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Fast Disintegration Tablets Problems and Evaluation

Akansha S Ganeshpure[1], Rushikesh Shinde[2], Avesh Iliyas Sumar[3], Nitin B. Kohale[4], Suraj B. Rathod[5]
Students[1,2,3], Principal[4] and Assistant Professor[5]
Vardhman College of Pharmacy, Koli, Karanja (Lad), Washim, Maharashtra, India
akanshaganeshpure4@gmail.com

Abstract: *Over the past ten years, the demand for fast disintegrating tablets (FDTs) has grown steadily, and the field is now one of the fastest-growing segments of the pharmaceutical industry. For many medications, oral drug delivery is still the preferred method of administration. Scientists have created FDTs that are more patient-friendly and convenient as a result of recent technological advancements. These tablets dissolve or disintegrate in the mouth when placed there without the need for additional water, making it simple to administer the active pharmaceutical ingredients. The formulation's acceptance and usefulness led to the creation of a number of FDT technologies. Solid unit dose forms known as FDTs dissolve or disintegrate quickly in the mouth without chewing or drinking. FDTs, orally disintegrating tablets, are advantageous for elderly and paediatric patients.*

Keywords: Fast dissolving tablets, freeze drying, spray drying, taste masking

I. INTRODUCTION

Dysphagia and Fast Disintegrating Tablets Fast Dissolving Drug Delivery System was conceived as a way to give patients access to traditional drug administration methods. Dysphagia, an inability to swallow due to physiological changes linked with, particularly, ageing and paediatric patients, is an issue that affects individuals of all ages. The paediatric and geriatric populations, as well as other patients who prefer the convenience of easily swallowable dosage forms, can benefit greatly from solid dosage forms that can be fragmented, dissolved, or suspended by saliva in the mouth. When placed on the tongue, this tablet instantly dissolves, releasing the medication that dissolves or disperses in the saliva. [1] Pharmaceutical treatments for elderly individuals have recently been looked into to increase their treatment compliance and quality of life. Rapidly disintegrating tabletsAre a desirable dosage form and pharmaceutical product that is patient-focused. They can quickly dissolve in saliva. [2] Many researchers are interested in the mouth-dissolving tablets. Tablets, pills, and powders can be challenging to swallow for many older individuals. These tablets are designed to dissolve or disintegrate in the mouth without the need for water to remedy this issue. Saliva aids in the disintegrating mass's smooth descent along the oesophagus, enabling even those who have trouble chewing or swallowing to absorb it without difficulty. [3] Dispersible pills come inTwo varieties that must be distinguished: One While one tablet formulation instantly dissolves in the mouth and can be ingested without the need for water, the other tablet formulation readily dissolves in water to create a dispersion that is simple for the patient to consume. [4]

1.1 Advantages of Fast Disintegrating Tablets

Fast disintegrating tablets (FDTs) are designed to be given to people who have trouble swallowing, including the elderly, people who have had strokes, people who are bedridden, people who have renal failure, and people who refuse to swallow, including children, the elderly, and people with mental illnesses. Drugs from the mouth, pharynx, and oesophagus are pregastricly absorbed by FDTs, resulting in improved bioavailability and fast absorption as saliva travels down the oesophagus. For disabled or immobile patients, as well as for tourists and busy persons who don't always have access to water, FDTs are user-friendly and patient-compliant. Particularly in young children, their pleasant tongue feel quality helps to change the perception of medication as a bitter tablet. The possibility of choking or suffocating while taking Recently, the phrase "or odispersible tablet" was adopted by the European Pharmacopoeia[5] to describe a tablet that is to be placed in the mouth, Where it quickly disperses before being swallowed, and that dissolves in less than 3 minutes. Neither the hardness nor the friability of these types of Tablets were specified. Because

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of this, there are several Rapidly Disintegrating Tablets (RDT) on the market that dissolve in under a minute or even under a minute, but are brittle and need special peelable blister packaging, which raises the price. [6]

II. DESIRED CHARACTERISTICS AND DEVELOPMENT CHALLENGES OF FASTDISINTEGRATING TABLETS

Most frequently, a fast-dissolving drug delivery system is a tablet that, when in contact with saliva, quickly dissolves or disintegrates in the oral cavity, causing the medicine to be dissolved or suspended. [7] Orally disintegrating tablets and orodispersible systems are other names for FDT dosage forms, which have the special ability to dissolve the tablet in the mouth in a matter of seconds. [8]

2.1 Taste of Active Ingredients

When giving medications orally, taste is a crucial factor. One of the major formulation issues that many medications have is unpleasant taste. A major Problem for healthcare practitioners is how to administer bitter medications orally while maintaining an adequate level of palatability. Oral medications now taste better Because to established techniques for bitterness inhibition and reduction. [9] Medicine taste masking can be accomplished by processing the drug to prevent it from coming in contact with the tongue or by adding competing taste-masking agents. Encapsulation in polymer systems or complexation can stop oral exposure of a solubilized medication. [10] The development of taste-masking technologies is increasingly concentrated on drugs with a strong bitter taste, such as penicillins, non-steroidal anti-inflammatory drugs, and macrolide antibiotics. Water-soluble bitter drugs' taste masking, especially those with is challenging to accomplish using only sweeteners at a high dose. As a result, sweeteners have been combined with more effective techniques like coating, microencapsulation, and granulation. [11]Freudenberg et al.[12] received a patent in 1953 for their method of CD complexation for disguising the unpleasant flavour of bromoisovaleryl urea. According to their findings, only compounds that are dissolved in water produce taste sensations; things that are fully insoluble in water have no taste. However, the drugs are frequently so intensely bitter that even at ppm levels, they are barely tolerable. [13]

2.2 Drug Properties

The tablet property of the ideal FDT technology shouldn't be greatly impacted byThe medication qualities. The performance of FDTs could potentially be impacted by a variety of pharmacological attributes. For instance, a drug's solubility, crystal morphology, particle size, hygroscopicity, compressibility, and bulk density can have a big impact on how strong and disintegrating theFinal tablet is. The FDT technology must to be adaptable enough to take into account the special qualities of every medicine. [14] The best moieties for FDTs in doses of 125 and 250 mg are those from Biopharmaceutical Classification System Class II, or those with low solubility and high permeability. [15,16] Tizanidine HCl,[1] Oxybutynin HCl,[2] Rofecoxib,[3] Ibuprofen,[4] Promethazine Theoclate,[17] prednisone,[18] Indomethacin,[19] Glyburide,[20] Fentanyl citrate,[21] Griseofulvin,[22] Hydrochlorothiazide,[23] Crystallized Paracetamol,[24] and Nimesulide[25] are few examples of drugs that has been formulated as fast-dissolving drug delivery system.

2.3 Tablet Strength and Porosity

There have been numerous reports of lyophilizing, shaping, and compressing wet powders to create highly porous structures in an effort to produce fast-disintegrating behaviour. [26] The drug substance needs to dissolve when the FDT is given orally in order for it to be absorbed. Wetting, disintegration, and dissolution are only a few of the different processes that make up the dissolution process. The complex series of steps that lead to the dissolution of FDTs, which typically contain multiple excipients, begins when the solvent contacts the solid and permeates the tablet matrix. Excipient effects are thought to be connected to solid matrix structure and particle surface characteristics. [27] The process of making lyophilized FDTs involves sublimating water from a drug's pre-frozen aqueous formulation, which also contains matrix-forming agents and other excipients such lyoprotectants, preservatives, and flavours, to produce a porous matrix. The FDTs are made up of two lyophilized matrix system component frameworks that cooperate to ensure the formation of a successful formulation. Water-soluble polymers like gelatin, dextran, alginate, and

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maltodextrin areThe initial component. [29] This element keeps the tablets' form while also giving them mechanical strength (binder).The second component, matrix-supporting/disintegration-enhancing substances like sucrose and mannitol, works by clinging to the porous framework created by the water-soluble polymer and hastens the FDT's decomposition. [30] Although there is a wealth of literature available that describes the preparation of .The majority of the research has focused on including mannitol in RDTs by lyophilization, where the number of matrix-supporting/disintegration-enhancing agents has been restricted to saccharides and polyols. [28,30] This is primarily due to the demanding requirements that must be met in order to incorporate these matrix-forming agents, including a reasonable drying time, stability during the freeze-drying process, and the creation of beautiful tablets with quick disintegration times and adequate mechanical properties.

2.4 Moisture Sensitivity

Of fact, hygroscopicity is a crucial feature of a powder. For a relatively soluble chemical, a general relationship between hygroscopicity and solubility can be demonstrated. [31,32] The sensitivity of FDTs to humidity ought to be minimal. Since numerous highly water-soluble excipients are included in formulation to improve fast-dissolving qualities as well as to provide good mouth feel, this be particularly difficult. Those excipients that are extremely water-soluble are vulnerable to moisture; some even deliquesce at high humidity levels. To shield FDTs from diverse environmental factors, a suitable package design or other tactic should be developed. [33]

III. FORMULATION PROCESSES FOR MAKING FAST-DISSOLVING TABLETS

3.1 Freeze Drying

Drugs with low solubility and high permeability are processed using the freeze-drying procedure to increase their dissolution rate and oral bioavailability (biopharmaceutic classification system Class II drugs). After the product has been frozen, water is sublimated from it during the freeze drying (Lyophilization) process. I) The medication is physically trapped in a water-soluble matrix (a water-soluble mixture of saccharide and polymer, intended to give rapid dispersion, and physical strength), which is then freeze dried to produce a product that dissolves quickly when placed in the mouth. A medication that is chemically stable and insoluble in water with particle sizes less than 50 m is needed for these kinds of formulations; [8,34])The development of porous solid forms produced by solvent extraction, a method of freezing an aqueous dispersion or solution of the active containing matrix by removing the water with an excess of alcohol, has the advantage that the thermolabile drugs can be formulated at non-elevatedTemperature, thereby eliminating adverse thermal effects, and stored in a dry state with few shelf-life stability issues;[35]Direct insertion of a solid form of lyophilized oil-in-water emulsion (porous solid galenic form) into the blister alveolus. [36] These dosage forms' primary drawbacks, in addition to the expensive manufacturing process, are the lack of physical resistance in typical blister packs and their restricted capacity to contain greater active drug concentrations. [37].To get the necessary concentration, gelatin was first dissolved in distilled water at roughly 40° C. The gelatin solution was then given the appropriate concentration of glycine and sorbitol (or mannitol). A magnetic stirrer was used to evenly distribute Nemusulide (NM) powder into the prepared aqueous solution, resulting in a dosage of 50 mg NM per 1 ml. A dose of 50 mg per tablet was then produced by pouring one millilitre of the suspension into each pocket of a Polyvinyl Chloride (PVC) blister pack having a diameter of 13 mm and a depth of 3 mm. After that, the tablet blister packs were put in a freezer set to -22° C for 24 hours. The ice-cold pills were. A Novalyphe-NL 500 Freeze Dryer withA condenser temperature of -45° C and a pressure of 7 10-2 mbar was used to lyophilize the frozen tablets for 24 hours. A water-soluble surface-active agent or polymer was then added to the formulations that performed the best (based on tablet characteristics) in order to speed up the disintegration process and/or increase friability. These accelerators of disintegration included sodium lauryl sulphate (SLS), three PEG grades (PEG 400, PEG 4000, and PEG 6000), three PVP grades. With the exception of SLS, which was added at a concentration of 1% w/v, all of these were.This method is employed by a number of patented technologies, including the Zydis, Quicksolv, and Lyoc technologies, which are employed in the production of RDTs as described below.

3.2 ZYDIS Technology

Zydis technology (ZT) is a method with a patent. [26] ZT makes completed dose units using a special freeze-drying method that are very different from traditional oral systems. In this technology, the drug is dissolved or suspended in

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water before being poured into preformed blisters, which gives the tablet its shape. The tablets are then put through a specially designed cryogenic freezing process to control the size of ice crystals, ensuring that the tablet has a porous matrix for quick disintegration. These frozen units are subsequently carried to large-scale freeze dryers for the sublimation process, where the majority of the remaining moisture from the tablets is evaporated, and open blisters are packed using a heat-sealing procedure (steps involved in freeze-drying process [Figure 1]

3.3 LYOC

A solid and porous galenic form known as lyoc is created by lyophilizing an oil-in-water emulsion that has been applied directly to the blister alveolus. [39] A thickened (paste-like) emulsion that contains the active in bulk or asCoated microparticles is prepared by freezing. This product has a low mechanical strength but can accommodate high doses and dissolves quickly. [40]

3.4 QUICKSO

By freezing an aqueous dispersion or solution of the drug-containing matrix and then drying it by eliminating the water with sufficient alcohol by solvent extraction, Quicksolv produces porous solid dosage forms. [41] The final form can only be utilised for pharmaceuticals that are insoluble in the extraction solvent and disintegrates very quickly due to its low drug content. A relative low aqueous solubility, fine particle size 50 m, and good aqueous stability in the suspension areThe ideal drug characteristics required for this technology.50 µm,[42] and good aqueous stability in the suspension.

3.5 MOLDING

By compressing a powder combination that has been previously moistened with solvent (often ethanol or water) to produce a wetted mass into mould plates, tablets made from soluble components, such as sugars, can be made.[43]The advantages of moulded tablets are that they dissolve more quickly and have a better flavour because they are made of water-soluble carbohydrates. Molded tablets dissolve more quickly and have better flavour because to the dispersion matrix, which is formed of water-soluble carbohydrates. These qualities are improved when components that have undergone physical modification during the moulding process are used or when tablets with porous structures are created. The moulding technique is a simpler way to make tablets that are easier to scale up for industrial use than the lyophilization procedure. Lyophilization and moulding processes result in RDT that is created through the lyophilization and moulding processes disintegrates in about 30 seconds, but has low physical resistance and high friability. On the other hand, direct compression tablets are less friable but disintegrate more slowly. [44]The compressed-molded tablets are dried in the air. The moulded tablet has a very porous structure due to the reduced compression force used than with traditional tablets, which accelerates the product's disintegration and dissolving. However, a very fine screen should be used to sift the powder mixture in order to further increase the product's rate of dissolution. For the soluble components (saccharides), which increase the mouth feel and tablet breakdown, the moulding technique is typically used. However, the low mechanical strength of moulded tablets causes handling erosion and fracture. [45]

3.6 COMPACTION

The disintegration time of RDT that has suitable hardness prepared by direct compression has been attempted to be sped up. Microcrystalline cellulose (MCC) and low-substituted hydroxypropyl cellulose (L-HPC) were employed as disintegrants by Bi et al. [46] and Watanabe et al. [47] to make RDT byDirect compression. The ratios of these two disintegrants, MCC/L-HPC, in the range of 8:2– 9:1, according to the authors, produced tablets with the quickest disintegration times. However, wet granules of lactose monohydrate were compressed by Bi et al. [48] and Sunada and Bi [49] before the resulting wet tablets were dried at 60° C andStored in a desiccator for 12 hours at ambient temperature. The disintegration time and hardness of the formed RDT were both shorter than 30 seconds.Mouth Dissolving Tablets (MDT) can be made using standard tablet manufacturing and packaging equipment, and the availability of tableting excipients with improved flow, compressibility, and disintegration properties makes direct compression the easiest and most affordable tablet manufacturing method.

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3.7 FLASHTAB

The tablets are directly compressed, however Flashtab is a proprietary method. Disintegrants and coated medication crystals in the form ofMicrogranules are also present in Flashtab. [50] In this technology, two different kinds of disintegrants are employed: one that has a high swelling force and the other a low swelling force. [51]

3.8 ORASOLV

Another patented invention is orasolv [Figure 2]. Orasolv tablets are weaker and more fragile than regular tablets since they are just barely crushed. For Orasolv, CIMA LABS creates a unique handling and packaging system. [53] Low levels of compaction have the benefit of preventing compression-induced fracture of the taste-masking particle coating.

3.9 DURASOLV

To create reliable MDTs, a second-generation proprietary technique called Durasolv was created. Due to the use of a higher compaction pressure during compression, Durasolv has a significantly better mechanical strength than Orasolv. As a result, it can be produced more quickly and cheaply and isPackaged in vials or conventional blister packs. Due to Durasolv's low drug loading capacity and high compaction pressure, taste-masked coated pellets cannot be incorporated into the drug.

3.10 WOWTAB

The proprietary Wowtab technology was created in Japan. The Benadryl Fast melt tablets were created using this method. By combining two different kinds of saccharides, this method creates a tablet formulation with a suitable hardness and quick disintegration rate. [54] The WOWTAB formulation is ideal for both standard bottle and blister packaging because to its substantial hardness, making it more resilient to environmental conditions than Zydis or Orasolv. The WOWTAB's exclusive taste-masking technology claims to provide a superior tongue feel because of its patented smooth-melt action. [55] Table 1 shows a few of CIMA Labs' commercially accessible, patent-protected product.

IV. GRANULATION METHOD

4.1 Wet Granulation

The procedure of adding a liquid to a powder in a vessel with any kind of agitation that may cause agglomeration or grains is known as wet granulation. The technique of making tablets by wet granulation, which is frequently employed, is made better by the creation of granulate, which has better flowability, homogeneity, and compressibility than the original drug-containing powder blend. High shear is the most widely utilised technique in the pharmaceutical business to generate granules. Wet Granulation is a complex process, similar to those used in most pharmaceutical production, and number of variables, including the type of binder used and the processing environment, will affect the final granule's physical characteristics. [57]

4.2 Dry Granulation

Slugging may be employed to create granules when tablet ingredients have sufficient inherent cohesive or binding qualities but are susceptible to moisture or cannot sustain high temperatures during drying. Dry granulation, Precompression, or double compression are terms used to describe this process.

4.3 Melt Granulation

A water-soluble carrier and an active ingredient are combined in melt granulation and heated until the ingredients are melted. In an ice bath, the melt quickly solidifies while being vigorously stirred, ground, and finally sieved. Rapid congealing is preferred because it leads to hyper saturation of the medication due to the rapid solidification's trapping of solute molecules. In the solvent matrix. On stainless steel plates connected to a cooling system to promote quick heat loss, the solidification process can be accomplished. Since there are no solvents used, the melt process has the benefits of simplicity and economy. [58] PEG-6-stearate, a hydrophilic waxy binder (super polystate), was used by Abdelbary et al. to create FDT. Waxy Super Polystate has a M. P. range of 33 to 37° C and an HLB value of 9. As it melts in the

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mouth and solubilizes quickly, it not only serves as a binder and boosts the physical resilience of tablets but also aids in their disintegration, leaving no residue behind. Super polystate was added to the FDT formulation using the melt granulation technique, in which the molten form of the material forms the granules. The formulation also contained mannitol as a water-soluble excipient, croscarmellose sodium as a disintegrating agent, and crystallised paracetamol as the model drug. [24]

4.4 Spray Drying

The microspheres were prepared by spray drying. Considering that it only calls for one step of processing and can be readily controlled and scaled up, spray drying is frequently utilised in the manufacturing of pharmaceuticals. [59,60] The final particle size of spray drying, which is widely employed in the pharmaceutical and biochemical industries, is influenced by a variety of variables, including the size of the processing nozzle. [61] The process of spray-drying is depicted .By using this technique, highly porous fine particles can be produced. This method was used by Allen and Wang to create FDT. The FDT formulations included mannitol as a bulking ingredient, sodium starch glycolate and croscarmellose sodium as a disintegrating agent, and hydrolyzed/unhydrolyzed gelatin as a matrix supporting agent. [63] The addition of effervescent components, such as citric acid (an acid) and sodium bicarbonate, further enhanced solubility and disintegration (an alkali).Spray drying the mixture produced a porous powder. This technique produced aFDT that disintegrated in about 20 seconds. [64,65] Orally disintegrating tablets with taste masking were created by Jianchen et al. Spray-drying a mixture of the model compound (famotidine) and a taste-masking substance resulted in the microspheres. [66]

4.5 Flash Heat Process

Several methods can be used to process flash flows. The processes of flash-heat and flash-shear are both extremely common. The feedstock material is heated sufficiently in the flash-heat process to produce an internal flow condition that forces some of the feedstock to move at a sub-particle level relative to the rest of the mass and exit through the openings built into the outer rim of a rotating head. The flowing feedstock material is flung outward from the head by the centrifugal force produced inThe spinning head, where it reforms with a different structure. The centrifugal force generated by the spinning head is what is required to separate and discharge the flowable feedstock. A preferred tool for using a flash heat procedure is aThe centrifugal force generated by the spinning head is what is required to separate and discharge the flowable feedstock. A machine that makes “cotton candy” is one of the primary tools for implementing a flash heat procedure. [67] FDT was [68]

4.6 Direct Compression

A direct compression procedure only requires a few process stages, typical equipment, and excipients that are easily accessible. Prior to the final mix, this procedure may entail granulation. The action of super disintegrants, water-soluble excipients, and effervescent agents, either separately or in combination, provides the basis for the direct compression tablet’s disintegration and solubilization. [69] Some examples of model medicinesThat have been synthesised as FDT by direct compression approach include tizanidine HCl, oxybutynin HCl, rofecoxib, [2], and ethenzamide[70].The kind of medicine being utilised has a significant impact on the superdisintegrant that is selected for a tablet formulation. For instance, the rate and method of tablet disintegration could be impacted by the medicinal component’s solubility. While insoluble materials often tend to disintegrate if an adequate amount of a disintegrant is included in the formulation, water-soluble materials typically tend to dissolve rather than disintegrate. [71] Table 2 lists a few disintegrants and superdisintegrants that have been employed by different researchers to create FDTs.

V. COMPACTION AND SUBSEQUENT TREATMENTS

5.1 Sublimation

The main cause of FDT’s quick disintegration is the tablet matrix’s inclusion of a very porous structure. Even while typical tablets contain chemicals that are extremely water soluble, they frequently fail to dissolve quickly due to limited porosity. Utilizing volatile substances during the tableting process, such as camphor, which sublimated from the formed tablet, can increase porosity. Recently, it was proven that a compressed tablet made of crystalline cellulose and L-HPC

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in the mouth of a human quickly disintegrated (within 15 seconds) in saliva (or a small amount of water). [47] However, because these kinds of pills don't completely dissolve in saliva, patients occasionally experience a gritty feeling in their mouth. The researchers tried using mannitol, a water-soluble substance, as an excipient in place of crystalline cellulose and L-HPC while making this sort of tablet in an effort to reduce the harsh texture in the mouth. By using camphor, a subliming substance extracted from compressed tablets made using a mannitol and camphor mixture, Koizumi et al. created FDT. After making the tablets, the camphor was sublimated in a vacuum for 30 minutes at 80° C. [74]

VI. TASK MASKING

6.1 Addition of Sweetners and Flavours

Materials used for flavour masking have frequently been categorised in accordance with the fundamental flavour that is covered up in Table 3. [71] Both natural and synthetic sources can be used to create flavourings and fragrances. Fruit juices, aromatic oils like lemon and peppermint, herbs, spices, and their distilled fractions are examples of natural products. They can be purchased as syrups, spirits, alcoholic or water-based solutions, concentrated extracts, or extracts. [76] Numerous compositions, such as alkaline earth oxide, alkaline earth hydroxide, or an alkaline hydroxide, have been discovered to exhibit effective taste-masking abilities with better flavour in addition to these traditional materials. [77] A different composition contains mixes of phosphorylated amino acids such phosphotyrosine, phosphoserine, and phosphothreonine. [78] Anethole successfully disguised. The aftertaste of zinc, which is unpleasant, as well as the bitter flavor with which the common cold is treated. [79] In formulations that are meant to be chewed or dissolved in the mouth before being ingested in solution, clove oil and calcium carbonate have been found to be especially helpful in masking the unappealing active ingredient. [80]If Orally Disintegrating Tablets (ODT) have a pleasant taste and mouth feel, patients will accept them the most. Various sweeteners and flavours are used to give tablets this feature. Excipients made of sugar are typically used because they are highly water soluble, dissolve quickly in saliva, and give the finished product a pleasant taste and mouth feel. [81

6.2 Adjustment of PH Values

Many medications become less soluble at pH levels other than the mouth's 5. 9 pH level. If the equilibrium concentration is below the taste threshold, drugs may not be sufficiently solubilized to be detectable by taste. [82] WhenSildenafil granules were dissolved in aqueous medium after a solubilization inhibitor, such as sodium carbonate, sodium bicarbonate, sodium hydroxide, or calcium carbonate, was added to increase the pH, the bitter taste of the drug was successfully covered up by a sweetener alone. [83]

6.3 Coating of Unpleasent Drugs

The use of an appropriate polymer to coat medications is a great way to keep the drug's flavour from being detected by the taste buds. Many different pharmaceutical formulations, including chewable tablets, effervescent tablets, powder, and liquid Dispersion, may contain the coated composition. [84– 86]Kato researched compounds with low melting points to cover up the drug's unpleasant taste. In order to create coated spheres with uniform particle size, micro powdered active ingredients (such as antiulcer methyl benactyzuim bromide) were combined with beef tallow, a substance with a low melting point. [87]When compared to Flucloxacillin preparations that are commercially available, Maccari et al. conducted a special study to evaluate the bioavailability of a Flucloxacillin preparation microencapsulated for taste abatement with 17% ethyl cellulose made up as a granular product for extemporaneous resuspension. It was demonstrated that Flucloxacillin microencapsulated for taste abatement is as bioavailable from the dosage form as the raw unprocessed antibiotics by the fact that both dosage forms were bioequivalent. [88]

VII. DETERMINATION OF DISINTEGRATION TIME OF FAST DISINTEGRATING

7.1 Tablets

In vivo determination of disintegration time ODTs typically disintegrate in about a minute, however patients may actually experience disintegration times of 5 to 30 seconds. The typical method of conducting a disintegration test for these dosage forms has a number of drawbacks and is insufficient for measuring extremely fast .

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7.2 Dissolution Teste

The process used to create dissolve methods for ODTs is comparable to and essentially equivalent to that used for regular tablets. When doing scouting runs for a bioequivalent ODT, the dissolution conditions for medications listed in pharmacopoeia monographs are an useful place to start. Much like with conventional tablets, other media like 0.1N HCl and buffers (pH – 4.5 and 6.8) should be assessed for ODT.You can utilise USP Dissolution Apparatus 1 and 2. There are several uses for the USP 1 Basket device, but occasionally, tablet pieces or disintegrated tablet masses may get stuck on the inside top of the basket near the spindle, where little to no effective stirring occurs, leading to irreproducible dissolving profiles. The most acceptable and popular option for ODTs, the USP 2 Paddle apparatus, with a regularly used paddle speed of 50 rpm, was proposed by Kancke[93]. When using USP monograph conditions, ODT typically dissolves very quickly; as a result, slower paddle speeds may be used to obtain a profile.Drugs that have been taste-masked can also be tested for dissolution using the USP 2 Paddle equipment at 50 to 100 rpm. To enhance the test's usefulness, theMedia for the taste-masked medication should be the same as the final product. Due to the inclusion of UV-absorbing ingredients, particularly flavours and sweeteners, high-performance liquid chromatography is frequently needed to examine dissolving aliquots.Since the formulation is intended to have a pleasant taste and mouth feel, the excipient to drug ratio may be larger, which would reduce the drug's ability to be detected in the UV spectrophotometer. [45]

VIII. FAST DISINTEGRATING TABLET FORMULATION EXAMPLES

8.1 OraSolv® and DuraSolv® Technology

The primary ODT tablet-based technologies used by CIMA are OraSolv and DuraSolv. Polyols as fillers, a disintegrant that may include an effervescence pair, flavour, a sweetener, and a lubricant are among the elements in the technique. If necessary, the medicine may have its flavour concealed via a fluid-bed coating method. The direct compression step of the tabletting process allows for a wide range of potencies, from less than 1 mg to asMuch as 500 mg. OraSolv tablets should have an effervescence pair as well as drug microparticles enclosed in a rupturable coating. [94].The manufacturing process compresses the tablets at a low hardness, which encourages quick disintegration. The dosage forms must be packaged in dome-shaped foil-foil aluminium blisters that have an impact on physical protection and moisture impermeability. This is what the PakSolv Technology entails. [38] Tablets created with DuraSolv technology include a lubricant and a filler that cannot be directly compressed. They may or may not be effervescent, and the taste of theMedicine is not required to be covered up. [52] Comparatively to OraSolv, DuraSolv tablets are compressed at a harder level, allowing for packaging in bottles or pushing through blisters. Low cost of goods, standardised manufacturing techniques, standardised packaging formats and materials, and low development costs and risks are some benefits of tablet-based technology. A little bit longer disintegration timeIs one drawback.

8.2 WOWTAB Technology

The "Without Water Tablet" (WOWTAB®) technology was created and commercialised by Yamanouchi Pharmaceutical Co. Ltd. In Japan. The WOWTAB® tablet is sufficiently hard to preserve the dosage form's mechanical and physical integrity before coming into contact with saliva.[95] Common tablet excipients that are Generally Recognized As Safe (GRAS) substances make up WOWTAB®. When WOWTAB® is placed in the mouth, it quickly softens due to saliva absorption and dissolves or disintegrates within 15 to 20 seconds. When pressure is applied to the WOWTAB® tablets with theupper jaw and tongue or by licking them, the tablets dissolve more quickly. Conventional granulators, tablet[96]

8.3 WOWTAB Tablets

The pills' major components are low- and high-moldable sugars. Mannitol, lactose, and glucose are among the low-moldable carbohydrates that hasten dissolution. Upon compaction, high-moldable sugars like maltose, sorbitol, and maltitol enhance good hardness. In a fluid-bed granulator, the active ingredient and additional excipients are combined with a solution that contains both sugars. The resulting granules are combined with flavours and lubricants before being compressed to create tablets. The pills are then packaged in blisters or bottles after conditioning storage in a controlled humidity and temperature system. Cyclodextrins can be used to disguise the taste of the active ingredient.[97]

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8.4 FLASHTAB Technology

A swellable agent (modified starch or MCC) and a super disintegrant make up the Flashtab tablet matrix (crospovidone or croscarmellose). Instead of the previously indicated swellable agent, the system may additionally contain, depending on the necessity, a highly water-soluble polyol with binding capabilities, such as mannitol, sorbitol, maltitol, or xylitol. [97] Direct coating hides the flavour of the active. This technology creates durableTablets by first granulating the excipients using a wet or dry process,Combining the coated drug with the excipient granules, and compressing The mixture into tablets that can be handled and packaged using standard Processing tools. Tablets used in blister packaging can withstand the Pressure used to pry them from the blister card's lidding foil.

IX. CONCLUSION

Oral drug delivery systems that dissolve or disintegrate quickly when placed in the mouth and don't need water to help with swallowing are referred to as quick-dispersing oral drug delivery systems. The FDT dosage forms are perfect for a variety of patient populations, including geriatrics, children, and those who have trouble swallowing. The ability to deliver the advantages of a liquid drug in the form of a solid preparation is one of the key benefits of FDT dosage forms. This function enables the patient to take the prescribed dose whenever they choose, without having to use water or cause any bother. These technologies and products address a clear medical need and offer beneficial clinical outcomes.

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