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FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLET OF ASPIRIN FOR MYOCARDIAL INFRACTION

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ABSTRACT

Due to its simplicity and ease, oral dissolving films are one of the best subjects to shoot. Orodissolvable films are oral devices that dissolve and when placed in mouth it disintegrate in one minute. Metabolism of drug is prevent initial access by using this dosage form, thereby drug bioavailability is increased. Oral dissolving films reduce dosage, increase the threshold of action and eliminate choking problems. In the production of oral films and taste masking agents for API are laminated using solvent casting, which can affect the appearance and performance of the film. Solvent casting is preferred over other methods because it provides consistent thickness, good preparation, good film quality, and excellent physical properties. Orodispersible films are evaluated according to various factors such as thickness, physical properties such as resistance to cracking and folding, and breaking time. This review provides details on packaging, product reviews, manufacturing processes, and other products containing oral dissolving films.

KEYWORDS: Tablets, Direct compression, Sublimation.

1. INTRODUCTION

Understanding the impact of formulation processing variables was made easier by the systematic formulation technique.[1] One important drug delivery technology that is rapidly gaining momentum is rapidly dissolving drug delivery. Rapid dissolution formulations are widely used in innovative drug delivery systems because they improve patient compliance and are easy to use. Conventional formulations are difficult for geriatric patients and children to swallow. This formulation dissolves, or disintegrates, in the mouth in approximately one minute without the need for drinking or chewing. Other names for rapidly dissolving tablets

include Rapimelt, foaming tablets, mouth-dissolving tablets, orally dispersible tablets, and immediate dissolving tablets. Rapidly dissolving formulations are becoming increasingly popular, and both companies and scientists are realizing their benefits.[2] Mucous membranes, up to 4-1000 times. Most popular route of administration is oral route because of its numerous benefit such as comfort of intake, painlessness, adaptability compliance of patient. Commonly used dosage forms are tablets and capsules. In response to increasing patient compliance requirements, extensive research has been conducted over the past two decades. Location of this area. Approximately 350 drug delivery systems have been developed based on patient compliance. Older people may have difficulty chewing or swallowing tablets, which can lead to poor compliance and treatment failure. Oral dissolving agents are an excellent solution to this problem. Without the need for water, it dissolves and dissolves faster in saliva. This therefore explains why patients comply well with treatment.[3] MDTs are a medication that is administrated without water. It is used in Parkinson's disease, bedridden patients, patients with psychosis, and for use when traveling.[4]

Fig. 1: Aspirin powder.

2. Advantages of mouth dissolving tablet

- It can be taken without water in emergency time anywhere.[5]
- The compatibility for older people and young people
- It is helpful when an extremely quick response is needed, like in the circumstances of motion sickness, allergic reactions, or coughing.
- An enhanced bioavailability resulting from the quick dissolving and crumbling of these tablets, especially for insoluble and non-polar medicines.
- In oral cavities, it should be slightly non-ionized.[6]
- It avoids the high risk of suffocation or chocking during administration.[7]

3. Disadvantages of mouth dissolving tablet

- The cautious handling required due lack of mechanical strength.
- It has cost high-priced packaging.

4. Ideal properties of mouth dissolving tablet

- Permit heavy drug loading.
- Work well with other excipients and flavor masking.
- Feel good in the mouth.
- After oral delivery, produce little to no residue in the mouth.
- It has enough strength to endure the challenges of manufacture and handling after manufacturing.
- It Shows minimal susceptibility to external factors like temperature and humidity.[8]

5. Various methods used for manufacturing

5.1 Freez drying

The process of sublimating water out of a frozen product is called freeze drying. Using this method, an amorphous porous structure that dissolves quickly is produced. The medicinal solution or dispersion is frozen. Next to continue the process of freeze-drying, In refrigerator cabinets the frozen blister packs are placed. Using a blister-sealing machine, the aluminum foil backing is attached after freeze-drying. The blasters are then wrapped and dispatched.

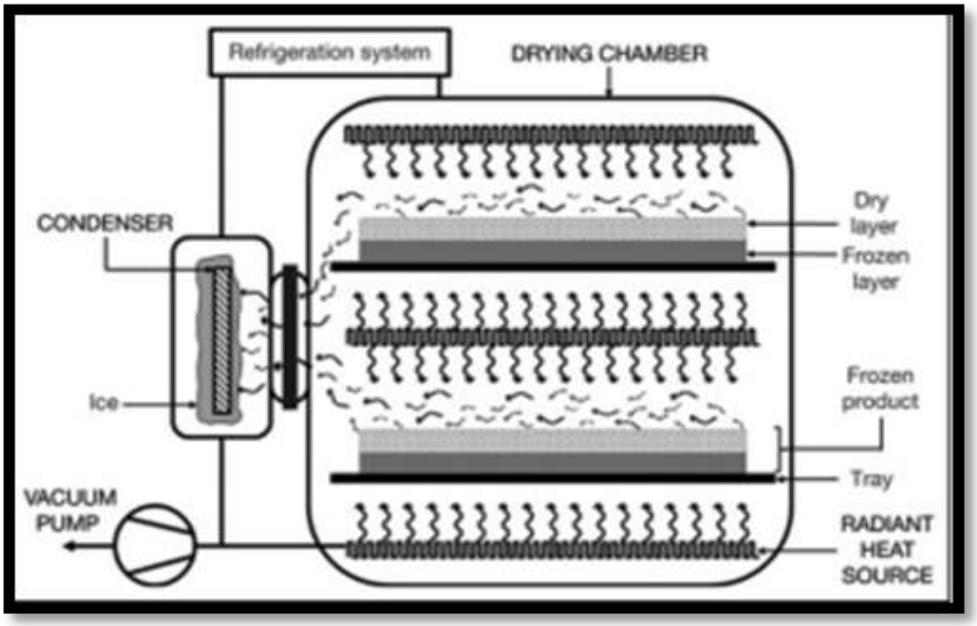

Fig. 2: Freeze dryer technique.

5.2 Direct compression

Direct compression is easy process and needs short time for operation. It is inexpensive process. In this method, there is less chances of microbial contamination. Other compounds in the formulation, such as effervescent and water-soluble excipients agents speed up the disintegration process even more.

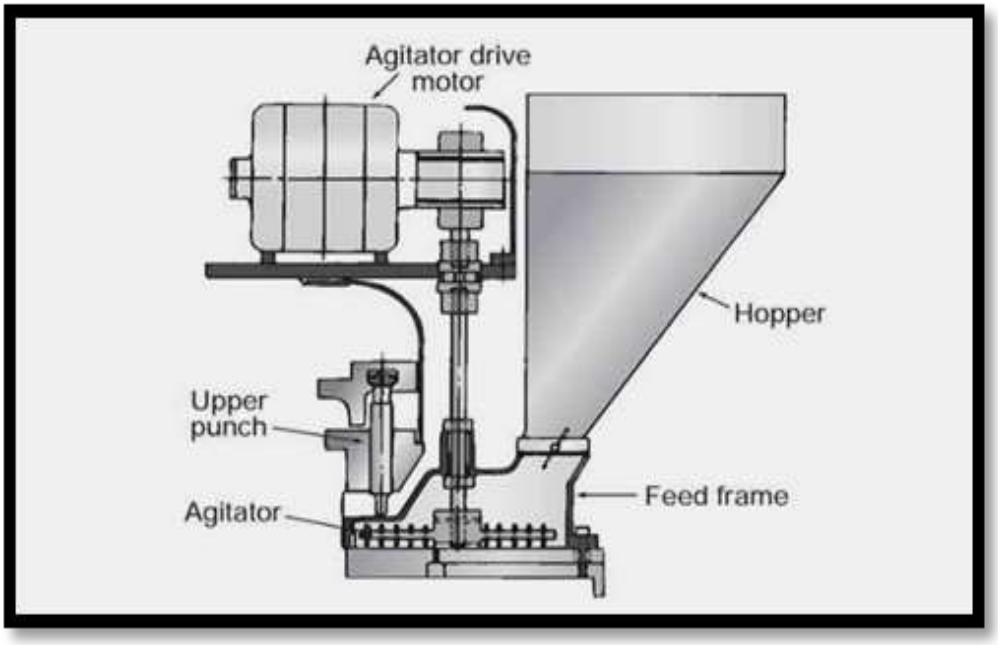

Fig. 3: Instrument for Direct compression method.

5.3 Spray drying

Gelatin can be employed in this method as a supporting agent, as a bulking agent mannitol is used, and as super disintegranting agents sodium starch glycolate and crospovidone is used. There have been reports of tablets are dissolve in an liquid media in less than 20 seconds which are made from spray-dried powder. Bulking agents like mannitol and lactose, super disintegrants like sodium starch glycolate and croscarmellose sodium, acidic (Citric acid) and/or alkaline (Sodium bicarbonate) substances were all present in the formulation. When compacted into tablets, this spray-dried powder demonstrated improved solubility and quick disintegration.

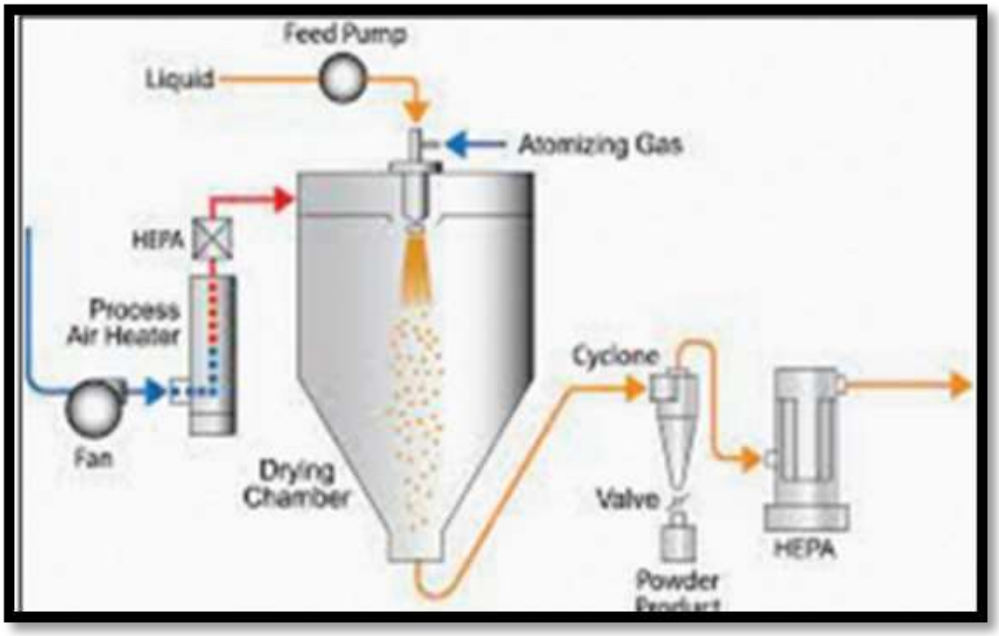

Fig. 4: Spray-drying technique.

5.4 Sublimation

In order to create a porous matrix, the formulation includes volatile chemicals that are subsequently sublimated. Ingredients that are extremely volatile include benzoic acid and camphor can be compacted into a tablet together with additional excipients. Sublimation is then used to remove this volatile substance, leaving behind a very porous matrix. It has been claimed that tablets made using this method often dissolve in 20 seconds.

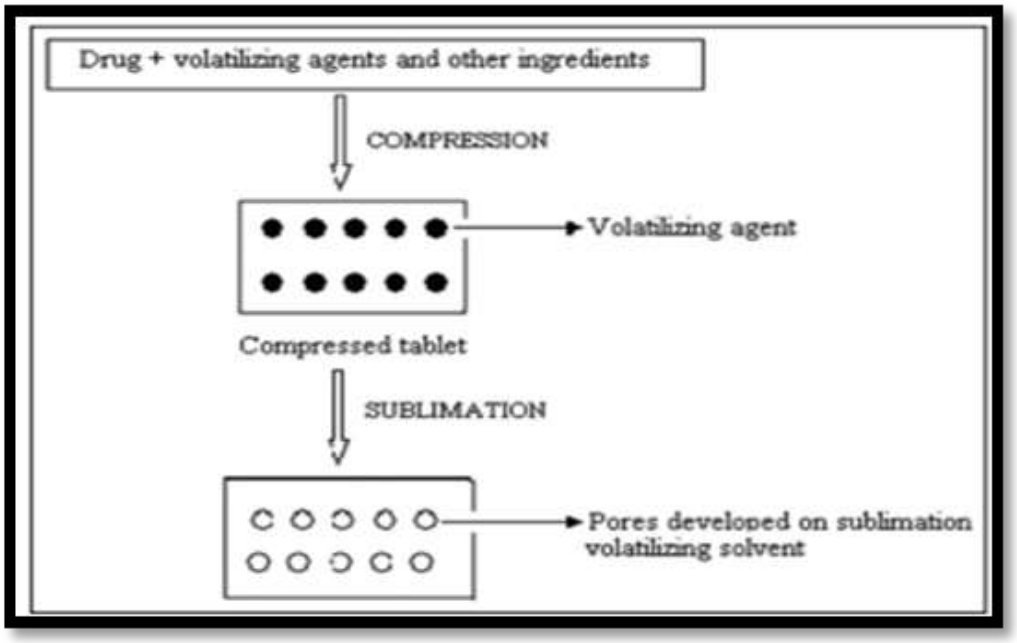

Fig. 5: Sublimation technique.

6. Excipients

Table 1: Different excipients used in manufacturing of MDTs.

Ingredients	Examples
1. Super disintegrating agents	Sodium starch glycolate, Carboxy methyl cellulose, crospovidone
2. Fillers	Calcium carbonate, Calcium sulphat
3. Binders	Hydroxy propyl methyl cellulose
4. Lubricants	Stearic acid
5. Sweeteners	Licorice, Mannitol, Sucralose
6. Flavors	Orange oil, Rosemary oil, Menthol, Peppermint oil
7. Surface active agents	Sodium lauryl sulphate

6.1 Super disintegrating agents

These are chemicals that, when in contact with saliva, help tablets dissolve more quickly. Example,

- Cross-linked polyvinylpyrrolidone or crospovidone: It is very good at accelerating disintegration.
- Croscarmellose sodium (Sodium carboxymethyl cellulose): When exposed to water, sodium carboxymethyl cellulose, also known as croscarmellose sodium, swells quickly, which facilitates the dissolution of tablets.[10]

6.2 Sweeteners

They are added in food to improve palatability and cover up the bitter taste of active pharmaceutical ingredients (APIs). As examples, consider are

- Mannitol: A sugar alcohol that is frequently added to medications as a sweetener.
- Sucralose: An artificial sweetener made from sucrose that has no calories.

6.3 Flavouring agents

Enhance the tablet's flavour and increase the patient's enjoyment of it. As examples, consider:

- Menthol: Offers a flavour that is refreshing and a cooling sensation.
- Peppermint oil: Enhances flavour with a hint of mint and can help cover up bad Flavors.

6.4 Binder

Creates a cohesive mass by holding the tablet's elements together Examples include:

- Polyvinylpyrrolidone (PVP): A commonly used binder in pharmaceutical formulations.
- Hydroxypropyl cellulose (HPC): Offers the binding properties while also aiding in disintegration.

6.5 Fillers

Give the tablet more volume and help with production. Examples include:

- Microcrystalline cellulose (MCC): Offers the good compressibility and flow properties.
- Dicalcium phosphate: Acts as a filler and a source of calcium in the tablet formulation.

6.6 Lubricant

Lubricants are used in tablet formulation to stop the tablet material from adhering to the dies and punches during compression. Example includes,

- Magnesium stearate: One of the lubricants that is most frequently utilized in tablet formulation is magnesium stearate. During tablet compression, it serves as a releasing agent as well as a lubricant.
- Stearic acid: Stearic acid, like magnesium stearate, is used to stop tablet grains from adhering to tablet dies and punches.
- Talc: In tablet formulations, talc serves as a glidant and lubricant. During compression, it facilitates the powder combinations' easy flow.

6.7 Surface active agent

- Sodium lauryl sulphate: Tablet surfaces can be consistently wetted thanks to surfactants like SLS, which facilitate tablets' increased ability to absorb water. This is especially crucial for tablets that must dissolve and disintegrate quickly when swallowed.

7. Formulation table

Weight of 1 Tablet= 150mg, Batch 1 = 10 Tablets,

Table 2: Formulation table.

Ingredient	Role	Quantity (mg)
Aspirin	Active pharmaceutical Ingredient (API)	100mg
Carboxy Methyl Cellulose Sodium	Super disintegrating agent	20mg
Magnesium Stearate	Lubricant	3mg
Calcium Carbonate	Filler	20mg
sucrose	sweetener	5mg
Sodium lauryl sulphate	Surface active agent	2mg
Orange oil	Flavoring agent	Q. S

8. Procedure for direct compression method

8.1 Formulation detail

Selection of active pharmaceutical ingredient: Select an API with the right flow and compressibility properties.[11]

Selection of excipient: To improve the end product's flow, compressibility, and stability, use the right excipients. Diluents (like microcrystalline cellulose), binders, disintegrants, lubricants, and glidants are examples of common excipients.

8.2 Preparation of raw material

Weighing: Measure the API and excipients precisely in accordance with the formulation

Screening: In order to eliminate lumps and guarantee a consistent distribution of particle sizes, run the raw materials through a sieve.

8.3 Blending

Mixing: To guarantee that all of the ingredients are distributed evenly, blend the API with the excipients. You can use a double-cone blender, V-blender, or other appropriate mixing apparatus for this.

Sampling and testing: Samples should be taken from various portions of the blend to ensure homogeneity. Make sure the mixture satisfies the necessary requirements.

8.4 Lubrication

Adding lubricant: To lessen friction when compressing tablets, add the lubricant (such as magnesium stearate) to the mixture.

Blending: To uniformly spread the lubricant without over-mixing, which could lead to segregation, gently blend the liquid once more.

8.5 Compression

Tablet press setup: Assemble the tablet press apparatus using the proper dies and punches.[12]

Feeding: Fill the tablet press's hopper with the powder mixture.

Compression: Using the tablet press, press the powder blend into tablets. To obtain the required tablet hardness and other physical attributes, modify the compression force.

Sampling and Testing: Take periodic samples of the tablets to measure their weight, thickness, hardness, disintegration time, and other characteristics of quality.[13]

9. Chalenges in mouth dissolving tablet

- Palatability
- Mechanical strenth
- Hygroscopicity
- Amoutn of drug
- Tablet size[14]

10. Evaluation test

- Weight variation test
- Friability test
- Disintegration test
- Hardness test
- General appearance
- Shape and Size

10.1 Content uniformity test

Tablets are selected randomly, each was measured separately, the average weight and the standard deviation was computed. A weight variation's percentage difference should fall inside the allowable bounds.[15]

Table 3: Weight variation test.

Tablet Number	Observed weight (mg)	Average weight (mg)	Percentage Deviation (%)
1	149	150	-0.66
2	151	150	0.66
3	152	150	1.33
4	154	150	2.66
5	148	150	-1.33
6	151	150	0.66
7	154	150	2.66
8	149	150	-0.66
9	147	150	-2
10	153	150	2

10.2 Test for friability

For carrying out this test the Roche Friabilator is used. Four days of pre-weighed tablets were spun at 25 rpm in the Friabilator. Minutes or as many as 100 rotations. With every spin, the

tablets are dropped from a distance of six inches. After the fines were removed, the weight of tablet is measured again, and the percentage of weight reduction was determined.

Fig. 6: Friability tester

10.3 Test for hardness

The hardness of tablets are checked by Monsanto hardness tester. The hardness is measured in terms of kg/cm^2. The force needed to break a tablet across its diameter is a measure of its hardness. The tablet's hardness affects how resistant it is when handled both before and during storage transition to abrasion, chipping, or shattering.

10.4 Disintegrating test

Since fast-dissolving pills must dissolve without the presence of water in order for the test to be correct, their disintegration times must be altered. For this, take 25 ml beaker with 10 ml of water inside of it objective. The tablet is dropped into the beaker, and it is seen how long it takes for it to completely crumble into tiny bits.

Fig. 7: Before disintegration test.

Fig. 8: After disintegration test.

10.5 General appearance

Customers are impacted by a tablet's dimensions, shape, color, flavor, surface texture, physical faults, consistency, and readability when judging its overall appearance, visual identity, and degree of "elegance" of any identifying symbols.

Fig. 9: General appearance in terms of shape and size.

10.6 Shape and Size

The tablet's shape and size can be controlled and monitored based on its measurements.[16]

11. RESULT

Sr. No.	Evaluation test	Observed value
1	Disintegration test	1 min 6.34 sec
2	Friability test	1%
3	Hardness test	3.2 kg/cm^2

12. DISCUSSION

Rapid dissolving tablets play a significant function in the market's effort to eradicate various disease-related circumstantial attacks. Other names for fast dissolving tablets include rapimelts, porous tablets, melt-in-mouth tablets, mouth-dissolving pills, and quick-dissolving tablets. Many patients, particularly the elderly, have trouble swallowing pills, capsules, or liquids. As a result, they frequently do not take their prescriptions as directed, which leads to a high rate of non-compliance. However, research has produced a number of safer and more advanced drug delivery systems. This drug delivery system is significant because it is simple to use, enhances patient compliance, has a quick start of action, and may have better bioavailability. It is also perfect for patients who are young or elderly and has a quick start of action.

14. CONCLUSION

It's creating a new, economical one-step FDDT manufacturing technique using traditional tabletting technology to make sturdy tablets fit for traditional packaging. This patented method can be used with a variety of medicinal substances increasing value by incorporating generics—that is, "supergenerics" for use in human or veterinary medicine. This market category presents a clear possibility for the emergence of new, improved oral products. Swallowing problems affect about one-third of the population, mostly the elderly and young. This causes patients to take their oral medication regimens less consistently, which lowers the effectiveness of therapy as a whole. The rapid dissolving tablet is a novel tablet dosage type that provides the benefits of convenient dosing without the need for water as well as ease of administration.

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