Cortisone Acetate, Desoxymethasone, Dexamethasone, Fludrocortisone Acetate, Flunisolide, Flucortolone, Fluticasone Propionate,

Hydrocortisone, Methylprednisolone, Prednisolone, Prednisone, Triamcinolone.

Diuretics

Acetazolamide, Amiloride, Bendrofluazide, Bumetanide, Chlorothiazide, Chlorthalidone, Ethacrynic Acid, Frusemide, Metolazone, Spironolactone, Triamterene.

Enzymes : All The Enzymes.

Anti-Parkinsonian Agents

Bromocriptine Mesylate, Lysuride Maleate.

Gastro-Intestinal Agents

Bisacodyl, Cimetidine, Cisapride, Diphenoxylate, Domperidone, Famotidine, Loperamide, Mesalazine, Nizatidine, Omeprazole, Ondansetron, Ranitidine, Sulphasalazine.

Histamine H₂-Receptor Antagonists

Acrivastine, Astemizole, Cinnarizine, Cyclizine, Cyproheptadine, Dimenhydrinate, Flunarizine, Loratadine, Meclozine, Oxatamide, Terfenadine, Triprolidine.

Lipid Regulating Agents

Bezafibrate, Clofibrate, Fenofibrate, Gemfibrozil, Probucof.

Local Anaesthetics

Lidocaine

Neuro-Muscular Agents

Pyridostigmine.

Nitrates And Other Anti-Anginal Agents

Amyl Nitrate, GlycerylTrinitrate, IsosorbideDinitrate, IsosorbideMononitrate, PentaerythritolTetranitrate.

Nutritional Agents

Betacarotene, Vitamin A, Vitamin B 2 , Vitamin D, Vitamin E, Vitamin K.

Opioid Analgesics

Codeine, Dextropropoxyphene, Diamorphine, Dihydrocodeine, Meptazinol, Methadone, Morphine, Nalbuphine, Pentazocine.

Oral Vaccines

Vaccines designed to prevent or reduce the symptoms of diseases of which the following is a representative Influenza, Tuberculosis, Meningitis, Hepatitis, Whooping Cough, Polio, Tetanus, Diphtheria, Malaria, Cholera, Herpes, Typhoid, Hiv, Aids, Measles, Lyme Disease, Travellers Hepatitis A, B And C, Otitis Media, Dengue Fever, Rabies, Parainfluenza, Rubella, Yellow Fever, Dysentery, Legionnaires Disease, Toxoplasmosis, Q-Fever, Haemorrhagic Fever, .

Proteins, Peptides And Recombinant Drugs

Insulin(Hexameric/Dimeric/Monomeric Forms), Glucagon, Growth Hormone (Somatotropin), Calcitonins and synthetic modifications thereof, Enkephalins, Interferons (Especially Alpha-2 Interferon for treatment of common colds).

Sex Hormones

Clomiphene Citrate, Danazol, Ethinyloestradiol, Medroxyprogesterone Acetate, Mestranol,

Methyltestosterone, Norethisterone, Norgestrel, Oestradiol, Conjugated Oestrogens, Progesterone, Stanozolol, Stiboestrol, Testosterone, Tibolone.

Stimulants

Amphetamine, dexamphetamine, dexfenfluramine, fenfluramine, mazindol, pemoline.

Evaluation of Powder Properties of Tablet

The quality of tablet, once formulated by rule, is generally dictated by the quality of physicochemical properties of blends. There are many formulation and process variables involved in mixing and all these can affect the characteristics of blends produced. The various characteristics of blends tested are as given below:

1. Angle of Repose

The frictional force in a loose powder can be measured by the angle of repose θ . It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. If more powder is added to the pile, it slides down the sides of the pile until the mutual friction of the particles producing a surface angle, which is in equilibrium with the gravitational force.

The angle of repose was determined by the funnel method suggested by Newman. Angle of repose is determined by the

Formula

$$\tan \theta = h/r$$

Therefore $\theta = \tan^{-1}h/r$

Where θ = Angle of repose

h = height of the cone

r = Radius of the cone base

Angle of Repose less than 30 ° shows the free flowing of the material.

Table 2: Angle of Repose as an Indication of Powder Flow Properties

Sr. No.	Angle of Repose (θ)	Type of Flow
1	< 20	Excellent
2	20 – 30	Good
3	30 – 34	Passable
4	> 34	Very Poor

2. Bulk Density

Density is defined as weight per unit volume. Bulk density, pb, is defined as the mass of the powder divided by the bulk volume and is expressed as gm/ cm³. The bulk density of a powder primarily depends on particle size distribution, 'particle shape and the tendency of particles to adhere together. There are two types of bulk density. The particles are packed in such a way so as to leave large gaps between their surfaces 'resulting up in light powder of low bulk density. Here the smaller particles shift between the large particles resulting in heavy powder of high bulk density.

Bulk density is very important in the size of containers needed for handling, shipping, and storage of raw material and blend. It is also important in size blending equipment. A standard procedure used for obtaining bulk density or its reciprocal bulkiness is given, below. A sample of about 50 cm³ (blend) is carefully introduced in a 100ml graduated cylinder. The cylinder is dropped onto a hard wood surface three times from a height of 1 inch at two second interval. The bulk density is then obtained by dividing the weight of sample in gms by final volume in cm³.

$$Pb = M/Vp$$

Where

pb = Bulk Density "

M = Weight of sample in gm

V = Final volume of blend in cm³

3. Bulkiness

Specific bulk volume or reciprocal of bulk density is called bulkiness or bulk. Bulkiness increases with a decrease in particle size. In a mixture of material of different sizes, however the smaller particle shifts between the larger particles and tends to reduce the bulkiness. The bulkiness can be calculated by the following formula

$$\text{Bulkiness} = 1/ p b$$

where

pb = Bulk Density.

Loose bulk density

It is defined as the ratio of weight of blend in gms to the loose bulk volume (untapped volume) in cm³ Loose bulk density

$$\text{Loose bulk density } p u = \text{Weight in gms} / V b$$

Where

V b = Bulk volume (untapped volume)

4. Void Volume

The volume of the spaces is known as the void volume v

$$V = Vb - Vp$$

Where

Vb = Bulk volume (volume before tapping)

V = True volume (volume after tapping)

5. Porosity

The porosity ϵ of powder is defined as the ratio of void volume to the bulk volume of the packaging.

The porosity of the powder is given by

$$\epsilon = \frac{V_b - V_p}{V_p} = 1 - \frac{V_p}{V_b}$$

Porosity is frequently expressed in percentage and is given as

$$\% \epsilon = (1 - \frac{V_p}{V_b}) \times 100$$

The porosity of powder indicates the types of packaging powder undergoes when subject to vibrations, when stored, or in tablet machine when passed through hopper or feedframe.

6. Percent Compressibility

It is an important measure obtained from bulk density and is

Defined as,

$$C = \frac{P_b - P_u}{P_b} \times 100$$

Where P_b = tapped density of powder

P_u = bulk density of powder

If the bed of particles is more compressible the blend will be less flowable and flowing materials.

Table 3: Relationship between % compressibility and flow ability

% Compressibility	Flow ability
5 – 12	Excellent
12 – 16	Good
18 – 21	Fair Passable
23 – 35	Poor
33 – 38	Very Poor
< 40	Very Poor

Evaluation Test For Fast Dissolving Tablet

Tablets from all the formulation were subjected to following quality control test.

1. General Appearance

The general appearance of a tablet, its visual identity and overall "elegance" is essential for consumer acceptance. Included are tablet's size, shape, colour, presence or absence of odour, taste, surface texture, physical flaws and consistency and legibility of any identifying marking.

2. Size and Shape

The size and shape of the tablet can be dimensionally described, monitored and controlled.

3. Tablet thickness:

Tablet thickness is an important characteristic in reproducing appearance and also in counting by using filling equipment. Some filling equipment utilizes the uniform thickness of the tablets as a counting mechanism. Ten tablets were taken and their thickness was recorded using micrometer.

4. Uniformity of weight

I. P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. The weight variation test would be a satisfactory method of determining the drug content uniformity.

Table 4: I. P. Specification for uniformity of weight

Average weight of Tablets(mg)	% Deviation
80 mg or less	±10
More than 80 mg but less	±7.5

than 250 mg
250 mg or more

±5

5. Tablet hardness

Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under condition of storage transformation and handling before use depends on its hardness. Hardness of the tablet of each formulation was determined using Monsanto Hardness tester.

6. Friability

It is measured of mechanical strength of tablets. Roche friabilator was used to determine the friability by following procedure. A preweighed tablet was placed in the friabilator. Friabilator consist of a plastic-chamber that revolves at 25rpm, dropping those tablets at a distance of 6 inches with each revolution. The tablets were rotated in the friabilator for at least 4 minutes. At the end of test tablets were dusted and reweighed, the loss in the weight of tablet is the measure

of friability and is expressed in percentage as

$$\% \text{Friability} = \frac{\text{loss in weight}}{\text{Initial weight}} \times 100$$

7. In Vivo Disintegration test

The test was carried out on 6 tablets using the apparatus specified in I. P. -1996 distilled water at $37^\circ\text{C} \pm 2^\circ\text{C}$ was used as a disintegration media and the time in second taken for complete disintegration of the tablet with no palable mass remaining in the apparatus was measured in seconds.

8. Wetting time

The method reported by Yunxia et al. , was followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small petridish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation was also determined.

In vitro dispersion time

In vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Sorenson's buffer pH 6.8. Three tablets from each formulation were randomly selected and in vitro dispersion time was performed.

9. Stability Study (Temperature Dependent)

The fast dissolving tablets are packed in suitable packaging and stored under the following conditions for a period as prescribed by ICH guidelines for accelerated studies.

(i) $40 \pm 1^\circ\text{C}$

(ii) $50 \pm 1^\circ\text{C}$

(iii) $37 \pm 1^\circ\text{C}$ and RH 75% \pm 5%

The tablets were withdrawn after a period of 15 days and analyzed for physical characterization (Visual defects, Hardness, Friability, Disintegrations, Dissolution etc.) and drug content. The data obtained is fitted into first order equations to determine the kinetics of degradation. Accelerated stability data are plotting according Arrhenius equation to determine the shelf life at 25°C .

CONCLUSION

Fast dissolving tablets constitute an innovative dosage form, which overcomes the problem of swallowing and provides a quick onset of action. The pediatric and geriatric populations are the primary targets, as both the groups found it difficult to swallow conventional tablets. The basic approach followed by all the currently available technologies engaged in the formulation of Fast dissolving tablets is to maximize the porous structure of the tablet matrix and

incorporate super disintegrating agents in optimum concentration so as to achieve rapid disintegration and instantaneous dissolution of the tablet along with good taste masking properties and excellent mechanical strength. The availability of the various technologies and manifold advantages of Fast dissolving tablets will surely increase its popularity in the near future.

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