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Next-Generation Pulmonary Therapies: Personalized Tablets as a Game Changer in Asthma Treatment

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Abstract
The third greatest cause of death worldwide is respiratory illness, which includes asthma and chronic obstructive pulmonary disease (COPD). Both adults and children can suffer from asthma, a chronic inflammatory illness that is characterized by reversible airway constriction and hyperresponsiveness. Prevalence rates are greater in metropolitan regions such as Delhi, Mumbai, and Kolkata (8-10%) than in rural areas (3-5%). Asthma is made worse by poor air quality, particularly during pollution surges; in Delhi, emergency visits increase by 50% during these months. Even though asthma is common, many patients-particularly in rural areas-do not obtain the right diagnosis or treatment, and only 40-50% of them utilize their inhalers as prescribed. According to a poll conducted in 2021, 60% of Indian asthma sufferers know very little about how to treat their illness. Potential remedies are provided by innovative dosage forms including orodispersible pills and personalized medications. Orodispersible tablets are particularly helpful for patients who have trouble swallowing or who need fast medication release since they dissolve swiftly in the mouth without the need for water. These dose forms are a viable alternative for the treatment of asthma and other chronic illnesses because they increase patient compliance and improve therapeutic results.

Keywords: Pulmonary drug delivery system, Asthma, Personalized medicines, Dosage forms, Orodispersible tablets, Evaluation parameters.

Introduction

Respiratory problems may vary widely in their severity and appearance. Effective therapy requires early diagnosis, medication, lifestyle modifications, and possibly surgery. Controlling symptoms and preventing complications in chronic diseases need ongoing therapy and monitoring. The third leading cause of mortality globally is respiratory illness, which affects the respiratory system. Infections and breathing difficulties can also result from respiratory conditions such as pneumonia, severe acute respiratory syndrome (SARS), asthma, and chronic obstructive pulmonary disease (COPD). Look at the death figures, the mortality rate was 7.6% in 2010. Following COVID-19, the mortality rate increased, as seen by the 2022 mortality rate, the 2023 mortality rate, and the 2024 mortality rate, which was greater than 2022 and 2023.
The chronic inflammatory airway disease known as asthma is typified by reversible and hyperresponsive bronchi. This frequent respiratory condition, which can affect both adults and children, has a wide range of morphologies, non-specific symptoms, and a diverse clinical outcome. One of the most prevalent chronic, non-communicable illnesses, asthma, is characterized by intermittent limitation of airflow and fluctuating respiratory symptoms. Variations in the kind and extent of airway remodelling and inflammation may affect the disease's severity and progression. According to a 2020 research, asthma affects 10% of youngsters in metropolitan India. urban areas particularly Delhi, Mumbai, and Kolkata had higher prevalence rates of asthma, with certain metropolitan populations having prevalence rates of 8-10%, whereas rural communities have prevalence rates of 3-5%. In 2020, Delhi often had "hazardous" values of the Air Quality Index (AQI), which ranges from 300 to 400. With a 50% rise in emergency visits for asthma episodes during months with the highest pollution levels, this directly affects asthma sufferers. According to a Delhi survey, barely 40-50% of asthmatics use their inhalers correctly, and 70% of children in rural regions do not obtain the right diagnosis or treatment for their condition. According to a poll conducted by the Indian Chest Society in 2021, 60% of Indian asthma patients know very little about the condition and how to treat it.

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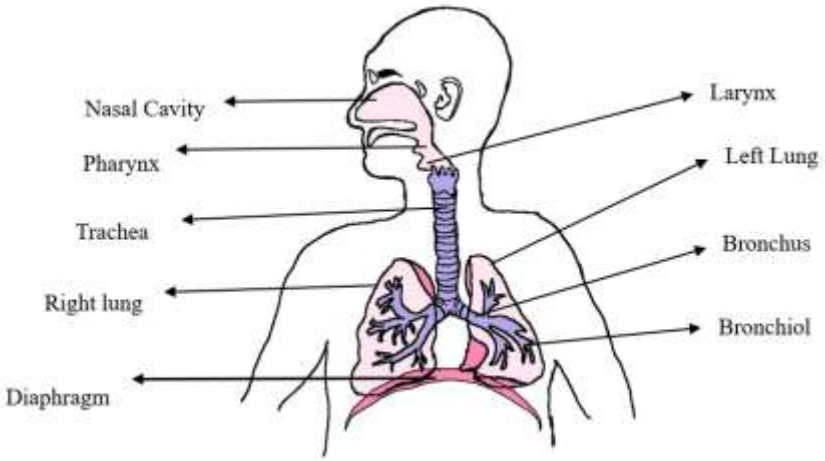

Figure 1: Human respiratory system

Conventional dosage form has limitations like Poor Bioavailability, First-Pass Metabolism, Inconsistent Drug Release, Patient Non-Compliance, Poor Solubility of Some Drugs, Difficulty in Administering in Special Populations and many more. The limitation with the conventional dosage forms can be overcome by using novel type of dosage forms, personalized medicines can be one of the them. Patients with long-term conditions like asthma may find that personalized medications are a game-changer. A unit dose of one or more drugs, with or without the necessary excipients, are included in these solid dosage forms, sometimes referred to as tablets, which are created by moulding or compression. The European Pharmacopoeia defines "orodispersible" as a tablet that dissolves rapidly in the mouth before being ingested. There is no need for water when administering these dose forms because they dissolve and disintegrate rapidly in saliva to release the drug. They appeal greatly to both young and old patients because of this property. Orodispersible tablets are sometimes referred to as oral disintegrating tablets, rapid disintegrating tablets, fast-melting tablets, and fast dissolving tablets (FDTs).

Pulmonary drug delivery system

A pulmonary drug delivery system is a way to deliver medicine directly to the lungs for either systemic or localized therapeutic effects. It effectively absorbs medications by taking advantage of the lungs' vast surface area, thin membranes, and abundant blood supply.Using medications including bronchodilators, corticosteroids, and antibiotics, this approach is frequently used to treat respiratory conditions like asthma, cystic fibrosis, and chronic obstructive pulmonary disease (COPD). Reduced systemic adverse effects and a quick commencement of action are made possible by direct administration to the lungs.[1,2,3]

Advantages of pulmonary drug delivery system

The technology for pulmonary drug administration has several benefits:

1. Less intrusive.
2. Improved patient adherence.
3. A lower risk of systemic and widespread exposure due to localized drug deposition.
4. Preventing first-pass metabolism.
5. Fast onset of effect because to rapid mucosal membrane absorption.
6. Simple formulation of water-insoluble/soluble drug compounds.
7. Preventing gastrointestinal disruption.[4]

Disadvantages of pulmonary drug delivery system

The technique for pulmonary medication administration has several drawbacks:

1. Limited efficacy and limited medication delivery volume per purn.
2. Focusing on issues.
3. Inadequate medication formulation stability.
4. Issues with protein-based drugs' immunogenicity.
5. Mucociliary clearance and phagocytosis provide quick drug remova.[5]

Applications of pulmonary drug delivery system

The following medications can be administered through the pulmonary route to treat a range of local and systemic disorders:

1. The conventional strongholds are asthma and chronic obstructive pulmonary disease (COPD).
2. Aerosols of insulin for hypoglycemia.

3. Therapy for migraines.
4. Nicotine aerosol for smokers who are addicted.[6]

Recent advances in pulmonary drug delivery system

There are some of the advances or the new technologyies are emerging in the pulmonary drug delivery system to provide better patient compliances and for the easy to use and provide safety and efficary of the drug product.

The some of the new advances in the pulmonary drug delivery system are as followed:

1. Nebulizer
2. Metered dose inhaler
3. Dry powder inhaler

Nebulizer

Nebulizers are the instruments used to turn liquid or solid suspensions or solutions into aerosols. Nebulizers are inhalation devices used to deliver drugs to the lower respiratory tract. The pulmonary bioavailability is significantly influenced by the insufflation equipment and formulation. For many years, nebulizers have been used to treat a variety of lower respiratory tract conditions.[7]

The nebulization system is further classified into different category:

1. Ultrasonic nebulizer
2. Vibrating-mesh nebulizer
3. Air-jet nebulizers

Ultrasonic nebulizer: A piezoelectric crystal is integrated into the bottom of the medicine reservoir or cup of these nebulizers. When exposed to an electric field, this crystal mechanically vibrates at a high frequency. Shockwaves produced by the crystal's vibrations travel through the reservoir filled with liquid, causing surface turbulence and cavitation that results in droplets at the liquid's surface. Cavitation is the process by which crystal vibrations cause voids to form in a liquid and then collapse. Above the liquid reservoir, the resultant droplets create a gentle aerosol cloud. Because of the turbulent liquid surface environment, the aerodynamic particle size distribution of aerosols is also polydisperse, but typically less dispersed than for air-jet systems. Afterwards, the aerosol cloud can be combined with inspiratory airflow to provide drugs to the lungs.

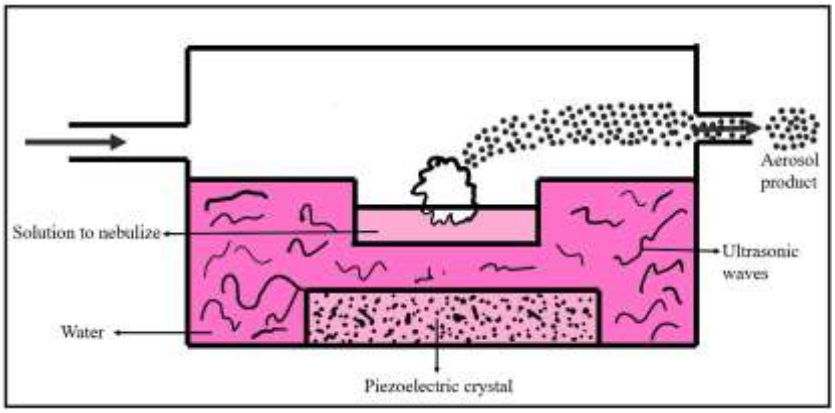

Figure 2: Systematic representation of ultrasonic nebulizers

Vibrating-mesh nebulizer: The vibrating-mesh nebulizer is a relatively new nebulizer technology that works with a greater range of formulations and has more consistent aerosol particle size distributions. These nebulizers fasten a piezoelectric crystal to a metal mesh that has been laser-drilled at the bottom of a reservoir or medication cup. The drug liquid is forced into the mesh's pores by the metal mesh's fast oscillations when the crystal is exposed to an electric field. The homogeneity of the laser-drilled holes in the metal membrane therefore results in the production of a mild aerosol with a constant aerodynamic particle size distribution. For patients on mechanical breathing, this aerosol can be given by an in-line connector, mouthpiece, or face mask.

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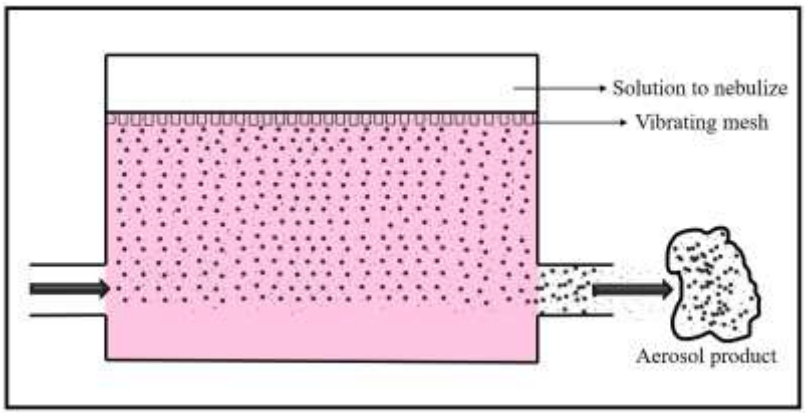

Figure 3: A systematic representation of vibrating mesh nebulizer

Air-jet nebulizer: Air-jet nebulizers are the original type of nebulizers and are produced by a variety of manufacturers. All air-jet nebulizers create an aerosol using the Bernoulli effect. In other words, pressure drops in a given region as air velocity increases. A volume of liquid is drawn up from a liquid reservoir into an area of intense shear stresses when compressed air flows through the air-jet nebulizer. The patient's breathing often creates a gentle stream of carrier air that moves the liquid out of the nebulizer once the liquid has been firmly divided into droplets.[8]

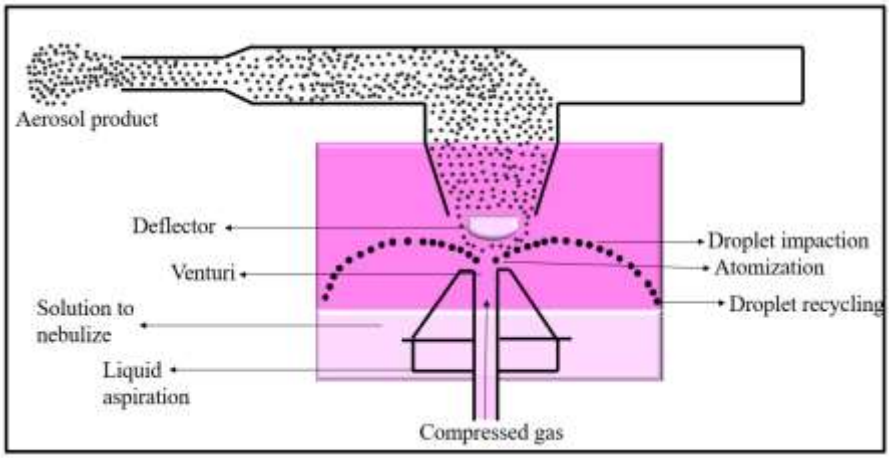

Figure 4: Systematic representation of air jet nebulizer

Metered dose inhaler

The pressurized metered dosage inhaler, also referred to as a metered dose inhaler, is the most widely used delivery system for drug aerosol administration. The ability to formulate a set dosage, portability, and the absence of an additional power source are some advantages of metered dose inhalers.[9] This preferred device, pMDIs, may be used to give medications such as steroids, bronchodilators, anticholinergics, and anti-inflammatory medicines. Effective aerosolization of medication is made possible by the pMDIs. A pMDI, a pressurized system, contains a mixture of propellants, flavorings, surfactants, preservatives, and the active medicine, which accounts for around 1% of the total contents.[10]

The medicine is administered through the pMDIs when the mixture is discharged from the delivery device via a metering valve and stem that fit into an actuator boot design. Small changes to the actuator design can affect the aerosol characteristics and output of the pressurized metered dosage inhaler.[11]

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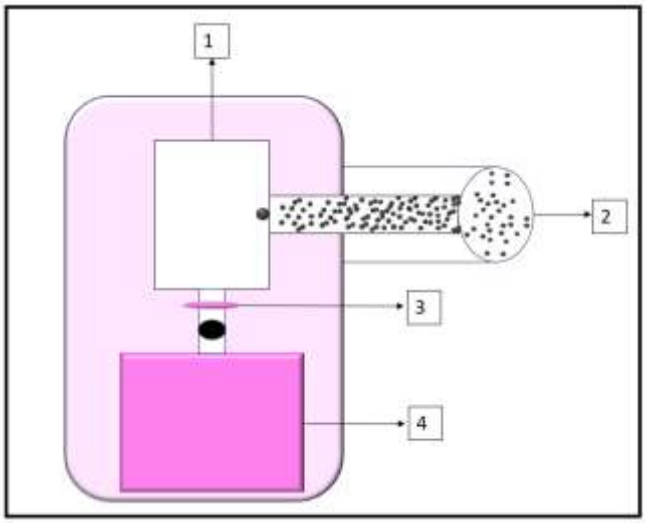

Figure 5: Systematic representation of metered dose inhaler, (1) The aerosolized drug delivery is actuated by the actuator in the expansion chamber, (2) Mouthpiece: release of aerosol particles at a high speed, (3) The metering valve is responsible for supplying the actuator with the necessary dose, (4) The propellant that activates the formulation is present in the liquid formulation

Dry powder inhaler

The dry powder inhaler delivers medication into the lungs as dry powder with little synchronization between the patient's breathing and the activation of the device. The aerosolized medication powder is delivered by the dry powder inhaler's formulation, which is exposed to higher dispersion forces to break down into individual particles. Among the devices that have been created are the Clickhaler, Multihaler, and Diskus. In order to separate the aggregated particles and produce the respirable particles, they can feed powder into a highspeed airflow. The deagglomeration mechanism brought on by particles impaction on the device surfaces is what the Spinhaler and Turbuhaler devices rely on.[12]

The design of dry powder inhalers is limited by the device's ability to balance the inhaler resistance and flow rate. Stronger impactions and quicker airflow—both necessary to enhance particle deagglomeration can result in a larger fine particle percentage in dry powder inhalers. Rapid airflow, however, can increase the risk of deposition in the oropharynx and reduce the quantity of medication powder that reaches the lungs.[13] The Aerohaler®, which was introduced in the middle of the previous century to deliver antibiotics, was the first time capsule-based DPI technology was used for medical purposes.

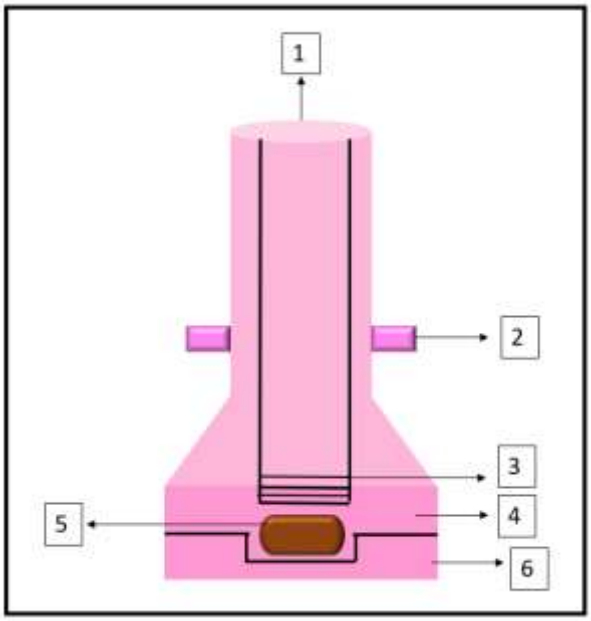

Figure 6: Systematic representation of dry powder inhaler,(1)The drug delivery device's mouthpiece acts as an air outlet,(2)Button: designed to operate the apparatus,(3)Filter/Grid: This device handles variations in internal flow resistance,(4)Capsule Chamber: This part of the device holds the capsule,(5)Capsule: the dosage is administered

following the capsule's compression through the device's mouthpiece,(6)The aerosolization of the powder based on carriers is greatly impacted by the air intake.

The Spinhaler®, the third DPI introduced at the close of the 1960s, was the first to employ a powdered form of bronchoactive medication in a gelatin capsule that could be placed within the device prior to the patient administering it. Since then, the performance of DPI systems has frequently been upgraded in tandem with technological advancements. The majority of DPIs now on the market are made by combining small powder medications (less than 5 μm in particle size) with larger carrier particles, frequently lactose.
To enhance the powder's flow, lactose is added prior to the medication formulation being aerosolized. According to the findings of every study, powder formulations may be transported via the airways and settle in the precise lung regions that require increased activity.[14]

DPI systems are classified into two categories.
1. DiskusTM
2. Turbuhaler

Diskus TM: The Diskus inhaler is a dry powder inhaler with the following characteristics:
A. Connected cover: The cover keeps the gadget compact.
B. Grip—to increase the interoperability of the device.
C. mouthpiece: used to inhale the drug.
D. doses counter: the component of the device that keeps a constant dosage.
E. Dosage releaser: Slide the dosage out of the dose counter to release it.

Turbuhaler: Although there are additional types, the most advanced nebulizers are those that deliver the formulation at the nanoscale. Advances in nanotechnology and advanced liquid nebulization techniques enable the delivery of these intelligent aerosolized particles, leading to the development of new, smarter drug carriers. Turbuhaler is more effective than DiskusTM.[11]

Pulmonary diseases
A few of the lung diseases that have been linked to a wide range of persistent pulmonary conditions such as
1. Asthma.
2. Chronic obstructive pulmonary disease (COPD).
3. Cystic fibrosis.
4. Lung cancer.
5. Pulmonary tuberculosis.
6. Bacterial and fungal pulmonary infections.
7. Extreme progressive pulmonary hypertension.
8. Idiopathic pulmonary fibrosis (IPF).
9. Multiple interstitial pulmonary diseases.[15]

Asthma, pulmonary tuberculosis (TB), chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis (IPF), and other chronic lung conditions pose substantial therapeutic hurdles. The most prevalent form of interstitial lung disease, IPF, affects 45% of patients and is challenging to treat since there is no cure that completely restores lung function.16 Asthma affects millions of people worldwide, and COPD and IPF rates increase with age. These illnesses still have no known treatment, despite improvements.[17] With 3 million fatalities and 10 million new cases in 2018, pulmonary tuberculosis continues to be a major cause of mortality.[18] Numerous drugs, such as peptides, antibodies, and genetic molecules (shRNA, miRNA, and siRNA), are used in treatment; nevertheless, none of them completely reverse damage.[19]

Asthma
The chronic inflammatory airway disease known as asthma is typified by reversible and hyperresponsive bronchi. This frequent respiratory condition, which can affect both adults and children, has a wide range of morphologies, non-specific symptoms, and a diverse clinical outcome. One of the most prevalent chronic, non-communicable illnesses, asthma, is characterized by fluctuating respiratory symptoms and intermittent airflow limitation. Complex interplay between genetic predisposition and environmental circumstances result in heterogeneity in the condition's clinical expression. Variations in the kind and extent of airway remodeling and inflammation may affect the disease's severity and progression.[20]

Sign and symptoms
1. Wheeze.
2. Pressure in the chest.
3. Coughing and respiratory distress.

4. Usually linked to fluctuating airflow restriction.
5. Inflammation.[21]

Personalized medicine

The categorization of patient groups according to biomarkers to assist in treatment decisions is known as "personalised medicines." The term also apply to personalized dosage forms. More precisely, individualized medicine is applicable to patient groups like elderly patients who often need treatment adjustments because of their rapidly changing physiological and metabolic conditions, as well as paediatric patients whose medication is usually adjusted before being administered because it is based on the child's age and body weight. The active dose strength, pill shape and size, dissolve rates, and disintegration times may therefore be altered with personalized medicine. Additionally, it will save costs to the healthcare system associated with hospital stays and adverse drug reactions. In addition to lowering prescription, dispensing, and packing expenses, manufacturing medications at the PoC will also do away with the need for long-term stability.[18]

The severity of asthma, a complicated, episodic illness with several causes, can change throughout the course of a person's life. An estimated 5.4 million individuals in the UK suffer with asthma, with an estimated £1.1 billion spent on treatment each year. This presents a significant and growing strain on the National Health Service. The majority of asthmatics in many nations receive care in primary care, and while asthma makes up a small percentage of primary care visits, many of these are standard yearly examinations that are not tailored to the patient's needs; considering how asthma symptoms change over time, it may be questioned how much benefit this is to the patient or the clinician.

Personalized medicines can play a game changer for the patients with chronic diseases like asthmas.[19]

Table 1: Classification of Personalized dosage form[18,19]

S. No.	Types	Description
1.	Oral Solid Dosage Forms	Each patient can have their dosage strength, release profile, and quantity of pills or capsules taken according to their needs, for instance Personalized pill packs with tablets or capsules
2.	Oral Liquids	Depending on the patient's precise dosage needs, customized oral suspensions, solutions, and flavoured liquids can be made with a particular concentration of an active component. This is especially helpful for kids or anyone who have trouble swallowing.
3.	Topical Dosage Forms	Personalized transdermal patches and customized creams, gels, or ointments can be made to fit the skin type of the patient and offer the best excipients and medication concentration for a specific body region.
4.	Injectable and Infusion Dosage Forms	Depending on their condition, certain individuals could need particular intravenous, subcutaneous, or intramuscular injectable formulations. Optimizing medication distribution and reducing adverse effects can be achieved by adjusting the concentration, volume, or pH.
5.	Sublingual and Buccal Dosage Forms	These forms are helpful for individuals who may have trouble swallowing and require a quick commencement of action. Sublingual or buccal formulations can be customized to include the appropriate dosage, release rate, and any extra excipients needed to increase bioavailability or stability.
6.	Pharmacogenetic-Based Dosage Forms	Using Genetic Profiling to Customize Dosage Pharmacogenomics developments enable the development of customized drugs based on genetic variables.
7.	Paediatric and Geriatric Dosage Forms	Tailored dosages that take into account variables including weight, metabolic rate, and organ function (such as liver and kidney function) in order to meet the unique requirements of juvenile or geriatric populations.
8.	Personalized Drug Delivery Systems	According to a patient's particular requirements, customized formulations can be created to release a

		medication gradually, guaranteeing that it stays effective for extended periods of time or throughout the day.
9.	Patient-Centric Combination Therapies	Patients who need polypharmacy can have many drugs mixed into a single pill or dose form, according to their specific requirements.
10.	Allergen-Free Dosage Forms	Certain excipients or inactive chemicals in drugs may cause allergies in certain people. Without these allergies, a customized medicine may be prepared, guaranteeing safety and enhancing adherence.

Dosage form

The physical presentation of a drug for patient administration, known as a dosage form, affects security and convenience. Tablets, capsules, liquids, creams, and injections are among the forms available, depending on the patient's

Classification of dosage form

Dosage forms are classified according to their characteristics, intended use, and mode of active ingredient release. The following are some of the most popular categories:

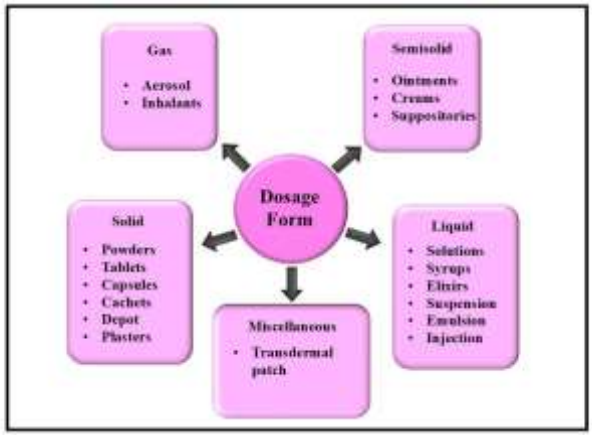

Figure 7: Classification of dosage form

Tablet dosage form

A unit dose of one or more drugs, with or without the necessary excipients, are included in these solid dosage forms, sometimes referred to as tablets, which are created by molding or compression. Tablets can be consumed whole or chewed. Some are given after being diluted or spread out in water. For some, the active ingredient is inserted into the mouth and released at a predetermined rate. Implants or passeries can also be presented as tablets.

Classification of tablet dosage form

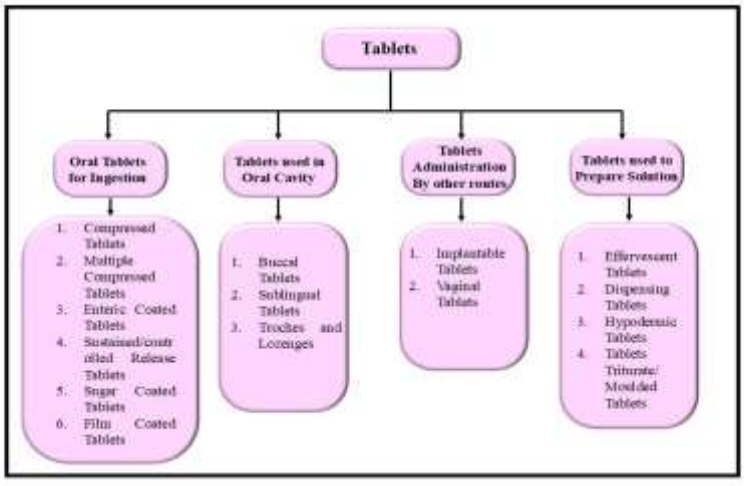

Figure 8: Classification of tablet dosage form

Advantages of tablet dosage form

1. They have the best mechanical, chemical, and microbiological stability of any oral dosage form.
2. They are the least expensive of all the oral dose forms.
3. They are the smallest and lightest of all the oral dose forms.
4. They are the most affordable and straightforward to package and ship.
5. Certain specific release profiles, including enteric or delayed release products, are well suited for them.
6. Tablets work better than other unit oral dosage forms when it comes to largescale manufacture.
7. They are the most well-suited oral dose form in terms of chemical, mechanical, and microbiological stability.

Disadvantages of tablet dosage form

1. Compression issue with the crystalline medication.
2. 100% Swallowing is challenging, particularly for young patients and sick (unconscious) individuals.
3. Compressed tablets are not appropriate for hygroscopic medications.
4. It might be challenging to manufacture medications with delayed dissolving and low or poor water solubility.
5. Coating and encapsulating to eliminate bitter and disagreeable tastes may raise production costs.

Ideal property of tablet dosage form

1. A biocompatible tablet should be free of pollutants, excipients, and microbes that might endanger patients.
2. The tablet should be strong enough mechanically to resist erosion and breakage while being handled.
3. Make sure the tablet contains the right amount of medication.
4. A regulated and repeatable method of medication release from the tablet is required.
5. Throughout its life, the tablet should be stable in terms of chemistry, physical properties, and microbiology.
6. The tablet should be elegantly designed, with constant weight, size, and look.[22]

Orodispersible tablets

The European Pharmacopoeia defines "orodisperse" as a tablet that dissolves rapidly in the mouth before being ingested. The orodispersible pill was designed to improve patient compliance. There is no need for water when administering these dose forms because they dissolve and disintegrate rapidly in saliva to release the drug. They appeal greatly to both young and old patients because of this property. Traditional pills or capsules are sometimes difficult for people of all ages to swallow, but elderly and dysphagic people are most affected. Alternative titles for orodispersible tablets include fast-melting tablets, oral disintegrating tablets, rapid disintegrating tablets, and fast dissolving tablets (FDTs).

Advantages of orodispersible tablets

1. Rapid disintegration tablets are intended for patients who are bedridden, old, stroke victims, have renal impairment, or have swallowing difficulties, such as geriatric, pediatric, or psychiatric patients.
2. Faster drug treatment and improved bioavailability and absorption with RDT are made possible by the pre-gastric absorption of drugs from the mouth, oesophagus, and throat as the saliva passes.
3. Pre-gastric absorption may improve bioavailability and improve clinical performance by reducing side effects due to the lower dose.
4. Patients with impairments, those who are bedridden, and those who do not always have access to water can all benefit from the use of orodispersible tablets.
5. Because of physical difficulties, there is a lower risk of asphyxiation when taking standard formulations orally, increasing safety.

Disadvantages of orodispersible tablets

1. Because it is hygroscopic, orodispersible must be stored in a dry environment.
2. It can occasionally have a mouthfeel.
3. Special packaging is needed for ODT to be adequately stabilized and safe of stable product.
4. Uniformity of dose is a technological difficulty.

Ideal properties of orodispersible tablets

1. It must be cost-effective.
2. Preferable dispersible tablets for oral administration need very little or no water; the formulation has to dissolve or disintegrate easily in the oral cavity in a couple of seconds.
3. The formulation must be sufficiently firm and free of friability concerns to meet the demanding criteria of the production process and the target patient's handling of the finished product.
4. It should adhere to the present packaging and processing protocols, be stable, and have a low manufacturing mold.
5. The dispersible pills need to be able to hold a lot of medicine.

6. The formulation should dissolve or disintegrate quickly in the oral cavity when taken orally in order to provide an immediate impact.
7. Steer clear of the first pass effect, which increases the bioavailability of the quickly dispensed tablets.[23]

Selection criteria for the orodispersible tablets drug candidate

1. When choosing drug candidates for delivery as ODT dosage forms, a number of factors need to be taken into account:
2. Drugs that produce a significant amount of toxic metabolites mediated by first pass liver metabolism and gastric metabolism, as well as those that have a substantial fraction of absorption in the oral cavity and segments of the pre-gastric GIT.
3. Drugs that have the ability to diffuse and partition into the epithelium of the upper GIT (log P > 1, or preferable > 2) and those that can penetrate oral mucosal tissue are thought to be perfect for ODT formulations.
4. ODT formulations may not be appropriate for patients with Sjogren's syndrome or dry mouth brought on by reduced saliva production, as well as patients who are taking anticholinergic medicines simultaneously.
5. Drugs that require regulated or sustained release, have a short half-life and require frequent doses, are extremely bitter, or have an unpalatable flavour whose taste masking is impossible are not suitable for ODT formulation.[24]

The technologies used for manufacturing orodispersible tablets

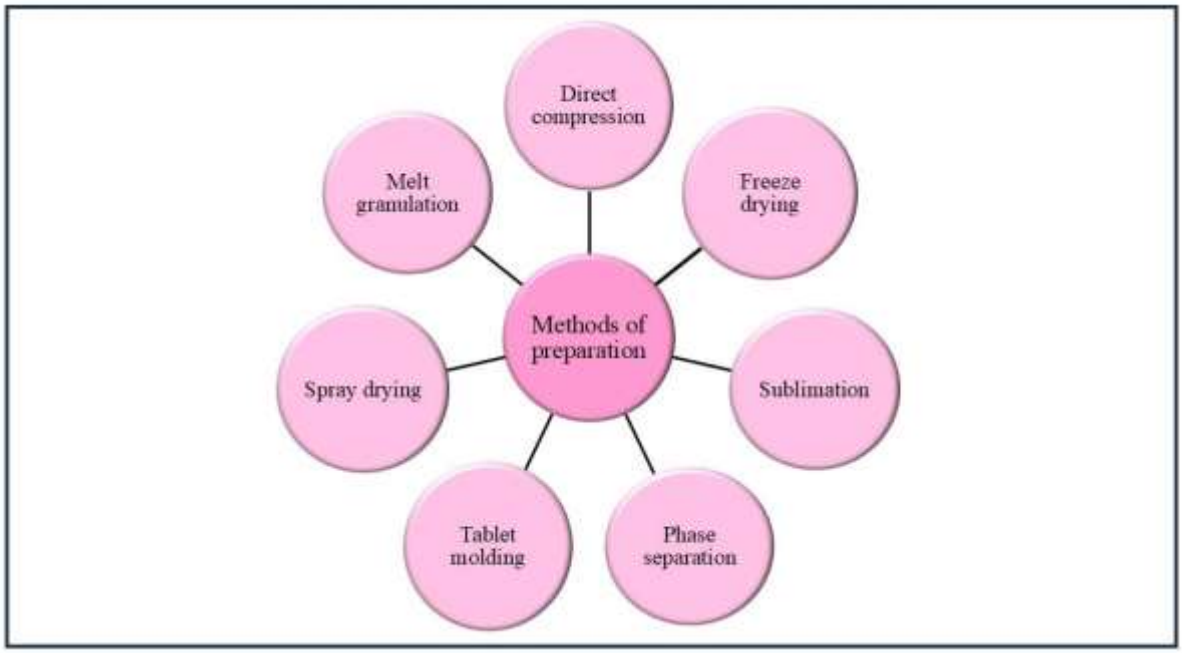

Figure 9: Classification of method of preparation

Direct compression

For ODTs, direct compression is the most straightforward and economical method of producing tablets because it can be done with standard tablet manufacturing and packaging equipment and because tableting excipients with better flow, compressibility, and disintegration qualities are readily available, particularly tablet disintegrants, effervescent agents, and sugar-based excipients.

Lyophilization

Lyophilization, also known as freeze drying, is the process of extracting solvent from a frozen medicine suspension or solution that contains excipients that give it structure. The tablets made with this method are often quite light highly permeable, enabling them quick breakdown. Excipients' glassy amorphous porous structure and the drug material created by freeze drying both contribute to improved solubility. The whole freeze drying procedure is conducted at a non-elevated temperature, hence eliminating any potential negative thermal effects that might compromise the stability of the medicine throughout processing.

Sublimation

Even highly water-soluble chemicals in compressed tablets dissolve slowly because of the tablets' limited porosity. The remaining tablet components were combined with inert solids that volatilize easily, such as urea, ammonium carbonate, ammonium bicarbonate, hexamethelenetetramine, camphor, etc., and the combination was compacted into tablets.

Sublimation was then used to eliminate the volatile components, creating porous structures in the process. Furthermore, a number of solvents (such as benzene and cyclohexane) can be employed as pore-forming agents. According to reports, tablets made using this method often dissolve in 10–20 seconds. Camphor and mannitol were utilized as the sublimating material and tablet matrix, respectively. To create pores in the tablets, camphor was sublimated in a vacuum at 80°C for 30 minutes.

Phase separation
A new technique that uses sugar alcohol's phase transition to create ODTs with enough toughness. ODTs are created using this method by compressing and then heating tablets that include two sugar alcohols, one having a low melting point and the other with a high one.The heating procedure strengthens the bonds between the particles, giving the tablets enough hardness where they wouldn't have been otherwise because of poor compatibility.

Tablet Molding
Water-soluble compounds are usually the main elements of moulded tablets. A solvent, often water or ethanol, is used to wet the powder combination before it is formed into tablets under less force than is typically applied while compressing tablets. Compression moulding is the term for this method. The solvent can then be eliminated by letting it air dry. A more porous structure is produced to improve the dissolving since moulded tablets are often crushed at a lower pressure than traditional compressed tablets. It is typically necessary to run the powder mix through an extremely fine screen in order to increase the rate of dissolution. Lately, the moulded shapes have also been made straight from a molten matrix that contains the medication is dispersed or dissolved (a process called heat moulding) or by removing the solvent at room pressure from a medication suspension or solution (no vacuum lyophilization).

Spray drying
The method of spray drying can be used to create fine, very porous powders. The pharmaceutical sector always uses spray dryers to create very porous powders. Orally disintegrating tablets consist of sodium starch glycolate, croscarmellose, mannitol as a bulk agent, and hydrolysed or unhydrolyzed gelatine as a matrix supporting agent salt as an agent for disintegration. Citric acid and sodium bicarbonate are occasionally used to enhance dissolving and disintegration. Lastly, a spray drier is used to dry the composition. This approach produces ODTs that dissolve in less than 20 seconds. When compared to tablets made by direct compression, the kollidon CL excipient base had the highest drug release and the shortest disintegration time, demonstrating the superiority of the spray-dried excipient base methodology over the direct compression method.

Evaluation of orodispersible tablets
Pre-compressional evaluation
In order to ascertain the powder blend's properties, the formulations can be evaluated for:

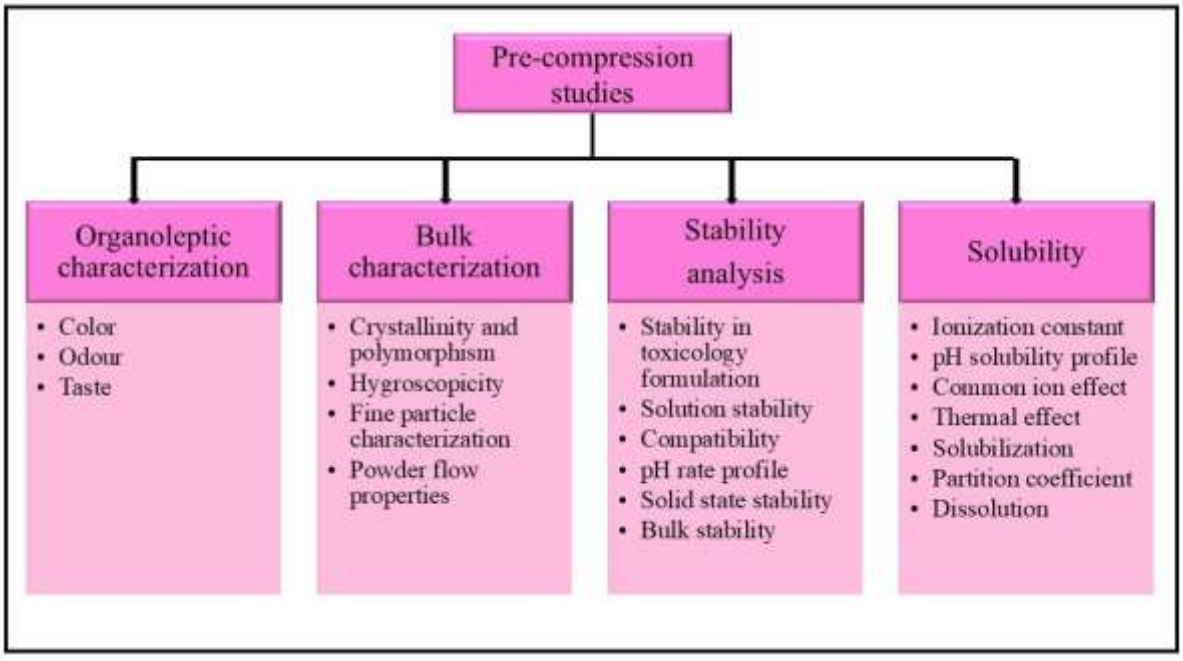

Figure 10: Classification of pre-compression studies

Post-compressional evaluation

Hardness: A tablet's hardness is determined by the force required to shatter it throughout its whole diameter. The tablet's ability to withstand breaking, abrasion, and chipping while being stored its hardness determines how it is transformed and handled before use. Using a Monsanto Hardness tester, the hardness of each formulation's tablet was assessed. ODTs typically have a lower hardness than regular tablets because a higher hardness causes the tablet to dissolve more slowly. For uncoated tablets, a hardness of around 3-5 kg/cm2 is deemed adequate, and the force is expressed in kilograms.

Friability test: Friability is the weight loss of the tablet in the container as a result of the surface being cleared of tiny particles. The purpose of the friability test is to determine whether the tablet can tolerate abrasion during handling and packaging as well as transportation. The Roche friabilator is used to determine the tablets' friability. A plastic container that rotates at 25 rpm and drops the tablets six inches high with each rotation makes up the friabilator. A sample of tablets that had been previously weighed was put in the friabilator and rotated 100 times. Tablets were cleaned with a gentle muslin towel and then weighed again; the weight loss indicates how friable the tablet is.

Weight variation: To perform a weight variation test, 20 tablets are weighed separately, their average weight is determined, and the weight of each tablet is compared to the average weight.

Thickness: The tablets' diameter and thickness were measured with a Micrometre screw gauge. Each formulation type was tested with five tablets, and average values were computed. The way it is stated in mm.

Water absorption ratio: A little Petri dish with six millilitres of water was filled with a piece of tissue paper that had been folded twice. A tablet was placed on the paper, and the amount of time needed for it to completely wet was recorded. This moistened tablet was weighed after that.

Wetting test: A tablet was placed on a piece of tissue paper (12 cm × 10.75 cm) that had been folded twice and placed in a small Petridish (ID = 9 cm) with 6 cc of pH 6.8 phosphate buffer. The time it took for the paper to completely wet was seen. Each formulation's average wetting time was recorded after three tablets were chosen at random.

Disintegration test: The traditional disintegration test equipment might not provide accurate disintegration test results for ODTs. Less than 6 millilitres of saliva are accessible in the mouth cavity. In contrast, the traditional disintegration test device uses a significant quantity of dihydrogen monoxide with extremely quick kineticism up and down. The simplest way to overcome this limitation was to fill a 25 ml measuring cylinder with 6 ml of phosphate buffer at a pH of 6.8. A constant temperature of 37± 2°C was maintained. An ODT was conducted, and the amount of time needed for the pill to completely disintegrate was recorded.

Dissolution test: It is a crucial test since it may be used to determine the drug-release profile. You can utilize one of the USP dissolution test devices. Orodispersible pills dissolve quickly. Thus, USP is 2 Dissolution testing is done using a paddle-type device at 50–100 r/min. Tablet fragments or fragmented tablet masses may become caught on the inside top of the basket at the spindle, however USP Type I basket equipment has a specific use in the case of orodispersible tablets. When there is little to no effective stirring, an incorrect dissolving profile is produced. Because Type II has a reproducible-dissolution profile, it is thus selected.[25]

Conclusion

Respiratory diseases, including asthma and chronic obstructive pulmonary disease (COPD), are major global health concerns and the third leading cause of mortality. Asthma, a chronic inflammatory disease characterized by reversible airway narrowing and hyperresponsiveness, affects both adults and children, with prevalence rates higher in urban areas like Delhi, Mumbai, and Kolkata (8-10%) compared to rural areas (3-5%). Poor air quality, especially during pollution spikes, exacerbates asthma, with emergency visits rising by 50% during high pollution months in Delhi. Despite the widespread nature of asthma, many patients, especially in rural areas, do not receive proper diagnosis or treatment, and compliance with inhaler use is low (40-50%). A 2021 survey revealed that 60% of asthma patients in India have limited knowledge about managing the condition.

Conventional dosage forms, like tablets and capsules, have limitations, including poor bioavailability, first-pass metabolism, inconsistent drug release, and patient non-compliance. These challenges are particularly relevant for chronic conditions like asthma, where ongoing therapy and monitoring are essential. Novel dosage forms, such as personalized medicines and orodispersible tablets, offer potential solutions. Orodispersible tablets, which dissolve quickly in the mouth without the need for water, are especially beneficial for patients with difficulty swallowing or those requiring rapid drug release. These dosage forms enhance patient compliance and improve therapeutic outcomes, making them a promising option for managing asthma and other long-term conditions.

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