

REVIEW ARTICLE

Mouth Dissolving Tablets Highlighting Innovative Techniques and Use of Natural Super disintegrant- a concise review

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Abstract

Mouth dissolving tablets are increasing more conspicuousness as a novel medication conveyance framework and develops as one of the prevalent and broadly acknowledged measurement shapes, particularly for pediatric patients in light of fragmented advancement of solid and sensory system and if there should be an occurrence of geriatric patients experiencing Parkinson's issue or hand tremors, frames like tablets and cases are presently days confronting the issues like dysphagia, bringing about the high incidence of rebelliousness and making the treatment incapable. From both pharmaceutical commercial enterprises as well as patients since they are advantageous to be fabricated and controlled, free of side impacts, offering quick discharge and improve bioavailability, in order to accomplish better patient compliance. Oral course is the most favored course for organization of different medications since it is viewed as most secure, most helpful and temperate course. As of late analyst built up the quick deteriorating tablets with enhanced patient consistence and comfort. Fast dispersible tablets deteriorate either quickly in water, to shape a balanced out suspension, or scatter promptly in the mouth to be gulped without the guide of waters.

Keywords: Mouth dissolving tablet, Manufacture technologies, Patent, Marketed formulation, Superdisintegrant

INTRODUCTION:-

The oral course is the most acceptable routes among the different courses for various age gathering of the patients since it is viewed as most secure, most advantageous and

prudent course. Rapid dissolving drug-conveyance frameworks was started and created in the late 1970s as a distinct option for tablets, containers, and syrups for pediatric and geriatric patients who encounters challenges in gulping conventional oral dosage form. Fast dissolving tablets have gotten perpetually expanding request amid the most recent decade, and the field has turned into a fast developing zone in the pharmaceutical area. Especially the quick dissolving drug conveyance frameworks defined with regular polymers have more request since normal materials like gums and adhesives have been broadly utilized as a part of the field of medication conveyance for their simple accessibility, ease organization, non-poisonous quality, and non-aggravation nature and so on.¹ The rate of solvency of medication influences the rate of retention of the drug. Fast breaking down tablets are strong measurements frames which disintegrate quickly in spit without biting and extra water. Quick crumbling tablets defeat the hindrances of customary dose frame particularly dysphagia (trouble in gulping) in pediatric and geriatric patients. Normal materials have favorable circumstances over engineered ones since they are artificially idle, nontoxic, less costly, biodegradable and generally accessible. Such a tablet breaks down into littler granules or melts in the mouth from a hard strong to a gel-like structure, permitting simple gulping by patients. Oral Disintegrating Tablets (ODT) as characterized as "A strong dose structure containing restorative substances, which disintegrates rapidly, more often than not inside a matter of seconds, when put upon the tongue. "Drug conveyance through oral course has been the best course of organization since decades. It is most generally utilized courses of organization for the systemic conveyance of medications by means of different measurement shapes. Orally breaking down tablets likewise called as or dispersible tablets (ODTs), snappy deteriorating tablets, and mouth dissolving tablets, quick crumbling tablets, fast breaking down tablets, permeable tablets or quick melts

Criteria for fast dissolving tablets:-

1. Fast Melting tablets (FMT) or fast disintegrating /dissolving tablets (FDT) are single unit strong unit dose frames that deteriorate or disintegrate quickly (in few moments) in mouth without the need of water or biting. These measurement frames demonstrate great dependability, simplicity of assembling and ease of taking care of by patient. The medication is promptly discharged from measurement shape and is promptly accessible for retention, enhancing its onset of activity and its bioavailability in some cases(soluble medications), to some degree it is addi-

tionally conceivable to accomplish assimilation of a few medications crosswise over the oral mucosa straightforwardly into the systemic dissemination, keeping away from first pass digestion system and its subsequent side effects.²

2. Upon ingestion, the saliva serves to quickly break up the dosage form. The salivation containing the dissolved or dispersed medicament is then gulped and the medication ingested in the GIT. Medication is ingested from the mouth, pharynx and throat as the spit goes down into the stomach. In these cases bio-availability of medications is more noteworthy than those saw from standard dose forms.
3. The fundamental criteria for quick crumbling (dissolving) tablet is to deteriorate or disintegrate quickly in oral depression with spit in 15 to 60 seconds, without need of water and ought to have pleasant mouth feel.

Salient Features & Advantages

1. Provides fast medication treatment intercession.
2. Ease of organization to patients who can't or declines to swallow a tablet, for example, pediatric, geriatric, psychiatric and incapacitated patients.
3. Does not require water while organization great deterioration and disintegration of the dosage form in oral cavity
4. Ability to give focal points of fluid solution as strong planning.
5. Can be intended to leave insignificant or no buildup in the mouth after organization furthermore to provide a lovely mouth feel.
6. FDTs help maintains a strategic distance from hepatic digestion system by permitting pre-gastric drug ingestion in this way reducing the measurement of medication required.
7. Patient's consistence for incapacitated confined to bed patients and for voyaging and occupied individuals, who do not have prepared access to water.
8. Good mouth feel property of FDTs changes the essential perspective of pharmaceutical as "bitter pill", especially for pediatric patients because of enhanced taste of astringent medications.
9. More quick medication retention from the pre-gastric territory i.e. mouth, pharynx and throat.
10. Produce quick onset of activity.

Limitations of Fast Dissolving Tablets

1. The tablets for the most part have deficient mechanical quality. Consequently, cautious taking care of is required
2. The tablets may leave obnoxious taste and/or dirt in mouth if not formulated properly.³

Manufacture Technologies

Manufacture Technologies for Fast Dissolving Tablets

CONVENTIONAL TECHNOLOGIES

1. Freeze Drying
2. Tablet Molding
3. Spray Drying
4. Direct Compression
5. Sublimation
6. Cotton Candy Process
7. Mass Extrusion²⁴

PATENTED TECHNOLOGIES

1. Zydis Technology
2. Durasolv Technology
3. Orasolv Technology
4. Wowtab Technology
5. Flashdose Technology
6. Flashtab Technology

Figure No. 1: Manufacture Technologies for fast dissolving tablet

CONVENTIONAL TECHNOLOGIES:-

Freeze Drying

Freeze-drying permits quick disintegration of the tablets as a result of their high porosity, and upgrades drug sol- idness, particularly for dampness touchy substances; then again, a permeable system is connected with low physical resistance and high friability. Exceptional bundling is required now and again. The significant point of preference is that the tablets created by this innovation have low breaking down time and have incredible mouth feel because of quick dissolving impact.⁴

Tablet Molding

Molding process is of two sort's i.e. dissolvable strategy and warmth technique. Dissolvable strategy includes saturating the powder mix with a hydro alcoholic dis- solvable took after by pressure at low weights in shaped plates to frame a wetted mass (pressure forming). The

dissolvable is then expelled via air-drying. The tablets fabricated in this way are less minimal than packed tablets and gangs a permeable structure that rushes disintegration. The warmth shaping procedure includes readiness of a suspension that contains a medication, agar and sugar (e.g. mannitol or lactose) and pouring the suspension in the rankle bundling wells, setting the agar at the room temperature to shape a jam and drying at 300C under vacuum. The mechanical quality of shaped tablets is a matter of awesome concern. Tying specialists, which expand the mechanical quality of the tablets, should be consolidated. Contrasted with the lyophilization strategy, tablets created by the embellishment method are simpler to scale up for modern production.⁵

Spray Drying

The formulations contained hydrolyzed and unhydrolyzed gelatin as a supporting specialists for the lattice, mannitol as a building operators and sodium starch glycolate/croscarmellose as a disintegrant. Breaking down and disintegration were further improved by including a corrosive (e.g., citric corrosive) or a soluble base (e.g., sodium bicarbonate). The suspension of above excipients was spray-dried to yield a permeable powder which was packed into tablets. Tablets made by this technique deteriorated in < 20 secs in a watery medium.⁶

Direct Compression

It is the least demanding approach to produce tablets. Traditional hardware, usually accessible excipients and a set number of handling steps are included in direct pressure. Additionally high measurements can be obliged and last weight of tablet can without much of a stretch surpass that of other creation technique.

Advantages of direct compression

1. Requires less unit operations contrasted and wet Granulation (shorter handling time and lower vitality utilization).
2. Fewer security issues for actives that are touchy to heater dampness.
3. For certain mixes, quicker disintegration rates might be created from tablets arranged by direct pressure contrasted and wet granulation; for instance, norfloxacin.
4. Fewer excipients might be required in an immediate pressure formula.⁷

Sublimation

The slow disintegration of the packed tablet containing even exceptionally water-dissolvable fixings is because of the low porosity of the tablets. Dormant strong fixings

that volatilize promptly (e.g. urea, ammonium carbonate, ammonium bicarbonate, hexamethylenetetramine, camphor and so on.) were added to the next tablet fixings and the blend is compacted into tablets. The unstable materials were then evacuated through sublimation which produces permeable structures. Moreover, a few solvents (e.g. cyclohexane, benzene) can be likewise utilized as pore framing agents.⁸

Cotton Candy Process

This procedure is so named as it uses an exceptional turning instrument to deliver floss like crystalline structure, which imitate cotton confection. Cotton confection process includes arrangement of grid of polysaccharides or saccharides by synchronous activity of blaze softening and turning. The grid shaped is halfway recrystallized to have enhanced stream properties and compressibility. This confection floss grid is then processed and mixed with dynamic fixings and excipients and in this way compacted to ODT. This procedure can suit bigger medication measurements and offers enhanced mechanical quality. Be that as it may, high-handle temperature restrains the utilization of this procedure.⁹

Mass Extrusion

This innovation includes softening the dynamic mix utilizing the dissolvable blend of water solvent polyethylene glycol, utilizing methanol and removal of relaxed mass through the extruder or syringe to get a barrel of the item into even portions utilizing warmed cutting edge to shape tablets. The dried barrel can likewise be utilized to coat granules of severe tasting drugs and in this manner covering their sharp taste.¹⁰

PATENTED TECHNOLOGIES:-

Zydis Technology

Zydis definition is an extraordinary stop dried tablet in which medication is physically ensnared or broke up inside the lattice of quick dissolving transporter material. At the point when zydis units are put into the mouth, the stop dried structure breaks down promptly and does not oblige water to help gulping. The zydis network is made out of numerous materials intended to accomplish various targets. To bestow quality and strength amid taking care of, polymers, for example, gelatin, dextran or alginates are fused. These structures a shiny formless structure, which confers quality. To acquire crystallinity, style and hardness, saccharides, for example, mannitol or sorbitol are fused. Water is utilized as a part of the assembling procedure to guarantee generation of permeable units to accomplish fast crumbling. Different gums are utilized to counteract sedimentation of scattered medication particles in the assembling process. Breakdown protectants, for example, glycine keep the shrinkage of zydis

units amid stop drying prepare or long haul stockpiling. Zydis items are pressed in rankle packs to shield the def-

inition from dampness in the earth

CLASSIFICATION OF SUPERDISINTEGRANTS

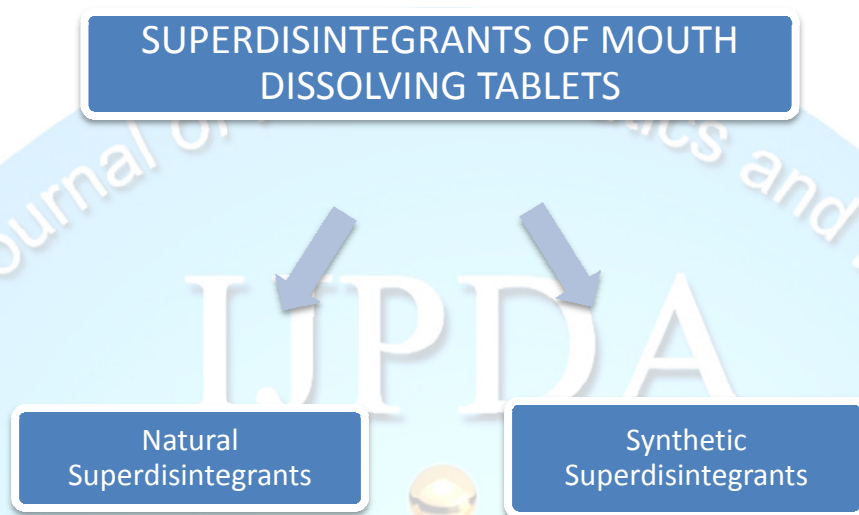


Figure No. 2: Various Superdisintegrant used in Mouth Dissolving Tablets

Limitations

1. The measure of medication could be joined ought to by and large be under 400mg for insoluble medications and less that 60mg for solvent medications.
2. The molecule size of the insoluble medications ought not to be under 50 μ m and not more than 200 μ m to forestall sedimentation amid preparing.

Advantage

1. Buccal pharyngeal and gastric locales are all regions of ingestion from this definition.
2. Any pre-gastric ingestion maintains a strategic distance from first-pass digestion system and can be preference in medications that undergo a lot of hepatic digestion system.
3. The zydis plan self-saving in light of the fact that the last water focus in the stop dried item is too low to take into account microbial development.

Disadvantage

1. The procedure of stop drying is a generally costly assembling process.
2. The plan is extremely lightweight and delicate, and along these lines ought not be put away in knapsacks or the base of handbags.
3. It has poor steadiness at higher temperatures and humidities.
4. The stop drying is tedious procedure

5. It has poor physical resistance

6. Loading of high dosage of water-solvent medications is unrealistic ages

Durasolv Technology

Durasolv is the licensed innovation of CIMA labs. The tablets made by this innovation comprise of a medication, fillers and an ointment. Tablets are set up by utilizing traditional tableting gear and have great unbending nature. These can be bundled into ordinary bundling framework like rankles. Durasolv is a proper innovation for items requiring low measures of dynamic fixings.

Advantages

1. Durasolv has much higher mechanical quality than its forerunner because of the utilization of higher compaction weights amid tableting.
2. The Durasolv item is along these lines created in a speedier and in more compelling way.

Disadvantages

1. It is not perfect with bigger measurements of dynamic fixings on the grounds that the definition is subjected to high weights on compaction.
2. The medication powder covering may broke amid compaction, uncovering the biting tasting medication to patient's taste buds.

Orasolv Technology

Orasolv Technology has been produced by CIMA labs. In this framework dynamic medicament is taste covered. It additionally contains bubbling deteriorating operators. Tablets are made by direct pressure method at low pressure power keeping in mind the end goal to minimize oral disintegration time. Customary blenders and tablet machine is utilized to create the tablets. The tablets created are delicate and friable and bundled in uncommonly composed pick and place framework.

Advantages

1. The Orasolv plans are not extremely hygroscopic
2. The plan can suit high dosages.
3. It additionally gives an unmistakable, charming impression of bubbling in the mouth.

Disadvantages

1. A weaker and more fragile tablet in examination with traditional tablets.
2. Poor mechanical quality.
3. The expense of quick dissolving tablets is higher than the expense of standard tablets made by direct pressure
4. Manufacturing requires a controlled domain at low relative dampness.

Wowtab Technology

Wowtab Technology is protected by Yamanouchi Pharma-

ceutical Co. WOW signifies "Without Water ". In this procedure, blend of low mouldability saccharides and high mouldability saccharides is utilized to get a quickly softening solid tablet. The dynamic fixing is blended with a low mouldability saccharide and granulated with a high mouldability saccharide and packed into tablet.

Advantages

1. Offers Superior mouth feel because of the smooth melt activity
2. It is suitable for both routine jug and rankle bundling
3. It more steady to the earth than the zydis and orasolv.

Flash Dose Technology

Flash Dose Technology has been licensed by Fuisz. Nurofen meltlet, another type of ibuprofen as melt - in-mouth tablets, arranged utilizing streak measurement innovation is the main business item propelled by Biovail Corporation. Streak dosage tablets comprise of self-tying shear structure grid termed as "floss". Shear structure grids are set up by blaze heat preparing.

Flashtab Technology

Prographarm labs have protected the Flashtab innovation. Tablets arranged by this framework comprise of a dynamic fixing as microcrystals. Drug micro granules might be set up by utilizing the routine methods like coacervation, microencapsulation, and expulsion spheronisation. All the preparing used customary tableting innovation.¹¹



NATURAL SUPERDISINTEGRANTS:-**Table No. 1: Natural Superdisintegrants used in Mouth Dissolving Tablets.**

S. No.	Natural Superdisintegrants	Marketed drug	Reference No.
1	Chitin and chitosan	Cinnarizine	12
2	Guar gum	Glipizide	13
3	Gum karaya	Amlodipine, granisetron hydrochloride	14
4	Agar and treated agar	Theophylline	15
5	Fenugreek seed mucilage	Metformin hydrochloride	16
6	Soy polysaccharide	Lornoxicam	17
7	Gellan gum	Metronidazole	18
8	Mango peel pectin	Aceclofenac	19
9	Lepidium sativum mucilage	Nimesulide	20
10	Plantago ovata seed mucilage	Granisetron HCl	21
11	Aegle marmelos gum	Aceclofenac	22
12	Locust bean gum	Nimesulide	23
13	Lepidium sativum	Nimesulide	24
14	Mangifera indica gum paracetamol	Metformin HCL,	25
15	Hibiscus rosa-sinensis mucilage	Aceclofenac	26
16.	Dehydrated banana powder	Ondansetron HCl, Propranolol, Hydro-chlorothiazide	27

SYNTHETIC SUPERDISINTEGRANTS:-**Table No. 2: Synthetic Superdisintegrants used in Mouth Dissolving Tablets.**

S. No.	Superdisintegrants	Marketed Drugs	Reference No.
1.	Crosscarmellose	Olopatadine HCl	28
2.	Sodium starch glycolate	Chlorpheniramine Lomotrigin	29
3.	Crosspovidone (XL10)	Levofloxacin	30
4.	Metacrylic copolymer with divinyl benzene	Famotidine	31
5.	Cross linked CMC	Hydrochlorothiazide	32
6.	Pregelatinized starch	Promethazine HCl	33
7.	Chitosan-alginate complex	Salubutamol sulphate	34
8.	Partially pregelatinized corn starch	Hydrochlorothiazide	35
9.	Ac-Di-Sol	Gliclazide	36
10.	B-cyclodextrin	Zidovudine	37
11.	Citric Acid	Levocetirizine HCl	38
12.	Kollidon CL	Fentanyl Citrate	39
13.	HPMC	Ambroxol hydrochloride	40
14.	Maltodextrin	Nicotine	41

Table No. 3: Patent for Mouth Dissolving Formulation

S. No.	Patent number	Formulation	Inventor	Ref No.
1.	US005501861A	Fast Dissolving Tablet And Its Production	Tadashi Makino et al	42
2.	US006733781B2	Fast dissolving tablet	KhaWla A. Abu-Izza et al	43
3.	US20030161875A1	Fast Dissolving Tablets Of Cyclooxygenase-Z Enzyme Inhibitors	Deepak Murpani et al	44
4.	EP0 553 777 A2	Fast dissolving tablet and its production.	Makino et al	45
5.	US005298261A	Rapidly Distintegrating Tablet	Walter S. Pebley et al	46
6.	US005837285A	Fast Soluble Tablet	Kouichi Nakamichi et al	47
7.	USO05464632A	Rapidly disintegratable Multiparticular tablet	Gérard Cousin et al	48
8.	USO05762961A	Rapidly soluble oral solid dosage Forms, methods of making same and compositions thereof	Bruce J. Roser et al	49

Table 4: List Of Marketed Mouth Dissolving Tablets^{50,51}

S. No.	Trade Name	Active Drug	Manufacturer
1.	Felden fast melt	Piroxicam	Pfiser Inc., NY, USA
2.	Claritin redi Tab	Loratidine	Schering plough Corp., USA
3.	Maxalt MLT	Rizatriptan	Merck and Co., NJ, USA
4.	Zyprexa	Olanzapine	Eli lilly, Indianapolis, USA
5.	Pepcid RPD	Famotidine	Merck and Co., NJ, USA
6.	Zofran ODT	Ondansetron	Glaxo Wellcome, Middlesex, UK
7.	Zoming-ZMT	Zolmitriptan	AstraZeneca, Wilmington, USA
8.	Zeplar TM	Selegiline	Amarin Corp., London, UK
9.	Tempra Quiclets	Acetaminophen	Bristol myers Squibb, NY, USA
10.	Febrectol	Paracetamol	Prographarm, Chateaufeuf, France
11.	Nimulid MDT	Nimesulide	Panacea Biotech, New delhi , India
12.	Torrox MT	Rofecoxib	Torrent pharmaceuticals , India
13.	Olanex instab	Olanzapine	Ranbaxy lab. Ltd. New-delhi, India
14.	Romilast	Montelukast	Ranbaxy lab. Ltd. New-delhi, India
15.	Benadryl Fastmelt	Diphenhydramine	Warner Lambert, NY, USA
16.	Propulsid Quicksolv	Cisapride monohydrate	Janssen pharmaceuticals
17.	Risperdal M Tab	Risperidone	Janssen pharmaceuticals
18.	Spasfon Lyoc	Phloroglucinol Hydrate	Farmalyoc
19.	Nurofen Flash Tab	Ibuprofen	Ethypharm
20.	Tempra Quicklets	Paracetamol	Cima Labs,Inc.
21.	Zolmig Repimelt	Zolmitriptan	Cima Labs,Inc.
22.	NuLev	Hyoscyamine Sulfate	Cima Labs, Inc.
23.	Gaster D	Famotidine	Yamanouchi Pharma Tech. Inc.
24.	Cibalgina DueFast	Ibuprofen	Eurand International
25.	Relivia Flash dose	Tramadol HCl	Fuisz Technology, Ltd.
26.	Hyoscyamine Sulfate ODT	Hyoscyamine Sulfate	KV Pharm.Co.,Inc.
27.	Abilify Discmelt	Aripiprazole	Otsuka America/Bristol-Myers Squibb
28.	Allegra ODT	Fexofenadine	Sanofi Aventis
29.	Aricept ODT	Donepezil	Eisai Co.
30.	Clarinet RediTabs	Desloratadine	Schering-Plough

CONCLUSION

The advancements in the arena of preparations ODTs are gone for both expanding the execution of the dose struc-

ture by diminishing the crumbling time .This article attempted to divulge the procedures that have been utilized by inventors for enhancing the execution of

Superdisintegrants. The utilization of Superdisintegrants for accomplishing these aims is not new. In any case, with the change advancement of super disintegrating agents it has ended up conceivable to create ODTs with decreased substance of superdisintegrants. So also, considerable research towards creating altered microcrystalline cellulose or starch with a specific end goal to architect them reasonable for direct pressure has altogether diminished the product development time for upgrading ODT formulation. Rapidly deteriorating measurement frames have been effectively marketed by utilizing different sorts of superdisintegrants. Superdisintegrants show quicker medication disintegration what's more, expanded bio-availability, along these lines, profiting in effective treatment and enhanced patient consistence.

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