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Preparation and Evaluation of Mouth Dissolving Tablet –A Review

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ABSTRACT: Drugs are rarely administered as pure chemical substances. They are most frequently given as formulated preparations or medicines, usually orally, the most popular dosage forms being tablets, capsules, suspensions, solutions and emulsion.Oral drug delivery is the simplest and easiest way of administering drugs.Because of the greater stability, smaller bulk, accurate dosage and easy production, solid oral dosages forms have manyadvantages over other types of oral dosage forms. Therefore, mostof the new chemical entities (NCE) under development these daysare intended to be used as a solid dosage form that originate aneffective and reproducible in vivo plasma concentration after oraladministration.

KEYWORDS: Mouth Dissolving Tablet,Superdisintegrants , Direct Compression.

INTRODUCTION

Tablets

Tablets may be defined as solid pharmaceutical dosage forms containing medicament with or without suitable excipients and prepared either by compression or moulding.

Advantages of Tablet

Some of the potential advantages of tablets are as follows.

1. They are the unit dosage form having greatest capabilities amongst all the oral dosage form for the dose precision and least content variability.
2. Their cost is lowest amongst all the oral dosage forms.
3. They are the lightest and the most compact amongst all the oral dosage form.
4. They are easiest and cheapest for packaging and transportation.
5. They lend themselves to certain special release profile products such as enteric or delayed release products.
6. Tablets are better suited to large-scale production than other unit oral dosage forms.

They have the best-combined properties of chemical, mechanical, microbiological stability amongst all the oral dosage forms.

Classification of Tablets

Based on the route of administration or the function, the tablets are classified as follows;

1. Tablets ingested orally.

a) Standard Compressed tablet
b) Multiple compressed tablet
i. Layered Tablet
ii. Compression coated Tablet
c) Repeat action Tablet
d) Delayed action and enteric coated Tablet
e) Sugar and chocolate coated tablet
f) Film coated tablet
g) Chewable Tablet
h) Targeted tablet
i. Floating tablet
ii. Colon targeted tablet

These tablets are meant to be swallowed intact along with a sufficient quantity of potable water. Exception is chewable tablet. Over 90% of the tablets manufactured today are ingested orally. This shows that this class of formulation is the most popular worldwide and the major attention of the researcher is towards this direction.

2. Tablets used in the oral cavity.

a) Buccal Tablet
b) Sublingual Tablet
c) Troches and Lozenges
d) Dental cones
e) Mouth dissolved tablet

The tablets under this group are aimed release API in oral cavity or to provide local action in this region. The tablets under this category avoids first-pass metabolism, decomposition in gastric environment, nauseatic sensations and gives

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rapid onset of action. The tablets formulated for this region are designed to fit in proper region of oral cavity.

3. Tablets administered by other routes.
a) Implantation Tablet
b) Vaginal Tablets

These tablets are administered by other route except for the oral cavity and so the drugs are avoided from passing through gastro intestinal tract. These tablets may be inserted into other body cavities or directly placed below the skin to be absorbed into systemic circulation from the site of application.

4. Tablets used to prepare solution.
a) Effervescent Tablet
b) Dispensing Tablet
c) Hypodermic Tablet
d) Tablets Triturates

The tablets under this category are required to be dissolved first in water or other solvents before administration or application. This solution may be for ingestion or parentral application or for topical use depending upon type of medicament used.

Mouth dissolving tablet:

Recent advances in Novel Drug Delivery System (NDDS) aims to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach is Mouth dissolving tablet.

The growing importance of mouth dissolving tablet was underlined recently when European Pharmacopoeia adopted the term Orodispersible Tablet as a tablet that to be placed in the mouth where it disperses rapidly before swallowing.A solid dosage form that dissolve or disintegrates rapidly in oral cavity, resulting in solution or suspension without the need of water is known as fast dispersing dosage form,mouth dissolving tablets,orally disintegrating tablets, fast-dissolving, rapid-melt, porous, orodispersible, quick dissolving.

These kinds of tablets are preferred when fast action or relief is desired. When this type of tablet is placed into the mouth, the saliva will serve to rapidly dissolve the tablet.Most commonly used drugs under this formulation are the agents active against migraine. The tablets are designed to disintegrate as well as dissolve within one minute or some within 10 seconds of oral administration in limited quantity of saliva. They liquefy on tongue and patient swallows the liquid, without the need of water. A number of techniques are used to prepare these tablets, including lyophilization, soft direct compression. Matrices having an API and high porosity are also being prepared using sublimation process. Urea, urethane, ammoniumcarbonate, ammonium bicarbonate, hexamethylene, benzoic acid, naphthalene and camphor are commonly used for sublimation processing as they volatize rapidly. After removal by sublimation, these inert volatile substances leave the matrices with a high porosity. Disintegrants and sugar based excipients, such as sodium starch glycolate, cross carmellose sodium, mannitol, xylitol, dextrose, fructose, maltose and polydextrose have been incorporated in almost all the orally disintegrating dosage forms (ODDFs). Loading of drug is made by preparing a blank and drug is post loaded. Generally the drug in solution is added after which the solvent evaporates. Taste masking poses numerous challenges since the drug product dissolves in mouth, any taste of drug must be covered, either by flavoring technique or by micro encapsulation or nano-encapsulation. A major drawback of most of these systems is that the packaging system needs a higher degree of protection due to the lower hardness and more friability of the porous nature of tablets. Keep the orally disintegrating tablet in the blister pack inside the outer foil pouch until the patient is ready to take the medicine. Make sure that operator's hands are dry and peel opens the blister to remove the tablet. Place the tablet on tongue and let it dissolve. These dosage forms have become a delivery system of choice for most patients as they provide comfort for administration throughout the day.

Some tablets are designed to dissolve in saliva remarkably fast, within a few seconds, and are true fast-dissolving tablets[8]. 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. When put on tongue, this tablet disintegrates instantaneously, releasing the drug, which dissolves or disperses in the saliva. Some drugs are absorbed from the mouth, pharynx and esophagus as the saliva passes down into the stomach. In such cases, bioavailability of drug is significantly greater than those observed from conventional tablet dosage form. In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either very porous or soft- moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle,

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which are difficult to handle, often requiring specialized peel-off blister packaging.

Mouth dissolving tablets are also known as fast dissolving, rapid –dissolve, rapimelt, fast melts, porous tablets, EFVDAS or Effervescent Drug Absorption system (Elan Corporation), Orosolv (Cima Labs Inc., USA), Zydis (R.P.Scherer, UK) etc.
(Slowson et al, 1985, Seager, 1998, Bradoo et al, 2001, Gupta et al 2008)

Needs

1. The current needs of the industry are improved solubility/stability, biological half-life and bioavailability enhancement of poorly absorbed drugs.
2. To improve safety (decreasing gastrointestinal side effects)
3. Improve efficacy for organ targeting
4. Improved compliance via sustained release
5. Easy to swallow this dosage forms.
6. In cases such as motion sickness and sudden episodes of allergic attack or coughing.
7. Patients with persistent nausea, who are travelling, or who have little or no access to water.(Dobetti, 2001)

Advantages of Mouth dissolving tablets

1. Improved patient compliance.
2. Rapid onset of action and may offer an improved bioavailability.
3. Patient having difficulty in swallowing tablet can easily administer this type of dosage form.
4. Useful for pediatric, geriatric and psychiatric patients.
5. Suitable during traveling where water is may not be available.
6. Gives accurate dosing as compared to liquids.
7. Good chemical stability.
8. Free of need of measuring, an essential drawback in liquids.

(Reddy et al, 2002, Kuchekar et al, 2001)

Salient Features of Fast Dissolving Drug Delivery System

1. Ease of administration for patients who are disabled and uncooperative.
2. Requires no water.
3. Quick disintegration and dissolution of the dosage form.
4. Overcomes unacceptable taste of the drugs.
5. Can be designed to leave minimal or no residue in the mouth after administration and also to provide a pleasant mouth feel.
6. Allows high drug loading.
7. Ability to provide advantages of liquid medication in the form of solid preparation.
8. Adaptable and ameanable to existing processing and packaging machinery
9. Cost- effective.

(Bhaskaran et al, 2002, Indurwade et al, 2002)

Potential Candidates

1. NSAID′S
2. Anti-emetics
3. Anti-histaminics
4. Anti-migraine
5. Anti-psychotic. (Neuroleptics)
6. Cardiovascular drugs
7. Drugs for erectile dysfunctions

(Devrajan et al, 2000)

Characteristics of Fast Dissolving Delivery Systems

1. **Ease of administration:** Fast Dissolving Delivery Systems are easy to administer and handle hence, leads to better patient compliance. Usually, elderly people experience difficulty in swallowing the conventional dosage forms (tablets, capsules, solutions and suspensions) because of tremors of extremities and dysphasia. Fast Dissolving Delivery Systems may offer a solution for these problems.
2. **Taste of the medicament:** As most drugs are unpalatable, mouth dissolving delivery systems usually contain the medicament in taste masked form. Delivery systems dissolve or disintegrate in patient's mouth, thus releasing the active ingredients which come in contact with the taste buds and hence, taste masking of the drugs becomes critical to patient compliance. The primary methods of taste-masking include adsorption onto or complexation with carriers and spray coating of drug particles.
3. **Hygroscopicity:** Several fast dissolving dosage forms are hygroscopic and cannot maintain physical integrity under normal condition from humidity which calls for specialized product packaging.
4. **Friability:** In order to allow fast dissolving tablets to dissolve in the mouth, they are made of either very porous or soft- moulded matrices or compressed into tablets with very low compression force, which makes the tablets friable and/or brittle, which are difficult to handle, often requiring specialized peel-off blister packaging. To overcome this problem, some companies introduced more robust forms of fast dissolving tablets.

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5. **Mouth feel:** Mouth feel is critical, and patients should receive a product that feels pleasant. Any large particles from the disintegrating tablet that are insoluble or slowly soluble in saliva would lead to an unpleasant gritty feeling. This can be overcome by keeping the majority of the particles below the detectable size limit. In some cases, certain flavors can imbibe an improved mouth feel perception, resulting in a product that is perceived as being less gritty, even if the only change is the flavor. Effervescence can be added to aid disintegration and improve mouth feel by reducing the "dryness" of a product.

(Chang et al,2000, Parakh et al, 2003)

Various Approaches for Mouth dissolving tablets/Fast Dissolving Tablets

The fast-dissolving property of the tablet is attributable to a quick ingress of water into the tablet matrix resulting in its rapid disintegration and instantaneous dissolution of the tablet. Maximizing the porous structure of the tablet matrix and incorporating an appropriate disintegrating agents or highly water soluble excipients in the tablet formulation are the basic approaches used in current fast dissolving tablet technologies. Basically, the disintegrant's major function is to oppose the efficacy of the tablet binder and the physical forces that act under compression to form the tablet.

The mechanism by which tablet is broken down into smaller particles and then produces a homogeneous suspension or solution is based on:

1. Capillary action
2. High swellabilty of disintegrants
3. Capillary action and high swellability
4. Chemical reaction (Release of Gases)

(Kuchekar et al, 2003, Makino et al,1993)

Methods of Preparation of mouth dissolving tablet

1. Freeze –drying or lyophilization
2. Tablet Molding
3. Direct compression
4. Spray drying
5. Sublimation
6. Taste masking
7. Mass extrusion
8. Wet granulation.

1. Freeze drying or lyophilization:

Lyophilization can be used to prepare tablets that have very porous open matrix network into which saliva rapidly moves to disintegrate lyophilized mass after it is placed in mouth. The drug is entrapped in a water soluble matrix which is freeze dried to produce a unit which rapidly disperses when placed in mouth. Apart from the matrix and active constituents, the final formulation may contain other excipients, which improve the process characteristics or enhance the quality of final product. These include suspending agents, wetting agents, preservatives, antioxidants, colors and flavors. The preferred drug characteristics for freeze drying formulations are water insoluble, low dose, chemically stable, small particle size and tasteless. Lyophilization results in preparations, which are highly porous, with a very high specific surface area, which dissolve rapidly and show improved absorption and bioavailability.

2. Molding:

In this technology, water-soluble ingredients are used so that tablet disintegrate and dissolve rapidly. The powder blend is moistened with a hydro alcoholic solvent and is molded into tablet using compression pressure lower than used in conventional tablets compression. The solvent is then removed by air-drying. Molded tablets have a porous structure that enhances dissolution. Two problems commonly encountered are mechanical strength and poor taste masking characteristics. Using binding agents such as sucrose, acacia or poly vinyl pyrrolidone can increase the mechanical strength of the tablet.

3. Spray drying:

Spray drying is a process by which highly porous, fine powders can be produced. Spray drying can be used to prepare rapidly disintegrating tablets. This technique is based on a particulate support matrix, which is prepared by spray drying an aqueous composition containing support matrix and other components to form a highly porous and fine powder. This is then mixed with active ingredients and compressed into tablets.

4. Sublimation:

The basis of this technique is to add inert solid ingredients that volatilize readily, (e.g. camphor, ammonium bicarbonate, naphthalene, urea, urethane etc) to other tablet excipients and the mixture is then compressed into tablets. Volatile material is then removed via sublimation, which generate a porous structure.(Furtado et al,2008,Shirsand et al,2008)

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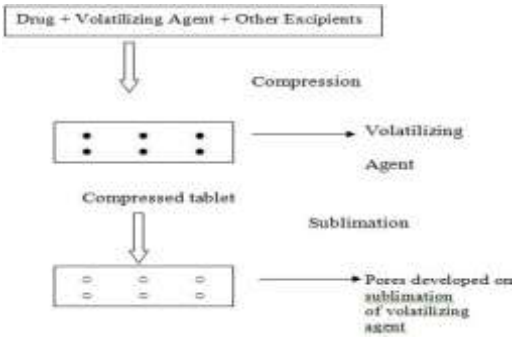
Figure.1 Steps Involved in Sublimation



5. Direct compression:

In this method, tablets are compressed directly from the mixture of the drug and excipients without any preliminary treatment. The mixture to be compressed must have adequate flow properties and cohere under pressure thus making pretreatment as wet granulation unnecessary. Few drugs can be directly compressed into tablets of acceptable quality. A type of disintegrant and its proportion are of prime importance. The other factors to be considered are particle size distribution, contact angle, pore size distribution, tablet hardness and water absorption capacity. All these factors determine the disintegration. The disintegrant addition technology is cost effective and easy to implement at industrial level.

i. Addition of disintegrants

Addition of disintegrants in fast dissolving tablets, leads to quick disintegration of tablets and hence improves dissolution. In many fast dissolving tablet technologies based on direct compression, the disintegrants principally affect the rate of disintegration and hence the dissolution. Microcrystalline cellulose, cross linked carboxymethyl cellulose sodium, cross linked polyvinyl pyrrolidone and partially substituted hydroxypropyl cellulose, though water insoluble, absorb water and swell due to capillary action and are considered as effective disintegrants in the preparation of first dissolving tablets.Fast disintegration of tablets can also be achieved by incorporating effervescent disintegrating agents, which generates carbon dioxide. This phenomenon also resulted in partial taste masking of unacceptable taste of the drug. The major drawback of effervescent excipients is their hygroscopicity (i.e., the ability to absorb atmospheric moisture). Hence, their manufacture requires control of humidity conditions and protection of the final product. This is reflected by the overall cost of the product.

Mechanism of Superdisintegrants

There are four major mechanisms for tablets disintegration as follows

a) Swelling

Perhaps the most widely accepted general mechanism of action for tablet disintegration is swelling. Tablets with high porosity show poor disintegration due to lack of adequate swelling force. On the other hand, sufficient swelling force is exerted in the tablet with low porosity.

It is worthwhile to note that if the packing fraction is very high, fluid is unable to penetrate in the tablet and disintegration is again slows down.

b) Porosity and Capillary Action (Wicking)

Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles. Water uptake by tablet depends upon hydrophilicity of the drug /excipient and on tableting conditions. For these types of disintegrants maintenance of porous structure and low interfacial tension towards aqueous fluid is necessary which helps in disintegration by creating a hydrophilic network around the drug particles.

Figure.2 Disintegration of Tablet by Wicking and Swelling

WICKING SWELLING

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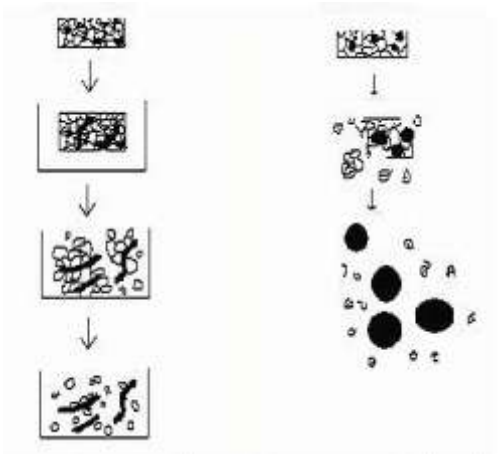


Water is pulled by disintegrant up and reduced the physical bonding force between particles

Particles swell and break the matrix form within

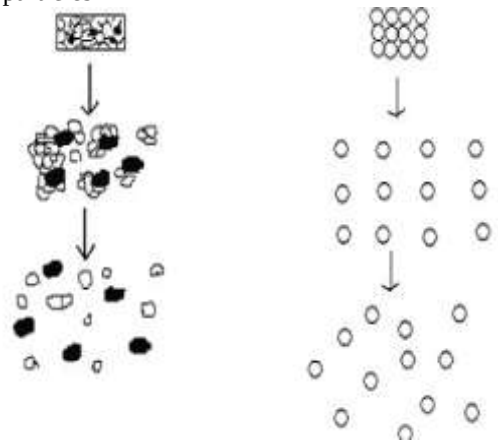
c) Due To Disintegrating Particle/Particle Repulsive Forces

Another mechanism of disintegration attempts to explain the swelling of tablet made with 'non-swellable' disintegrants. Guyot-Hermann has proposed a particle repulsion theory based on the observation that nonswelling particle also cause disintegration of tablets. The electric repulsive forces between particles are the mechanism of disintegration and water is required for it. Researchers found that repulsion is secondary to wicking.

d) Due to deformation

During tablet compression, disintegranted particles get deformed and these deformed particles get into their normal structure when they come in contact with aqueous media or water. Occasionally, the swelling capacity of starch was improved when granules were extensively deformed during compression. This increase in size of the deformed particles produces a break up of the tablet. This may be a mechanism of starch and has only recently begun to be studied.

Figure.3 Disintegration of Tablet by Deformation and Repulsion



DEFORMATION REPULSION

Particles swell to precompression, Water is drawn into pores and size and break up matrix particles repel each other because of resulting electrical force.

ii Sugar-based excipients

Another approach to fast dissolving tablets by direct compression is the use of sugar-based excipients (e.g., dextrose, fructose, isomalt, maltitok, maltose, mannitol, sorbitol, starch hydrolyse, polydextrose, and xylitol), which display high aqueous solubility and sweetness, and hence, impart taste masking and a pleasing mouthfeel.

(Gupta and Sharma, 2008)

6. Taste masking:

Taste masking is an essential requirement for fast dissolving tablets for commercial success. Taste masking of the active ingredients can be achieved by various techniques: - microencapsulating into pH sensitive acrylic

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polymers, Coating Fine granules of drug and disintegrant, coacervation using gelatin, Using Monoglycerides having a low melting point.and by using ion exchange resin also we can done taste masking.

Ion-exchange resins (IERs) are high molecular weight polymers with cationic and anionic functional groups. The most frequently employed polymeric network is a copolymer of styrene and divinylbezene.Ion-exchange resins are used in drug formulations to stabilize the sensitive components, sustain release of the drug, disintegrate tablets, and mask taste. Drug can be bound to the resin by either repeated exposure of the resin to the drug in a chromate graphic column or by prolonged contact of resin with the drug solution.Drugs are attached to the oppositely charged resin substrate, forming insoluble adsorbates or resonates through weak ionic bonding so that dissociation of the drug-resin complex does not occur under the salivary pH conditions. This suitably masks the unpleasant taste and odor of drugs. Ion exchange resins can be classified into four major groups:

. Strong acid cation-exchange resin.
. Weak acid cation-exchange resin.
. Strong base anion-exchange resin.
. Weak base anion-exchange resin.

Strong acid cation resins (sulfonated styrenedivinylbezene copolymer product) function throughout the entire pH range and can be used for masking the taste of basic drugs. Weak acid cation exchange resins function at pH values above 6.0. Similarly, strong base anion-exchange resins function throughout the entire pH range and can be used for masking the taste of acidic drugs, while the weak base anion exchange resins function well below pH 7.0. Polystyrene matrix cation-exchange resins (Indion CRP-244, Indion CRP-254) have been reported to mask the bitter taste of chlorpheniramine maleate, diphenhydramine HCl, ephedrine HCl, noscapine HCl, and amphetamine sulphate. Amberlite IRP-69, a cation-anion exchange resin, is used to mask the bitter taste of buflomedil.Oral liquid products of quinolones (orbifloxacin) and/or their derivatives are formulated using ion exchange resins, such as methacrylic acid polymer crosslinked with divinylbenzene, as the carrier. The formation of a quinolone-resin complex (resinate) eliminates the extreme bitterness of the quinolones to make the liquid oral dosage form palatable. The preparation procedure involves dissolving the quinolone in an aqueous media followed by the addition of an ion exchange resin to form a drug/ resin complex. The complex can be suspended directly into suitable vehicles with flavoring agents such as:

syrup base (malt extract) with the aid of an anticaking agent (colloidal silicone dioxide) and a preservative (sorbic acid). To reduce the bitterness of erythromycin and clarithromycin, a polymer carrier system was developed by adsorption on Carbopol 934. Taste masking was further improved by encapsulating the adsorbate particles with polymer coatings. Hydroxypropyl methylcellulose (HPMC) phthalate (HP-55) provided the best combination of suspension stability, taste protection, and bioavailability. Table 4 summarizes taste masking of drugs by complexing agents and ion-exchange resins. (Madgulkar et al, 2009, Pate et al, 2008, Khan et al 2007)

7. 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.

(Modi and Tayade, 2006, Reig et al, 2006,Ahemd et al, 2006)

Some Patented Technologies for Mouth dissolving tablets:

(Technology - Company's name)

Zydis – Scherer

Zydis, the best known of the mouth-dissolving/disintegrating tablet preparations was the first marketed new technology tablet. The tablet dissolves in the mouth within seconds after placement 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 – Cima

Durasolv is the patented technology of CIMA labs. The tablets made by this technology consist of a drug, fillers and a lubricant. Tablets are prepared by using conventional tableting equipment and have good rigidity. These can be

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packed into conventional packaging system like blisters. Durasolv is an appropriate technology for products requiring low amounts of active ingredients.

Orasolv – Cima

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 - Fuisz 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 shearform matrix termed as "floss". Shearform matrices are prepared by flash heat processing.

Wow Tab - Yamanouchi pharma

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 – Prographarm

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, micro encapsulation, and extrusion spheronisation. All the processing utilized conventional tabletting technology.

Oraquick - K.V.Pharmaceutical

The OraQuick fast-dissolving/disintegrating tablet formulation utilizes a patented taste masking technology. KV Pharmaceutical claims its microsphere technology, known as MicroMask, has superior mouthfeel over taste-masking alternatives.[11] 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 fast-dissolving/disinte-grating 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.

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