e-ISSN: 2582-5208
International Research Journal of Modernization in Engineering Technology and Science
(Peer-Reviewed, Open Access, Fully Refereed International Journal)
Volume:06/Issue:11/November-2024 Impact Factor- 8.187 www.irjmets.com

A COMPREHENSIVE REVIEW ON RAPID MELT TABLETS

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ABSTRACT

Oral drug administration is the most acceptable and prescribable method in terms of patient compliance. Pharmaceutical companies are creating innovative drug delivery methods in response to the requirement to provide medications to patients as effectively as possible while minimising negative effects. Nowadays, a few solid dosage forms, such as tablets and capsules, are dealing with issues such as dysphagia, which causes difficulties swallowing and leads to a high rate of non-compliance, ultimately rendering the therapy useless. An innovative dosage form called rapid melt tablets has been created to address these issues. Rapid melt tablets breakdown and disintegrate quickly in saliva, making them easy to swallow without the need for water. The fundamental method used in the development of rapid melt tablets is the utilisation of superdisintegrants such as croscarmellose sodium, crosspovidone, or formulations that maximise pore structure. Compared to traditional dosage forms, a rapid melt tablet offers a number of benefits. This review describes in detail advantages, disadvantages, significance, conventional methods of preparation, some patented technologies, and marketed formulations of rapid melt tablets.

Keywords: Rapid Melt Tablets, Oral Drug Delivery, Fast Dissolving Tablets (FDTs), Superdisintegrants.

I. INTRODUCTION

Traditional dosage forms, which make up 50-60% of the overall dosage, are commonly approved and include tablets and pills. Because of their ease of production, small size, ease of use, and ability to provide accurate amounts, tablets continue to be the most widely used traditional dosage forms in use today. One major drawback of solid dosage forms is that some people, particularly those who are young and old, have difficulty digesting or swallowing them (a condition known as dysphagia). Due to choking fear, dysphasia, hand tremors, and underdeveloped neurological and muscular systems, swallowing difficulties are common in senior patients. They are particularly common in young patients with schizophrenia, which impair patient compliance. Tablet and capsule swallowing problems can also occur in the absence of water, bronchitis, coughing, common colds, diarrhoea, and allergic reactions. Approximately one-third of the population suffers from swallowing issues, primarily in youngsters and the elderly. This can result in poor adherence to oral tablet pharmaceutical treatment and a reduction in total therapeutic efficacy. Consequently, there has been a lot of interest in pills that dissolve quickly in the oral cavity. As a delivery strategy, the rapid melt tablets breaks down quickly in the mouth when it comes into contact with saliva; consequently, it doesn't require extra water. It can pass through the pregastrium's mucosa and be absorbed. Other names for this kind of dosage form that have been documented include mouth dissolving/disintegrating tablets (MDTs), quick disintegrating tablets, fast/rapid dissolving or disintegrating tablets (FDTs), quick melt tablets, orodispersible tablets, and porous tablets. [1, 2]

A rapid melt drug delivery system is a dosage form that dissolves or disintegrates in the mouth without the need for water. Fast melt tablets (FMTs) are defined differently by the FDA and several pharmacopoeias. The United States Food and Drug Administration (USFDA) define a rapid melt tablet (RMT) as "a solid dosage form containing medicinal substances which disintegrate rapidly, usually within a matter of seconds when placed upon the tongue." Rapid melt tablets (RMT's), on the other hand, are defined as "uncoated tablets which should disintegrate within 3 minutes and which are intended to be placed in the mouth where they disperse rapidly before being swallowed. These pills are designed to dissolve or breakdown rapidly in saliva typically in less than 60 seconds. The tablet is an excellent intraoral, rapidly dissolving drug delivery device that meets market demands by being easy to use and administer, maintaining a straightforward and practical packaging, reducing bad taste, and being easy to manufacture. The tongue can have the tablet positioned on top or below. At the site of usage, it is held in place and quickly releases the active component for absorption locally and/or systemically.

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Furthermore, the creation of a fast melt tablet presents a chance for the market to expand in terms of assortment, encompassing a greater variety of medications (such as analgesics, cardiovascular, neuroleptic, allergy, and erectile dysfunction pills) than those that are competitors for this measurement structure. [3, 4]

Advantages of Rapid Melt Tablets:

- Simple to consume.
- The tablet can be swallowed without water.
- Increased stability.
- A pleasing taste and mouth feel (palatability).
- Simple administration for patients with mental disabilities, the elderly, and children.
- Permit heavy drug loading.
- Precise dosage (in contrast to liquids).
- Quick start of action.
- Transport is Simple.
- Reducing first pass metabolism results in enhanced bioavailability since saliva travels down the stomach and absorbs some medication from mouth, pharynx, and oesophagus.
- There's no chance of choking or suffocation, providing enhanced safety.
- Direct compression manufacturing is inexpensive and simple to do. [5]

Disadvantages of Rapid Melt Tablets:

- It needs to be stored in a dry environment.
- It's hard to make medications with bad flavours.
- The soft moulded metrics and low compression of the tablet make it fragile and friable, making it challenging to handle.
- Rapid melt tablets need specialised packaging in order to stabilize the product correctly and ensure its safety. [6]

Significance of Rapid Melt Tablets:

- **Accurate dosing:** As a unit solid dose form, it offers the convenience of precise dosing, permits maximum drug loading, and is a great substitute for elderly and paediatric patients.
- **Improved bioavailability:** Drugs that are absorbed before the stomach do so at a higher rate and with a lower dosage, which leads to better therapeutic outcomes.
- **Prompt action:** The tablet dissolves and absorbs into the oral cavity quickly, resulting in a prompt start of the therapeutic effect. Therefore, it helps with conditions like motion sickness, allergic reactions that happen suddenly, and coughing.
- **Patient compliance:** The dosage form can be swallowed without the requirement for water. Therefore, it is useful for patients on the go and people with busy schedules who don't always have access to water.
- **Administration ease:** Particularly for elderly, young, mentally challenged, and uncooperative individuals who have trouble swallowing, this medication is convenient to use.
- **Obstruction-free:** When ingested, there is no chance of suffocating in the airways owing to a physical obstruction, improving compliance and safety.
- **Better palatability:** Leaves little to no residue in the mouth, which results in a pleasant mouth feel. Additionally, taste masking is utilised to prevent medicine's unpleasant taste.
- **Good stability:** Less susceptibility to external factors contributes to its good stability.
- **Easy packaging:** No special packaging is required; it can be packaged in push-through blisters.
- **Business avenues:** Offer fresh prospects for growth through life cycle management, line expansion, product diversification, and promotion.
- **Cost-effective:** When compared to other commercially available items, it is more affordable to produce, package, and distribute due to its reduced costs.

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- **Versatile technology:** Because of its versatility, this technology can be used to generate improved over-the-counter, prescription, and veterinary care products. [7]

Ideal Properties of Rapid Melt Tablets:

- No water is needed.
- Feel good in the mouth.
- Possess a passable ability to conceal taste.
- Be less pliable and more firm.
- After administration, leave little to no residue in the mouth.
- Show minimal susceptibility to outside factors like humidity and temperature.
- Permit the use of standard processing and packaging tools in the manufacture of tablets. [8, 9]

Excipients used in Rapid Melt Tablets:

Excipients are important components in the formulation and design of rapid melt tablets. The qualities of the activities in rapid melt tablets are balanced by the excipients. To avoid interactions and inhibitions between these excipients' activities, a complete understanding of their chemistry and mechanism is required. The formulator must take the cost factor into consideration. Excipients give the product the desired organoleptic qualities and increase its efficiency when they are introduced to the formulation. Excipients are useful for a variety of tasks. [10]

Bulking Materials:

Bulking agents enhance the texture, which enhances the disintegration in the mouth while also lowering the concentration of the composition's active ingredient. More sugar-based bulking agents, such as mannitol, polydextrose, lactitol, DCL (direct compressible lactose), and starch hydrolysate, are advised for fast dissolving drug delivery systems in order to promote increased aqueous solubility and improved sensory perception. Generally speaking, bulking agents are added in the range of 10% to 90% of the final composition's weight. The brittleness of the excipients listed below is arranged in declining order:

Microcrystalline cellulose > Dried lactose > Beta lactose > Alpha lactose monohydrate > Dicalcium phosphate dihydrate. [11]

Emulsifying agents:

The formulation of rapid melt tablets is advised to use a wide variety of emulsifiers; Emulsifying agents are required ingredients in the formulation of tablets that dissolve quickly, as they facilitate rapid medication release and disintegration without the need for chewing, swallowing, or drinking. The inclusion of the emulsifying ingredient also helps to improve bioavailability and stabilise the immiscible combinations. Examples include lecithin, sucrose esters, propylene glycol esters, and alkyl group sulphates. These agents are often combined in the final composition's weight range of 0.05% to around 15%. [12]

Lubricants:

When the tablets dissolve in the mouth, it will make them taste better. Lubricants eliminate grittiness and help the medication's mechanism move from the mouth into the stomach. Stearic acid, magnesium stearate, zinc stearate, talc, polyethylene glycol, liquid paraffin, magnesium lauryl sulphate, and colloidal silicon oxide are a few lubricating agents. [12]

Flavouring and sweetening agents:

Different flavours and taste masking agents are added to rapid melt tablets to increase patient compliance and palatability, as the majority of therapeutic agents have disagreeable taste and are bitter, which is not pleasant to patients. Therefore, adding fake or natural flavours can enhance the organoleptic characteristic of rapid melt tablets. Sweeteners are essential for enhancing the flavour of formulations. A wide variety of sweeteners are available, including sugar, fructose, and dextrose, as well as non-nutritive sweeteners including sucralose, sodium saccharin, aspartame, and sugar alcohols. [13]

Superdisintegrants:

The agents that speed up the disintegration process are called superdisintegrants. A very tiny concentration of 1-10% by weight of the superdisintegrants is utilised in relation to the total weight of the dose

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units. Instead of possessing a swelling property, these agents have an absorption property. They don't really absorb much water, yet they swell very quickly. Superdisintegrants facilitate the dissolution of solid dosage forms by weakening their structural integrity. The dose form expands and becomes physically dispersed as a result of exposure to a damp environment. Additionally, these particles can be compressed, which enhances the friability and hardness of tablets. Superdisintegrants improve compatibility and compressibility while having no detrimental effects on the mechanical strength of formulations containing high dose medications. [14]

Ideal Properties of Superdisintegrants:

- It should be compatible with other excipients.
- It should be non toxic.
- It should be inert.
- It should have good moulding and flow properties.
- It should not create a complex with pharmaceuticals. [15]

Table 1: Superdisintegrants with their mechanism of action [16]

Sr. No.	Superdisintegrants	Mechanism of action	Specific properties
1.	Xanthan gum	Extensive swelling properties for faster disintegration.	Low water solubility, low gelling tendency, and high hydrophilicity.
2.	Crospovidone	Combination of swelling and wicking action. Swells 7-12 folds in <30 s.	Effective concentration is 1-3%. Rapidly disperses & swells in water, available in micronized grades.
3.	Soy polysaccharide	Rapid dissolving	Does not contain starch or sugar so can be used in products meant for diabetics.
4.	Croscarmellose Sodium	Swells 4-8 folds in <10 s. Swelling and wicking action	Effective in low concentration (0.5-2.0%), high swelling capacity, cross-linking of the carboxyl ester groups.
5.	Gellan gum	Strong swelling properties upon contact with water.	Anionic polysaccharide of linear tetrasaccharides, good superdisintegrants property similar to modified starch & celluloses.
6.	Sodium starch glycolate	Strong swelling properties upon contact with water. Swells 7-12 folds in <30s.	Rapid absorption of water results in swelling up to 6%, high concentration causes gelling.
7.	Cross-linked alginic acid	Hydrophilic colloidal subs-tance which has high sorption capacity.	Disintegration results from the interaction of wicking action and swelling.

II. METHOD OF PREPARATION

A) Conventional Technologies:

Freeze Drying or Lyophilization Technology:

Lyophilization is the process of drying at a low temperature while removing water through sublimation. Medica tion in a water-soluble matrix that is freeze-dried to produce a structure with a high porosity. When inserted in the mouth, the lyophilised tablets dissolve quickly in less than five seconds because saliva enters the pores so quickly. For medications that are heat sensitive or thermolabile, lyophilization is helpful. Three phases are

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typically involved in the freeze-drying process: To lower the material below the eutectics point, it is frozen. 4% w/w of moisture is removed during primary drying of the dry product. To bring the bound moisture down to the necessary final volume, use secondary drying. [17]

Tablet Molding:

Using this approach, water-soluble components are used to make moulded tablets, which dissolve quickly and completely. A hydroalcoholic solvent is used to wet the powder blend before it is moulded into tablets at a pressure that is lower than that of traditional tablet compression. After that, the solvent is eliminated by air drying. Compared to compressed tablets, moulded tablets are significantly less compact. These are more soluble because of their porous nature. [18]

A. Heat Molding: This method involves dispersing or dissolving the medication into a molten matrix so that it can be moulded straight into ODTs. This procedure involves preparing the medication suspension or solution, mixing it with agar and sugar, and pouring it into the blister packing. It is then allowed to solidify at room temperature to create a jelly, and it is vacuum dried at 30°C.

B. Compression Molding: This method involves moistening the powder blend with a hydroalcoholic solvent, compressing it onto mould plates to create a wetted mass, and then air drying it to eliminate the solvent. [19]

Cotton Candy Process:

This process is called that because it uses a special rotating mechanism to produce a crystalline structure that resembles cotton candy and looks like floss. The procedure of making cotton candy involves melting and rotating sparkles instantly to build a matrix of polysaccharides, or sugar. The resulting matrix is partially recrystallised, giving it improved compressibility and flow characteristics. After being crushed, the candy floss matrix is combined with the excipients and active chemicals, and then it is compressed to create rapid melt tablets. Nevertheless, at temperatures 30–40% lower than sucrose, other polysaccharides, such as polymaltodextrins and polydextrose, can be twisted into fibres. This change makes the safe addition of thermolabile medications to the formulation possible. Because the sugars in the saliva dissolve quickly, the tablets produced by this technique have a very pleasant tongue feel and are very porous. [20]

Sublimation:

Rapid melt tablets dissolves quickly due to the tablet matrix's extremely porous structure. Because of their limited porosity, traditional tablets made of highly water-soluble chemicals sometimes don't dissolve quickly. Addition of volatile compounds like camphor, which sublimates from the tablet generated, might enhance porosity.

Agents that cause volatility: Ammonium bicarbonate, urea, urethane, camphor, etc. It is possible to use solvents like benzene and cyclohexane as pore-forming agent.

Figure 1: Manufacture Process in Sublimation [21]

Spray-Drying:

The pharmaceutical industry uses it to create extremely porous powders. The procedure of spray drying causes the processing solvent to evaporate quickly, making the product highly porous and suitable for use in the production of rapid melt tablets. Gelatine can be employed in this method as a matrix and supporting agent, mannitol as a bulking agent, and sodium starch glycolate, croscarmellose, or crospovidone as a superdisintegrant. It has been observed that the tablets made from the spray-dried powder dissolve in an aqueous solution in less than 20 seconds. Rapid melt tablets using bulking agents like lactose and mannitol, superdisintegrants like sodium starch glycolate and croscarmellose sodium, acidic compounds like citric acid, and/or alkaline substances like sodium bicarbonate can all be made using this technology. When compacted into tablets, this spray-dry powder demonstrated increased solubility and quick disintegration. [22]

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Mass Extrusion:

This process involves softening the active blend of methanol and water-soluble polyethylene glycol in a solvent mixture. The resulting softened mass is then fed into an extruder or syringe to form a cylinder-shaped product, which is subsequently divided into smaller pieces to form tablets. The resulting product can also be coated to hide the flavour in the case of bitter medications. [23]

Compaction:

PEG-6-stearate, a superpolystate waxy binder that is hydrophilic, is added to the melt granulation process to create it. This binder has a dual action, meaning that it improves disintegration as well as physical strength. The compaction method's property is that it melts quickly in the mouth, leaving little trace behind. [24]

Direct compression:

Direct compression is the easiest and most economical way to make tablets. In particular, for rapid melt tabletsmade by direct compression, conventional equipment and improved tablet Excipients-such as superdisintegrants and sugar-based Excipients-that promote faster tablet disintegration and improved solubility are needed. Currently, this process can be used to prepare rapid melt tablets.

Benefits of Direct Compression Method:

1) It is possible to provide high doses, and the tablet's final weight may be higher than with other methods.
2) The simplest method available for making tablets.
3) Excipients that are easily accessible and standard equipment are used.
4) There aren't many processing stages required.
5) Efficient use of finances.

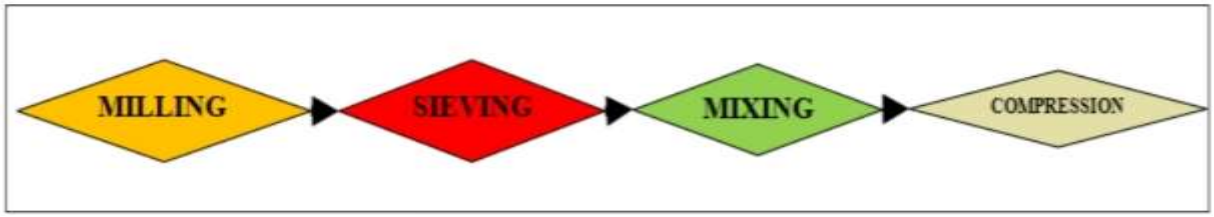

Figure 2: Direct Compression in Action [25]

B) Patented technologies used for preparation of rapid melt tablets:

Zydis Technology:

The medicine is physically entrapped or dissolved within the matrix of rapidly dissolving carrier material in the novel formulation freeze-dried tablet. The freeze-dried structure of zydis units dissolves instantly in the mouth and doesn't need water to facilitate swallowing. The zydis matrix is composed of many parts to achieve multiple functions. Polymers such as gelatin, dextran, or alginates are added to provide strength and resilience during handling. These combine to create a strong, glossy, amorphous structure. Saccharides like sorbitol or mannitol are added to achieve crystallinity, beauty, and hardness.During the manufacturing process, different gums are employed to avoid the sedimentation of dispersed drug particles, while water is used to ensure the formation of porous units to produce quick disintegration. Glycine and other collapse protectants stop zydis units from shrinking during the freeze-drying process or long-term storage. Zydis products are sealed in blister packets to keep the formulation dry from external moisture.

Durasolv Technology:

CIMA Labs' proprietary technique is called Durasolv. This method produces tablets with medicine, filler, and lubrication. Tablets are made with good stiffness and typical tabletting equipment. These can be put into blisters or other traditional packaging systems. Durasolv is a suitable technology for products that need to have small concentrations of active substances. [26]

Flashtab® Technology:

Granular excipients are used in this technology to create ODTs. Disintegrating and swelling agents as well as taste-masked medication microgranules are among the excipients employed. Polyvinylpyrrolidone and carboxymethylcellulose are examples of disintegrating agents. Starch, microcrystalline cellulose and so on are

examples of swelling agents. Excipients can be granulated using either a dry or a wet granulation procedure, after which the tablets are compressed. When placed into blisters, the generated ODTs can withstand pressure. The most crucial thing to remember is that blisters should be made of premium aluminium foil or polyvinyl chloride to keep the hygroscopic components dry.

Advatab® Technology:

The tablet surface is lubricated externally as the foundation of Eurand's patented Advatab® technology. The hard and long-lasting tablets produced by this technology do not require the significant compression forces required in their production. In this method, a gastro-soluble polymer is used to surround the API using microencapsulation. This facilitates the rapid dissolution of API in the gastrointestinal system while restricting its dissolution in the mouth. Polymers such as hydroxypropylmethylcellulose phthalate, cellulose acetate phthalate, and ethyl cellulose are examples of those utilised in the microencapsulation of bitter medications. For individuals who have trouble swallowing, Advatab® ODTs are usually convenient because they dissolve in the mouth in less than 30 seconds and don't require water. [27]

Wowtab® Technology:

Using traditional granulation and tableting methods, WOWTAB technology creates fast-dissolving tablets by combining low- and high-moldability saccharides. Lactose, mannitol, glucose, sucrose, and xylitol are examples of low moldability saccharides, while maltose, sorbitol, and oligosaccharides are examples of high moldability saccharides. Adequate hardness and rapid oral disintegration are not achievable at the same time when tablets are manufactured solely by compressing saccharides with low and high moldability. Moreover, rapid disintegration and dissolution in the mouth are not possible if saccharides with low and high moldability are combined (physically) prior to tableting. Because of this, a high-moldability saccharide was used as a binder when a low-moldability saccharide was granulated. [28]

Orasolv technology:

Orasolv was created by CIMA Labs. Here, the active medication is disguised by taste. The disintegration agent that they contain is effervescent in nature. Oral disintegrating tablets are manufactured with an extremely low compression ratio utilising a direct compression process or technology to reduce the amount of time it takes for the medication to dissolve or disintegrate. In order to produce tablets, we employ both traditional blenders and tablet machines. The resulting soft or friable tablets from this process need to be packaged using a specific method.

Flash dose technology:

The flash dose method was created by Fuisz Nurofen and is the most recent version of Ibuprofen available on the market. It is produced or prepared using this process and melts in the mouth. The first commercial product of its sort that Biovail Corporation introduced was this technology. The binding shear creates a matrix known as floss that is used to make tablets produced using the flash dosage method. Example: The flash heat processing technique is typically used to create shear form matrices. [29]

Nanocrystal Technology:

The method increases surface area and decreases particle size to speed up the dissolving process. Drug particles with a diameter of less than 1000 nm are known as nanocrystals, and they are created by milling the drug material using a weight-milling approach. Based on nanocrystals, the nanocrystal fast dissolving technology provides a large range of doses per unit (up to 200 mg of API per unit). Goods with exclusive and patent-protected technical components might be appropriately categorised. The pharmacokinetics of oral medications is enhanced. It is efficient and cost-effective to use non-moisture-sensitive actives. Pharmaceutical nanocrystalline colloidal dispersions and water-soluble GRAS (Generally Recognised as Safe) components are combined to create lyophilised product wafers. They are quite strong, but they dissolve quickly in tiny amounts of water, which is useful when working with strong or hazardous substances. This reduces the need for steps like mixing, tableting, and granulation. This process's reduced manufacturing loss also makes it possible to turn small amounts of medications into rapidly dissolving tablets. [30]

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Table 2: Marketed formulations along with category [31]

API	Trade Name	Category
Piroxicam	Felden fast melt	NSAID
Hyoscyamine Sulfate	Hyoscyamine Sulfate ODT	Anti-ulcer
Loratidine	Claritin redi Tab	Antihistamine
Tramadol HCl	Relivia Flash dose	Analgesic
Rizatriptan	Maxalt MLT	Migraine
Olanzapine	Zyprexia	Antipsychotic agent
Zolmitriptan	Zolmig Repimelt	Anti-migraine
Famotidine	Pepcid RPD	Antiulcer
Ondansetron	Zofran ODT	Anti-emetic
Selegilline	Zeplar TM	Parkinson's disease
Acetaminophen	TempraQuiclets	Analgesic
Paracetamol	Febrectol	Anti- pyretic and analgesic
Nimesulide	Nimulid MDT	NSAID
Rofecoxib	Torrox MT	Used in treatment of osteoarthritis
Olanzapine	Olanexinstab	Antipsychotic agent
Montelukast	Romilast	Anti-allergic drug
Risperidone	RisperdalMTab	Schizophrenia

III. CONCLUSION

Rapid melt tablets (RMTs) have emerged as a promising oral drug delivery system, offering improved patient compliance, rapid onset of action, and enhanced bioavailability. With their unique properties and features, RMTs have shown potential in various therapeutic areas, particularly in pediatrics, geriatrics, and patients with swallowing difficulties. Despite limitations, such as limited drug loading capacity and sensitivity to environmental factors, advancements in excipients, technologies, and manufacturing processes have mitigated these challenges. In conclusion, rapid melt tablets have demonstrated significant advantages and opportunities for innovation, making them an exciting area of research and development in pharmaceutical science.

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