A SYSTEMATIC OVERVIEW ON IMMEDIATE-RELEASE TABLETFORMULATIONS

Ansari Mushahid[1]*, Patil Pratik[1], Chavhan Sandip[1], Avinash Gangurde[1], Vinod Bairagi[1]

[1*]K. B. H. S. S. Trust's Institute of Pharmacy, Malegaon (Nashik), Maharashtra.

***Corresponding Author:** Ansari Mushahid

* K. B. H. S. S. Trust's Institute of Pharmacy, Malegaon (Nashik), Maharashtra.

Email: mushahid4296@gmail.com

Article History: Received:12/10/2022 Revised: 15/11/2022 Accepted: 20/12/2022

ABSTRACT

The field of pharmaceutical drug delivery is faced with significant challenges, but traditional pharmaceutical dosage forms continue to maintain their dominance. Immediate release dose forms refer to pharmaceutical formulations in which a minimum of 85% of the indicated quantity dissolves within a period of 30 minutes. Superdisintegrants are employed in order to enhance the effectiveness of solid dosage forms. The formulation of the tablet primarily involves the utilization of superdisintegrants such as croscarmellose, sodium starch glycolate, and crospovidone, among others. The superdisintegrants facilitate rapid disintegration of the tablet upon ingestion in the gastric environment. Consequently, the reduction in disintegration time leads to an improvement in the rate at which the drug dissolves. The quick disintegration observed in this context can potentially be attributed to the swift absorption of water from the surrounding medium, resulting in swelling and subsequent bursting, which in turn enhances the bioavailability. Tablet formulations are predominantly favoured due to their cost-effectiveness in terms of manufacturing, packaging, and distribution, as well as their enhanced stability. Tablets are widely recognized as a highly effective and commercially viable method of oral medication administration, offering numerous advantages over alternative dosage forms. This article presents a comprehensive analysis that highlights the importance of superdisintegrants in facilitating the quick release of tablets. It also explores the mechanism of disintegration, as well as the standard procedures and new granulation technology employed in the preparation of immediate-release tablets.

Keywords: Immediate release, Dosage form, Superdisintegrants, API, Dissolution.

DOI: 10.53555/ecb/2022.11.12.229

1.0 Introduction:

The oral route is very desirable for achieving systemic effects due to its ease of ingestion, simplicity, safety, convenience, non-invasiveness, adaptability, and, most significantly, patient compliance. Solid oral delivery systems can be created at a low cost due to their lack of requirement for sterile conditions. (1) In recent years, there has been a growing emphasis and attention on the field of controlled release and targeted drug delivery systems. Specifically, there has been a significant interest in developing tablet dosage forms that are designed to be ingested as a whole, rapidly disintegrate, and promptly release their therapeutic substances within the gastrointestinal tract. (2)

An appropriate dosage regimen for pharmacological therapy is characterized by the prompt attainment of the optimum therapeutic drug concentration in plasma (or at the site of action) and its sustained maintenance during the whole duration of treatment. (3) The user's text does not provide any information to rewrite in an academic manner. Recently, researchers have directed their efforts towards the development of an instantaneously released tablet formulation. The development of a fast-disintegrating tablet is achieved by the utilization of appropriate diluents and super disintegrants. (4)

1.2 Definition:

Immediate release tablets have been developed to disintegrate and release its dosage form without incorporating any specific rate-controlling mechanisms, such as specialized coatings or other approaches. Immediate release tablets refer to a type of medication that rapidly disintegrates and dissolves in order to release the active ingredients. (5) The oral bioavailability of a medicine is contingent upon its breakdown, solubility, and many physiological variables. (6) The utilization of an immediate release dosage form enables a manufacturer to expand their market presence while concurrently providing patients with a convenient and easily administered dose form or regimen. (7)

1.3 Requirements for Immediate release tablets: (8)

- Disintegration in short period of time.
- Show less sensitivity towards external environmental factors like temperature and moisture.
- Fast onset of action.
- No residue is left behind.
- Can be used along with taste masking agents.

1.4 Advantages of Immediate Release Tablets: (9)

Rapid Onset of Action: Immediate release tablets are designed for quick drug release, leading to a rapid onset of therapeutic action. This is particularly advantageous in the treatment of acute conditions where prompt relief is essential.

Patient Convenience: The simplicity of immediate release tablets often enhances patient compliance. Patients find them easy to swallow, and the straightforward dosing regimen contributes to better adherence to prescribed medications.

Flexible Dosing: Immediate release formulations offer flexibility in dosing, allowing healthcare providers to tailor the dosage to meet the specific needs of individual patients. This is particularly beneficial in conditions with variable symptom severity.

Lower Cost: The manufacturing processes for immediate release tablets are often simpler and more cost-effective compared to controlled or sustained-release formulations. This can result in lower production costs and, consequently, more affordable medications.

Ease of Formulation: Developing immediate release tablets typically involves fewer formulation challenges compared to controlled-release formulations. This simplicity can lead to faster development times and quicker regulatory approval.

Responsive to Patient Needs: Immediate release tablets are well-suited for drugs with a short half-life or those requiring a rapid response to fluctuating conditions, aligning well with the immediate needs of patients.

1.5 Disadvantages of Immediate Release Tablets: (8)

Short Duration of Action: The rapid release of the drug can lead to a relatively short duration of action. For medications requiring sustained therapeutic levels, immediate release tablets may necessitate frequent dosing, impacting patient convenience.

Potential for Side Effects: The quick absorption of the drug may result in higher peak plasma concentrations, potentially increasing the risk of side effects. This is a concern for drugs with a narrow therapeutic index or a propensity for adverse reactions.

Fluctuating Plasma Levels: Immediate release tablets may lead to fluctuating plasma drug levels, especially if the dosing interval is extended. This can result in variations in therapeutic effects and potential challenges in maintaining consistent drug concentrations.

Limited Control Over Drug Release: Unlike controlled-release formulations, immediate release tablets offer limited control over drug release kinetics. This lack of sustained release may be a drawback for medications requiring a more controlled and prolonged release profile.

Compliance Challenges: The need for frequent dosing may pose challenges to patient compliance, especially for individuals with busy schedules or those who may forget to take medication at specified intervals.

Not Suitable for Certain Drugs: Some drugs, particularly those with poor solubility or those that cause irritation to the gastrointestinal tract, may not be suitable for immediate release formulations. This limitation may necessitate alternative dosage forms.

Food Interactions: Certain immediate release formulations may be affected by food interactions, impacting the drug's absorption and bioavailability. This can lead to variations in therapeutic outcomes depending on whether the medication is taken with or without food.

Understanding these advantages and disadvantages is essential for pharmaceutical scientists, clinicians, and patients alike, as it informs decision-making regarding the choice of dosage form based on the specific characteristics of the drug and the therapeutic requirements of the patient.

2.0 Techniques used in preparation immediate release tablets:

There are various technologies that can be utilized for the production of immediate-release tablets. The predominant techniques employed for preparation include molding, lyophilization (freeze drying), direct compression, spray drying, and sublimation. (10)

2.1 Tablet Molding techniques:

The tablet molding technique involves the incorporation of water-soluble substances to enhance the disintegration and dissolution of the tablet, resulting in a more rapid breakdown.

Hydroalcoholic solvents are employed for the purpose of moistening a powder blend, followed by the application of compression pressure at a level lower than that typically utilized for conventional tablet compression, in order to shape the tablet. The solvent is subsequently eliminated by the process of air-drying. The enhancement of dissolution is facilitated by the presence of a porous structure within molded tablets. (11)

2.2 Direct Compression:

The direct compression method refers to the process of compressing tablets directly from a powder blend consisting of appropriate excipients and active pharmaceutical ingredients (APIs). The necessity of pre-treatment of blended powder by dry or wet granulation procedures is not required. The utilization of this method has several advantages, primarily in terms of enhanced production efficiency. This is achieved through the reduction of machinery requirements, a decrease in the number of persons involved, a streamlined number of unit operations, and a substantial reduction in processing time. Additionally, the implementation of this method results in increased product stability. (12)

2.3 Granulation Technique:

The phenomenon being described involves the growth of particles, resulting in the formation of larger agglomerates and subsequently enhancing the physical strength of the material. There are advantages to preventing the segregation of the components of the product, improving the flow and handling of the refined powder, and reducing the amount of dust generated. The ideal shape of the particle is spherical, as it allows for efficient filling of the vacant spaces between granules, especially when the particle size is smaller. This approach can also be categorized into two distinct categories. Dry granulation and wet granulation. (13)

2.3.1 Wet Granulation:

The wet granulation method is utilized in medication manufacturing to facilitate the production of finely divided particles that can be easily fed into the formulation. Typically, the instant release formulation involves the granulation of tiny particles by incorporating them into an aqueous solution of a binding polymer. The formulation for controlled release involves the

granulation process with the incorporation of a binder polymer solution. (14) There are several advantages of wet granulation like improved flowability and compressibility, improved bioavailability, improved dose uniformity, and it is the fast method for the production of table. (16)

2.3.2 Dry Granulation:

The dry granulation process involves the compression of a powder combination without the application of heat or solvent. There are two fundamental methods involved in this process. The first step is to create a dense material by applying compression. Subsequently, the compact is subjected to milling in order to achieve granulation. Dry granulation is a process that involves the compaction of powders without the use of liquid binders. In this context, two distinct technologies are commonly employed for dry granulation. (17) Dry granulation utilises slug formation or roller compaction for formation of granules. (18)

2.4 Mass extrusion:

The present study involves the utilization of technology to facilitate the incorporation of an active drug into a water-soluble solvent, namely methanol and polyethylene glycol. The resulting mixture is subsequently introduced into an extruder to obtain a cylindrical shape of the final product. To create tablets as the desired dosage form, the extruded mass is segmented using a heated blade. (18)

2.5 Solid Dispersion:

Solid products typically consist of a combination of at least two distinct components, namely a hydrophilic matrix and a hydrophobic medication. The matrix can exist in either a crystalline or amorphous state. This approach addresses the difficulty of achieving a homogeneous mixture between a matrix and a drug, particularly at the molecular level. It is worth noting that matrix and drug components typically exhibit low miscibility. When developing immediate release solid dosage forms for oral administration in the gastrointestinal system of humans, it is frequently advantageous to enhance the dispersion of solid amorphous formulations within the dosage form. (19, 20)

2.6 Lyophilisation:

The outcome is contingent upon the fundamental notion of sublimation. Sublimation is a chemical process wherein a substance undergoes a conversion from a solid state to a vapor state, without transitioning through the liquid phase.

The process of lyophilization is carried out at temperature and pressure settings that are lower than the triple point. The entire procedure is conducted under conditions of reduced temperature and pressure through the use of a vacuum, making it well-suited for the dehydration of thermolabile substances. (21)

3.0 Novel Granulation Technologies:

3.1 Pneumatic Dry Granulation (PDG):

The dry approach employs a unique technology wherein the process of formulating granules is automated or semi-automated. The technique of granulation has superior features in comparison to dry granulation, direct compression, and wet granulation. Granules demonstrate notable characteristics such as high compressibility and flowability. The desired result can be achieved without the need for applying uncommon and expensive additives. (22)

3.2 Freeze Granulation Technology (FGT):

The frozen GT process, developed by Integrated Biosystems, Inc. located in California, USA, yields spherical and free-flowing granules that exhibit optimal homogeneity. The process necessitates the application of a suspension including powder, which is sprayed into liquid nitrogen. This rapid freezing of the droplets results in the formation of granules. Subsequently, these granules are subjected to freeze-drying, resulting in the production of dry granules. (23)

3.3 Spray Drying Granulation:

The utilization of this technique has resulted in enhanced flow, uniform dispersion of colors, reduced drug content, and less reliance on lubricants in comparison to wet massed goods. One approach to enhance the bioavailability and dissolution rate of various therapeutic products involves the co-precipitation of an active pharmaceutical ingredient with a compatible polymer. This process results in the formation of a stable amorphous solid dispersion. (24)

3.4 TOPO (TOPO Granulator) Technology:

Hermes Pharma has successfully created an innovative technology for conducting single pot granulation, which necessitates only a minimal quantity of liquid to initiate the sequential process. Either pure water or water-ethanol mixes are employed. The company known as TOPO Technology specializes in the production of granules used in tablet manufacturing. These granules are composed of a minimum of one solid crystalline substance, an organic acid, and either an alkaline or alkaline earth metal carbonate. When these components are combined in an aqueous solution, a chemical reaction occurs, resulting in the formation of carbon dioxide. Consequently, the end products, which are devoid of any solvent residue and granules, exhibit exceptional levels of hardness and durability. The TOPO vacuum granulation method, which is patented by Hermes Pharma, was utilized in the production of effervescent tablets. To prevent uncontrolled chain reaction, it is necessary to do granulation under vacuum conditions. (25)

3.5 Moisture Activated Dry Granulation (MADG):

This technology utilizes moisture as a means to initiate the production of granules, eliminating the necessity of employing heat for the purpose of drying these granules. The MADG process consists of two primary steps. (26)

3.6 Continuous flow technology:

This approach does not employ a liquid medium to initiate a chain reaction. The granules are prepared within an inclined drum, where the powder is introduced through the inlet duct and the created granules are subsequently extracted from the opposite side. The CF technology has the capability to manufacture up to 12 tons of granules on a daily basis. (27)

3.7 Thermal Adhesion Granulation Process:

The process of agglomeration, known as dry granulation, serves as an alternative to wet granulation. This method involves the utilization of a minimal amount of binder liquid and the application of heat to facilitate the formation of agglomerates. Furthermore, the granulation process is facilitated with the application of heat. The combination of excipient and active pharmaceutical ingredient (API) is subjected to heating within a closed chamber, with temperatures ranging from 30 to 130 °C. This chamber is specifically designed for tumble rotation, which facilitates the agglomeration of the powder particles. This technology effectively concludes the drying process by utilizing a less quantity of liquid, which is then consumed during the agglomeration of powder particles. Once the mixture has undergone the cooling process and has been passed through a sieve, it is possible to achieve granules of the desired particle size. (27)

3.8 Granurex Technology:

The method described consistently and accurately performs powder layering procedures, including single and repeated coating processes, resulting in precise powder layers. These layers exhibit improved precision and a more effective drug release mechanism. (29)

3.9 Foamed Binder Technologies:

The utilization of methocel polymers and the homogeneous distribution of binder solution to the drug combination contribute to the attainment of an enhanced wet granulation product. The utilization of this technology reduces the demand on water resources and ensures consistent replication. (30)

Along with these technologies certain formulation aspects like use of superdisintegrants is necessary for the formulation of immediate release tablets;

4.0 Superdisintegrants:

Disintegrants are compounds or combinations of compounds that are added to pharmaceutical formulations to facilitate the dispersion or fragmentation of tablets and the contents of capsules, hence promoting quick dissolving. (31)

Superdisintegrants are the type of disintegrant that perform the work of disintegration very fast.

4.1 There are several advantages of superdisintegrants: (32, 33, 34)

- No lump development during disintegration due to the remarkable tendency of quick disintegration upon soaking.
- Fully compatible with excipients and medicinal substances that are often utilized.
- Doesn't adhere to the dyes and punches.
- Functions well at lesser dosages.
- Minimal impact on flow capacity and compressibility.
- Higher intragranular efficacy.

- Biocompatible.

4.2 Ideal properties of superdisintegrants: (35, 36, 37)

- It is expected to result in quick breakdown.
- It ought to have acceptable flow characteristics and molding.
- Its compressibility index, hydration capacity, and particle size should all be favourable.
- It ought to be poorly soluble in water.
- Less friable, compactable tablets should be the result.
- It Has a very low concentration threshold and ought to have a higher disintegration efficiency.
- It should feel good in the mouth and not toxic.
- It shouldn't be prone to forming drug compounds.
- It should have the desired tableting qualities and be compatible with the other excipients.

4.3 Types of Superdisintegrants:

1. Natural Superdisintegrants:
    a. Ispaghula Husk Mucilage (Plantago ovata)
    b. Xanthan Gum
    c. Gellan Gum
    d. Locust Bean Gum
    e. Mango Peel Pectin
    f. Soy Polysaccharide
2. Synthetic Superdisintegrants
    a. Modified Starch (Sodium starch glycolate, Primojel)
    b. Cross-linked Polyvinyl Pyrrolidone (Crospovidone)
    c. Modified Celluloses (Croscarmellose Sodium)
    d. Microcrystalline Cellulose (Avicel)
    e. Alginates

4.4 Mechanism of action of superdisintegrants: (38)

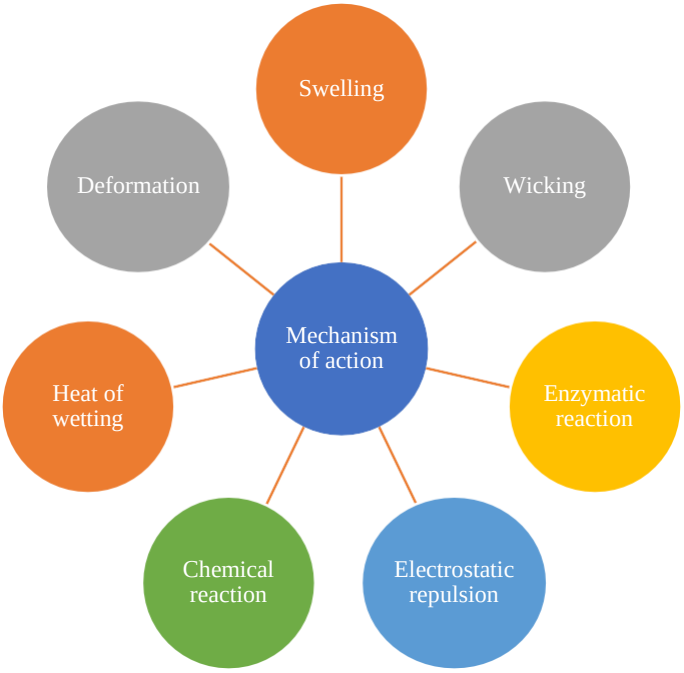

Fig. 1: Mechanism of action of superdisintegrants

5.0 Recent development in immediate release tablets:

Recently some novel techniques are developed for the formulation of immediate release tablets. Some of these techniques are as follows;

5.1 Novel hole technology:

The primary goal of this technique is to create fast-dissolving tablets using cutting-edge hole technology. It's a creative approach to reducing the disintegration time and increasing patient compliance. Through the usage of this technique, the tablet's overall surface area increases due to hole creation. The liquid seeps into the hole created in the tablet, causing it to break quickly.

A number of technologies were created to shorten the disintegration period, but the tablets produced using hole technology have a larger surface area since the holes have grown and the pore structure has enlarged. Sublimation is a concept used in hole technology. Compressed tablets may contain a variety of excipients including highly volatile substances such as ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, naphthalene, urea, urethane, and phthalic anhydride. Sublimation is then used to remove this additional volatile material, leaving behind a very porous matrix. It has been stated that tablets produced using this technique typically break up after 10–20 seconds. The tablets produced with hole technology exhibited all the characteristics, including weight fluctuation, friability, and hardness, within the specified limitations. (39)

5.2 A novel electrostatic dry powder coating process:

The main purposes of polymer film coat application in pharmaceutical dosage forms are to achieve improved stability, flavor masking, cosmetic quality, and drug release modification. The dissolution or dispersion of polymeric materials in organic or aqueous solvents serves as the general foundation for the coating process. Issues with toxicology, the environment, cost,

and safety arise when organic solvents are used. The advent of aqueous-based coating technologies has addressed these drawbacks. However, because evaporating water has a high heat of evaporation, aqueous film coating requires a slower drying procedure and a large initial energy input. Two distinct problems with aqueous film coating are the possibility of microbiological contamination and the decreased solid content of the coating solution. Certain medications that are sensitive to water may not be as stable when there is water present during the coating process or when there is leftover moisture in the film. Therefore, it is believed that removing solvents from pharmaceutical film coating is a highly effective way to reduce manufacturing costs, increase process effectiveness, and improve product quality.

For the first time, an electrostatic dry powder coating method using a pan coater system was created for pharmaceutical solid dosage forms. Using this method, two compositions for quick release coatings—Opadry® AMB and Eudragit® EPO—were applied successfully. To enhance particle deposition, reduce electrical resistivity from over $1\times1013\Omega m$ to less than $1\times109\Omega m$, and lower the Glass Transition temperature (Tg) of the coating polymer for film formation in the pan coater, a fluid plasticizer was sprayed onto the tablet cores' surface. To enhance the uniform deposition on the tablet surface, charged coating particles were sprayed using an electrostatic charging cannon after fluid plasticizer was used. As a potential alternative to the traditional aqueous-based coating procedure, the electrostatic powder coating approach has demonstrated the ability to produce a smooth and uniform coating sheet. (40)

6. Conclusion:

The majority of patients require prompt relief from medication, leading to suboptimal adherence to traditional drug regimens and subsequently diminishing the efficacy of therapy. A novel method, known as immediate release, has been devised to provide the combined benefits of simplified dosing and enhanced convenience. The tablets have been specifically formulated to facilitate the controlled and accelerated release of the active pharmaceutical ingredients. The aforementioned issues with conventional technologies underscore the necessity for enhanced manufacturing methods for immediate release pharmaceutical forms that possess mechanical strength, facilitating convenient handling and packaging, while maintaining production costs comparable to those of conventional tablets. In order to meet the medical prerequisites, researchers have invested significant resources into the development of an innovative tablet dosage form. This form is created using novel techniques including novel granulation technologies, electrostatic dry powder coating process, novel hole technology in fast dissolving tablets, hot-melt extrusion, and injection molding for continuous manufacturing of immediate-release tablets for oral administration. The objective of this development is to produce a tablet that disintegrates and dissolves rapidly, leading to enhanced dissolution. Additionally, the selection of excipients is also approached in a novel manner. A miniaturized method is employed.

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