Preparation and Evaluation of Ambroxol Hydrochloride fast dissolving Tablet by Solid Dispersion Technique

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Abstract- This study focuses on the preparation and evaluation of Ambroxol hydrochloride fast- dissolving tablets using the solid dispersion technique. Ambroxol hydrochloride, a mucolytic agent with poor aqueous solubility, poses challenges in achieving rapid dissolution and effective bioavailability. Solid dispersion, a promising approach to enhance solubility and dissolution rate, was employed in this research. Various solid dispersion formulations of Ambroxol hydrochloride were prepared using different carriers and methods. The prepared formulations were evaluated for their physicochemical characteristics such as drug content, dissolution rate, and morphology. The results indicated that solid dispersion significantly improved the dissolution rate of Ambroxol hydrochloride, attributing to enhanced drug-carrier interactions and reduced particle size. Fast-dissolving tablets were formulated using the optimized solid dispersion formulation, and there in vitro dissolution behavior was compared with commercially available conventional tablets. The findings suggest that solid dispersion- based fast-dissolving tablets of Ambroxol hydrochloride offer a promising strategy to improve therapeutic efficacy through enhanced dissolution and potentially improved patient compliance.

Keywords - Ambroxol hydrochloride, Fast dissolving tablet, Enhanced dissolution rate, Bioavailability, Drug delivery, Solubility enhancement.

I. INTRODUCTION

Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage form. Oral route is considered most natural, uncomplicated, convenient and safe due to its ease of administration, patient acceptance, and cost effective manufacturing process. Pharmaceutical products designed for oral delivery are mainly immediate release type or conventional drug delivery systems, which are designed for immediate release of drug for rapid absorption.

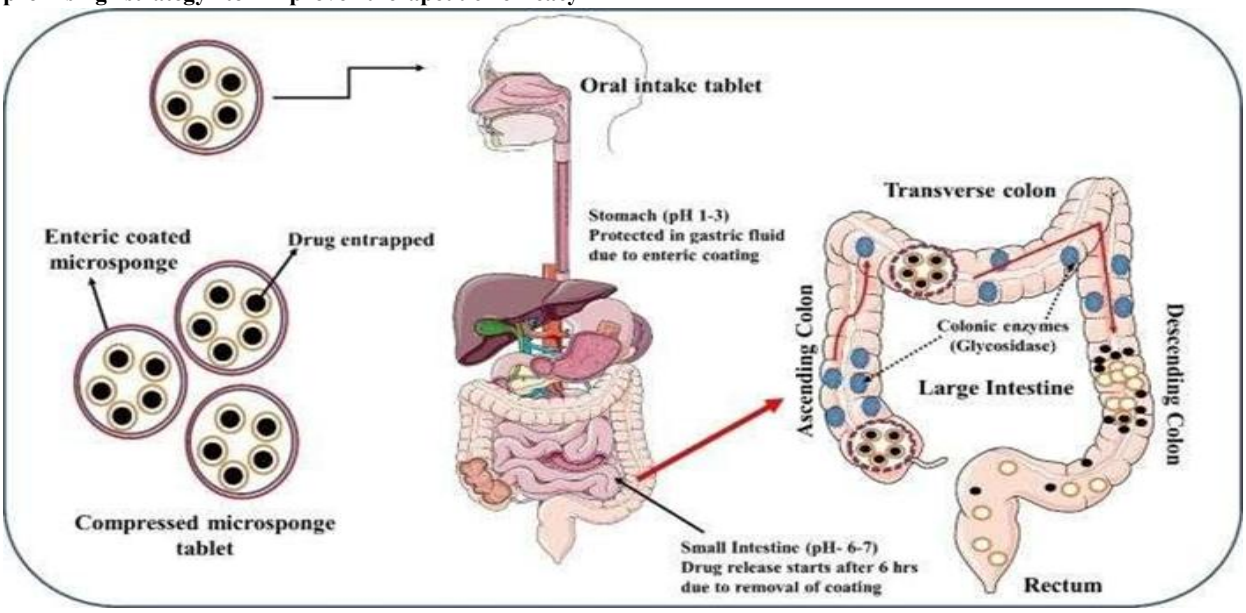


Fig 1: Oral drug delivery system These immediate release dosage forms have some limitations such as:

- Drugs with short half-life requires frequent administration, which increases chances of missing dose of drug leading to poor patient compliance.
- A typical peak-valley plasma concentration-time profile is obtained which makes attainment of steady state condition difficult.
- The unavoidable fluctuations in the drug concentration may lead to under medication or overmedication as the CSS values fall or rise beyond the therapeutic range.
- The fluctuating drug levels may lead to precipitation of adverse effects especially of a drug with small therapeutic index, whenever overmedication occurs.

Many technological developments have resulted in the creation of rapid drug delivery systems, which have the potential to transform medicine distribution and offer a multitude of therapeutic advantages. These systems address the shortcomings of traditional drug delivery methods.

Up to 50–60% of all dose forms are administered orally. This indicates widespread acceptability of this method. Solid dosage forms are widely used because they are simple to administer, precisely dose, allow for self-medication, reduce discomfort, and above all ensure patient compliance. Tablets and capsules are the most often used solid dose forms; nevertheless, some patients find these to be difficult to swallow. Swallowing oral dose forms is aided by the use of water. People frequently have difficulty swallowing traditional dose forms, such tablets, when water is scarce, when they have motion sickness (kinetosis), and when they suddenly start coughing up a cold, an allergy, or bronchitis. Tablets that may quickly dissolve or disintegrate in the oral cavity have drawn a lot of interest because of these factors.

In order to provide pediatric and elderly patients with an alternative to traditional dose forms, fast-dissolving drug delivery devices were originally created in the late 1970s. These pills are made to dissolve or break down quickly in saliva—usually in less than sixty seconds. Pharmaceutical technologists have created new oral dosage forms called mouth melting tablets (MMTs), mouth dissolving tablets (MDTs), orally disintegrating (dispersible) tablets (ODTs), fast disintegrating (dissolving) tablets (FDTs), or immediate release tablets that dissolve quickly in saliva, typically in a matter of seconds, without the need to take water, in order to fully meet these medical needs.

Fast dissolving tablets (FDTs) are described as "a solid dosage form containing a medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue" by the United States Food and Drug Administration (USFDA). According to recent market research, almost 50% of patients choose FDTs over alternative dose forms. The two primary methods used to make mouth dissolving tablets are the first is the use of super disintegrants such as crospovidone, sodium starch glycolate, and croscarmellose sodium. Using vacuum and freeze drying to maximize the tablets' pore structure is an additional technique. Direct compression is favored over other techniques due to its ease of use, speed, and affordability.

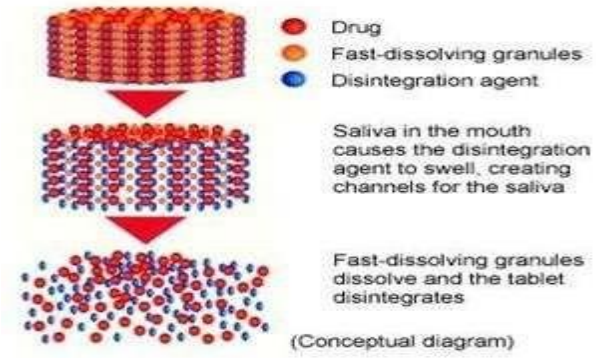


Fig 2: - Fast dissolving drug delivery systems.

Advantages of fast dissolving tablets:

1. No need of water to swallow the tablet.
2. FDTs can be easily administered to pediatric, elderly and mentally disabled patients.
3. Accurate dosing as compared to liquids.
4. Dissolution and absorption of the drug is fast, offering rapid onset of action.
5. Bioavailability of drugs is increased10as some drugs are absorbed from mouth, pharynx and esophagus through saliva passing down into the stomach.
6. Advantageous over liquid medication in terms of administration as well as transportation.
7. First pass metabolism is reduced, thus offering improved bioavailability and thus reduced dose and side effects.

8. Offering improved safety.

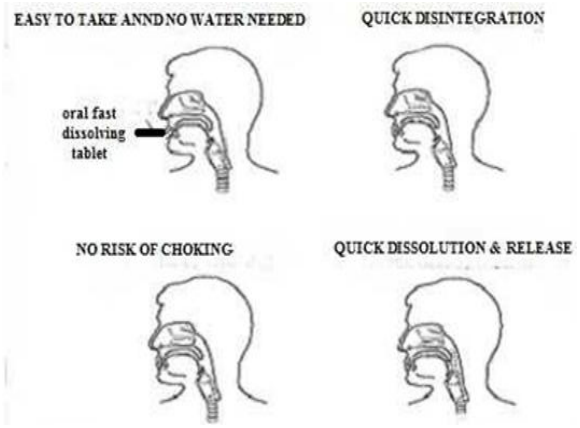


Fig 3:- Advantages of fast dissolving tablets.

Limitations of FDTS:

1. The major disadvantages of FDTs is related to the mechanical strength of tablets.
2. FDT are very porous and soft molded metrics or compressed in a tablet with low compression, which makes tablet friable and brittle which difficult to handle.
3. Bad tastes drugs are difficult to formulate as FDT; special precaution should have to be taken before formulate such kind of drug.
4. Several FDT are hygroscopic cannot maintain physical integrity under normal condition from humidity which requires specialized package.
5. Dryness of the mouth due to decreased saliva production may not be good candidates for these tablet formulations.
6. Rate of absorption from the saliva solution and overall bioavailability.
7. Drug and dosage form stability.

1.1. DISSEASE PROFILE:

Respiratory diseases:-

These are pathological conditions affecting the organs and tissues that make gas exchange difficult in air-breathing animals. They include conditions of the respiratory tract including the trachea, bronchi, bronchioles, alveoli, pleurae, pleural cavity, the nerves and muscles of respiration. Respiratory diseases range from mild and self-limiting, such as the common cold, influenza, and pharyngitis to life-threatening diseases such as bacterial pneumonia, pulmonary embolism, tuberculosis, acute asthma, lung cancer, and severe acute respiratory syndromes, such as COVID-19. Respiratory diseases can be classified in many different ways, including by the organ or tissue involved, by the type and pattern of associated signs and symptoms, or by the cause of the disease.

Respiratory diseases encompass a wide range of conditions affecting the lungs and respiratory system. Here are some common respiratory diseases:

- Asthma: A chronic inflammatory condition characterized by reversible airflow obstruction, bronchospasm, and increased mucus production, leading to symptoms such as wheezing, coughing, chest tightness, and shortness of breath.
- Chronic Obstructive Pulmonary Disease (COPD): An umbrella term for progressive lung diseases such as emphysema and chronic bronchitis, characterized by airflow limitation, difficulty breathing, and chronic cough.
- Pneumonia: An infection of the lungs caused by bacteria, viruses, fungi, or parasites. Symptoms include fever, cough, chest pain, difficulty breathing, and fatigue.
- Influenza (Flu): A highly contagious viral infection affecting the respiratory system, causing symptoms such as fever, cough, sore throat, runny or stuffy nose, body aches, and fatigue.
- Tuberculosis (TB): An infectious disease caused by the bacterium Mycobacterium tuberculosis, primarily affecting the lungs. Symptoms include coughing up blood, chest pain, fatigue, fever, and weight loss.
- Interstitial Lung Disease (ILD): A group of lung disorders characterized by inflammation and scarring of the lung tissue, leading to symptoms such as shortness of breath, cough, and decreased exercise tolerance.
- Lung Cancer: A malignant tumor that starts in the lungs and can spread to other parts of the body. Symptoms may include persistent cough, chest pain, hoarseness, weight loss, and difficulty breathing.
- Pulmonary Embolism: A blockage in one of the pulmonary arteries in the lungs, usually caused by blood clots that travel to the lungs from the legs or other parts of the body. Symptoms include sudden onset of shortness of breath, chest pain, cough, and sometimes coughing up blood.
- Sleep Apnea: A sleep disorder characterized by pauses in breathing or shallow breaths during

sleep, often leading to poor sleep quality and daytime fatigue.

- Cystic Fibrosis: A genetic disorder affecting the lungs and other organs, characterized by the production of thick, sticky mucus that can clog the airways and lead to respiratory infections.

These are just some examples of respiratory diseases, and each condition can vary widely in terms of causes, symptoms, severity, and treatment options. It's important for individuals with respiratory issues to seek medical attention for proper diagnosis and management.

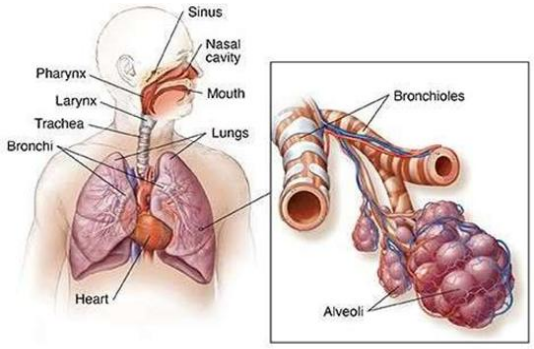


Fig 4:- Anatomical diagram of respiratory system.

1.1.1. Tracheobronchitis:-

It is also known as bronchotracheitis or simply bronchitis, is a common respiratory condition characterized by inflammation of the trachea (windpipe) and bronchial tubes (large airways in the lungs). It can be acute or chronic and is typically caused by viral or bacterial infections, although it can also result from exposure to irritants such as cigarette smoke or air pollution.

- Symptoms:-
  - Cough: Often starts as a dry cough and may progress to producing phlegm (sputum).
  - Sore throat: Irritation and discomfort in the throat.
  - Chest discomfort: Feeling of tightness or pressure in the chest.
  - Shortness of breath: Difficulty breathing, especially during physical exertion.
  - Fatigue: Feeling tired or run-down.
  - Mild fever: Some individuals may experience a low-grade fever.
- Causes:-
  - Viral Infections: Common cold viruses, influenza viruses, and respiratory syncytial virus (RSV) are frequent culprits.
  - Bacterial Infections: Bacteria such as Streptococcus pneumoniae or Haemophilus influenzae may cause bacterial bronchitis, particularly in individuals with weakened immune systems.
  - Irritants: Tobacco smoke, air pollution, dusts, and chemical fumes can irritate the airways, leading to inflammation.
- Treatment:-
  - Rest: Adequate rest helps the body fight off the infection and promotes healing.
  - Hydration: Drinking plenty of fluids helps thin mucus and soothe the throat.
  - Over-the-counter medications: Non-prescription cough suppressants, expectorants, and pain relievers can help manage symptoms.
  - Inhalation therapy: Using a humidifier or steam inhalation can help moisten the airways and ease breathing.
  - Antibiotics: If the cause is bacterial, antibiotics may be prescribed.
  - Avoiding irritants: Minimizing exposure to smoke, pollutants, and other irritants can prevent exacerbation of symptoms.

Most cases of acute tracheobronchitis resolve on their own within a few weeks with rest and symptomatic treatment. However, chronic bronchitis may require on-going management to control symptoms and prevent complications. It's essential to consult a healthcare professional for proper diagnosis and treatment, especially if symptoms are severe or persist for an extended period.

1.1.2. Bronchiectasis:

It is a chronic respiratory condition characterized by abnormal and irreversible widening (dilation) of the bronchial tubes (airways) in the lungs. This widening is often accompanied by inflammation and a build-up of mucus, which can lead to recurrent lung infections and other complications.

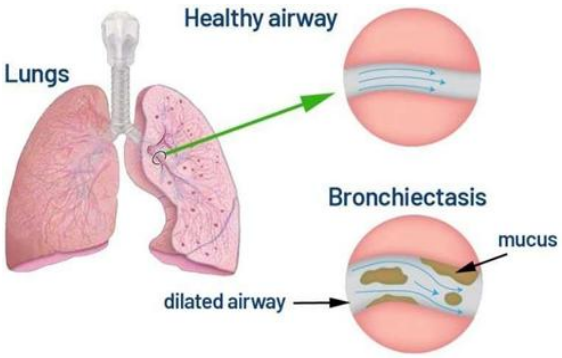


Fig 5:- Bronchiectasis

- Causes:-
  - Infection: Recurrent or severe respiratory infections, particularly in childhood, can cause damage to the airways, leading to bronchiectasis.
  - Cystic Fibrosis: This genetic condition affects the production of mucus, leading to thick and sticky secretions that can obstruct the airways and predispose individuals to bronchiectasis.
  - Immune System Disorders: Conditions that affect the immune system, such as immunodeficiency disorders, can increase the risk of developing bronchiectasis.
  - Inhalation of Foreign Objects: Inhaling objects into the airways can cause irritation and damage, leading to bronchiectasis.
  - Autoimmune Conditions: Some autoimmune diseases, such as rheumatoid arthritis or inflammatory bowel disease, may increase the risk of bronchiectasis.
- Symptoms:-
  - Chronic Cough: Persistent cough that produces large amounts of mucus.
  - Shortness of Breath: Especially during physical activity or when lying flat.
  - Wheezing: High-pitched whistling sound when breathing.
  - Chest Pain: Discomfort or tightness in the chest.
  - Fatigue: Feeling tired or weak.
  - Recurrent Infections: Frequent episodes of respiratory infections, such as bronchitis or pneumonia.
- Diagnosis:-
  - Imaging Tests: Chest X-rays or CT scans can reveal the characteristic signs of bronchiectasis, such as dilated airways and thickened bronchial walls.
  - Pulmonary Function Tests (PFTs): These tests measure lung function and can help assess the severity of bronchiectasis.
  - Sputum Culture: Analyzing a sample of mucus coughed up from the lungs can identify any bacteria or other pathogens causing infections.
  - Bronchoscopy: This procedure involves inserting a thin, flexible tube with a camera into the airways to examine them directly.
- Treatment:
  - Airway Clearance Techniques: Methods such as chest physiotherapy, postural drainage, and breathing exercises can help remove mucus from the airways.
  - Medications: Bronchodilators, antibiotics (for treating infections), and mucus- thinning medications may be prescribed.
  - Pulmonary Rehabilitation: Exercise programs and education to improve lung function and manage symptoms.
  - Surgery: In severe cases, surgery may be necessary to remove damaged portions of the lung or to prevent recurrent infections.
  - Management of Underlying Conditions: Treating any underlying causes or contributing factors, such as cystic fibrosis or immune disorders.

Early diagnosis and management of bronchiectasis are crucial for preventing complications and improving quality of life. Treatment is usually focused on controlling symptoms, preventing infections, and preserving lung function. Regular medical follow-up is important for monitoring the condition and adjusting treatment as needed.

1.1.3. Bronchospasm:-

It is a sudden and temporary contraction of the smooth muscles that surround the bronchial tubes (airways) in the lungs. This contraction narrows the airways, making it difficult for air to flow in and out of the lungs. When bronchospasm occurs in individuals with asthma, it can trigger or exacerbate asthma symptoms. Here's a closer look:

Fig 6:- Bronchospasm.

- Bronchospasm in Asthma:-
  - Triggers: Various triggers can cause bronchospasm in individuals with asthma, including allergens (such as pollen, dust mites, pet dander), respiratory infections, exercise, cold air, air pollutants, strong odors, smoke, and stress.
  - Mechanism: In asthma, the airways are chronically inflamed and sensitive to certain triggers. When exposed to triggers, the airway inflammation worsens, leading to bronchospasm and the characteristic symptoms of asthma.
  - Symptoms: Bronchospasm in asthma can cause a range of symptoms, including:
    - Wheezing: High-pitched whistling sounds during breathing.
    - Coughing: Often worse at night or early in the morning.
    - Shortness of Breath: Difficulty breathing, especially during physical activity or when exposed to triggers.
    - Chest Tightness or Pain: Feeling of pressure or discomfort in the chest.
    - Difficulty Speaking: Due to shortness of breath.

- Management of Bronchospasm in Asthma:-
  - Quick-Relief Medications: Short-acting bronchodilators, such as albuterol, are commonly used to rapidly relieve bronchospasm and alleviate asthma symptoms. These medications work by relaxing the smooth muscles of the airways, thereby opening them up and improving airflow.
  - Controller Medications: In addition to quick-relief medications, individuals with asthma may also use long-term control medications, such as inhaled corticosteroids, leukotriene modifiers, long-acting bronchodilators, or biologic therapies, to reduce airway inflammation and prevent bronchospasm.
  - Avoiding Triggers: Identifying and avoiding triggers that can induce bronchospasm is essential for managing asthma. This may involve measures such as allergen avoidance, using air purifiers, maintaining good indoor air quality, and avoiding exposure to smoke or other respiratory irritants.
  - Monitoring and Action Plans: Regular monitoring of asthma symptoms and lung function, along with the development of an asthma action plan in collaboration with healthcare providers, can help individuals recognize and manage bronchospasm and other asthma symptoms effectively.
  - Lifestyle Modifications: Adopting a healthy lifestyle, including regular exercise, maintaining a healthy weight, avoiding smoking, and managing stress, can also help improve asthma control and reduce the frequency and severity of bronchospasm episodes.
  - Emergency Care: In severe cases of bronchospasm or asthma exacerbations, emergency medical care may be necessary. This may involve the use of supplemental oxygen, oral or intravenous corticosteroids, and other supportive measures to stabilize breathing and oxygen levels.

Managing bronchospasm in asthma requires a comprehensive approach that includes medication management, trigger avoidance, monitoring, and education. Working closely with healthcare providers to develop a personalized asthma management plan is key to achieving optimal control of the condition and minimizing the impact of bronchospasm on daily life.

1.1.4. Bronchitis:

It is a common respiratory condition characterized by inflammation of the bronchial tubes, which are the airways that carry air to and from the lungs. It can be acute or chronic and is often caused by viral or bacterial infections, although it can also result from exposure to irritants such as cigarette smoke or air pollution.

- Types of Bronchitis:-
  - Acute Bronchitis: Typically caused by viral infections, such as the common cold or flu viruses. It is usually self-limiting and resolves within a few weeks with rest and symptomatic treatment. Acute bronchitis may also be caused by bacteria, but this is less common.
  - Chronic Bronchitis: A type of chronic obstructive pulmonary disease (COPD) characterized by persistent inflammation and irritation of the bronchial tubes. Chronic bronchitis is defined as a cough with sputum production that lasts for at least three months in two consecutive years. Smoking is the most common cause of chronic bronchitis, although long-term exposure to other respiratory irritants can also contribute.

- Symptoms of Bronchitis:-
  - Cough: Often starts as a dry cough and may progress to producing phlegm (sputum).
  - Sore Throat: Irritation and discomfort in the throat.
  - Chest Discomfort: Feeling of tightness or pressure in the chest.
  - Shortness of Breath: Difficulty breathing, especially during physical activity.
  - Fatigue: Feeling tired or run-down.
  - Mild Fever: Some individuals may experience a low-grade fever.

- Causes of Bronchitis:-
  - Viral Infections: Common cold viruses, influenza viruses, and respiratory syncytial virus (RSV) are frequent culprits.
  - Bacterial Infections: Bacteria such as Streptococcus pneumonia or Haemophilus influenzae may cause bacterial bronchitis, particularly in individuals with weakened immune systems.
  - Irritants: Tobacco smoke, air pollution, dust, and chemical fumes can irritate the airways, leading to inflammation.
- Treatment of Bronchitis:-
  - Rest: Adequate rest helps the body fight off the infection and promotes healing.
  - Hydration: Drinking plenty of fluids helps thin mucus and soothe the throat.
  - Over-the-counter Medications: Non-prescription cough suppressants, expectorants, and pain relievers can help manage symptoms.
  - Inhalation Therapy: Using a humidifier or steam inhalation can help moisten the airways and ease breathing.
  - Antibiotics: If the cause is bacterial, antibiotics may be prescribed. However, antibiotics are not effective against viral infections.
  - Avoiding Irritants: Minimizing exposure to smoke, pollutants, and other irritants can prevent exacerbation of symptoms.

Most cases of acute bronchitis resolve on their own within a few weeks with rest and symptomatic treatment. However, chronic bronchitis may require ongoing management to control symptoms and prevent complications. It's essential to consult a healthcare professional for proper diagnosis and treatment, especially if symptoms are severe or persist for an extended period.

1.1.5. Pneumoconiosis:-

It is a group of lung diseases caused by the inhalation of various types of mineral dust over an extended period. These conditions result in lung tissue damage and scarring, impairing lung function over time. Here's a closer look:

- Types: There are several types of pneumoconiosis, each caused by exposure to different types of dust:
  - Coal worker's pneumoconiosis (CWP): Caused by inhaling coal dust, primarily affecting coal miners.
  - Silicosis: Caused by inhaling silica dust, commonly found in industries like mining, quarrying, and construction.
  - Asbestosis: Caused by inhaling asbestos fibers, often occurring in industries like construction, shipbuilding, and manufacturing.
  - Berylliosis: Caused by exposure to beryllium dust, typically in industries like aerospace, electronics, and metalworking.
  - Byssinosis: Caused by inhaling cotton, flax, or hemp dust, commonly seen in textile workers.

- Symptoms:- The symptoms of pneumoconiosis can vary depending on the type and severity of the condition. Common symptoms include:
  - Chronic cough
  - Shortness of breath, especially with exertion
  - Chest tightness or pain
  - Fatigue
  - Respiratory infections

- Diagnosis:- Diagnosis typically involves a combination of medical history, physical examination, imaging studies (such as chest X-rays or CT scans), pulmonary function tests, and sometimes lung biopsy to confirm the presence of lung tissue scarring.

- Treatment:- There is no cure for pneumoconiosis, as the lung damage caused by these conditions is irreversible. Treatment primarily focuses on managing symptoms and preventing further lung damage. This may include:
  - Avoiding further exposure to the causative dust
  - Medications to relieve symptoms such as cough and shortness of breath
  - Oxygen therapy in advanced cases to improve breathing
  - Pulmonary rehabilitation to help improve lung function and quality of life
  - In severe cases, lung transplantation may be considered.

- Prevention:- Preventing pneumoconiosis involves minimizing exposure to the causative dust through workplace safety measures such as proper ventilation, dust control, and the use of personal protective equipment (such as masks or respirators). Regular health monitoring and screening for early detection are also essential for individuals at risk of exposure.

Overall, pneumoconiosis is a serious occupational lung disease that requires diligent prevention efforts and comprehensive management to minimize its impact on respiratory health.

1.1.6. Emphysema:-

It is a chronic lung condition characterized by the gradual destruction of the air sacs (alveoli) in the lungs, leading to difficulty in breathing. It is a type of chronic obstructive pulmonary disease (COPD), often occurring alongside chronic bronchitis.

Fig 7:- Emphysema

Here are some key points about emphysema:-

- Causes:- Smoking is the primary cause of emphysema. Long-term exposure to cigarette smoke leads to inflammation and damage to the delicate walls of the alveoli, impairing their ability to expand and contract properly. Other factors such as exposure to air pollution, secondhand smoke, or occupational dust and chemicals can also contribute to the development of emphysema.
- Pathophysiology:- In emphysema, the destruction of the alveoli reduces the surface area available for gas exchange in the lungs. This results in impaired oxygen uptake and carbon dioxide removal, leading to symptoms such as shortness of breath, coughing, and wheezing.
- Symptoms:- Common symptoms of emphysema include:
  - Shortness of breath, especially during physical exertion
  - Chronic cough
  - Wheezing
  - Chest tightness or discomfort
  - Fatigue
  - Weight loss (in advanced stages)
- Diagnosis:- Diagnosis of emphysema involves a combination of medical history, physical examination, pulmonary function tests (such as spirometry), chest X-rays or CT scans, and sometimes blood tests to assess oxygen levels. These tests help evaluate lung function and severity of the disease.
- Treatment:- While there is no cure for emphysema, treatment aims to relieve symptoms,

slow disease progression, and improve quality of life. Treatment options include:

- Smoking cessation: The most important step in managing emphysema is to quit smoking to prevent further lung damage.
- Medications: Bronchodilators and inhaled corticosteroids can help open airways and reduce inflammation.
- Pulmonary rehabilitation: Exercise training, breathing exercises, and education programs can help improve lung function and overall well-being.
- Oxygen therapy: Supplemental oxygen may be prescribed to improve oxygen levels in the blood.
- Surgical options: In severe cases, surgical interventions such as lung volume reduction surgery or lung transplantation may be considered.

- Prevention:- The best way to prevent emphysema is to avoid smoking and exposure to lung irritants. For individuals with occupational exposure, proper workplace safety measures should be followed to minimize risk.

Early detection and management of emphysema are crucial for slowing disease progression and improving outcomes. Regular medical follow-ups and adherence to treatment plans can help individuals with emphysema lead fulfilling lives despite their condition.

1.1.7. Asthma:

It is a chronic respiratory condition characterized by inflammation and narrowing of the airways, leading to difficulty breathing, wheezing, coughing, and chest tightness. It is one of the most common chronic diseases worldwide, affecting people of all ages, but often begins in childhood.

Here are some key points about asthma:

- Causes:- The exact cause of asthma is not fully understood, but it is believed to involve a combination of genetic and environmental factors. Triggers such as allergens (e.g., pollen, pet dander, dust mites), respiratory infections, irritants (e.g., tobacco smoke, air pollution), exercise, cold air, and certain medications can provoke asthma symptoms in susceptible individuals.
- Pathophysiology:- Asthma is characterized by inflammation of the airways, which leads to swelling and increased mucus production. Additionally, the muscles surrounding the airways may tighten (bronchoconstriction), further narrowing the air passages. These changes result in airflow limitation, making it difficult for air to move in and out of the lungs.
- Symptoms:- Symptoms of asthma can vary in severity and frequency and may include:
  - Wheezing (a whistling sound when breathing)
  - Shortness of breath
  - Coughing, especially at night or early in the morning
  - Chest tightness or discomfort
- Diagnosis:- Diagnosis of asthma involves a combination of medical history, physical examination, lung function tests (such as spirometry), and sometimes additional tests such as peak flow measurement or allergy testing. The diagnosis is often confirmed if a person experiences recurrent episodes of symptoms and demonstrates reversible airflow obstruction on lung function tests.
- Treatment:- Asthma management aims to control symptoms, prevent exacerbations, and minimize lung function decline. Treatment options include:
  - Controller medications: These medications, such as inhaled corticosteroids, long-acting beta-agonists, leukotriene modifiers, and immunomodulators, are taken regularly to reduce airway inflammation and prevent symptoms.
  - Reliever medications: Short-acting beta-agonists (e.g., albuterol) are used as rescue medication to quickly relieve symptoms during asthma attacks or exacerbations.
  - Allergy management: Avoiding triggers and using allergy medications or immunotherapy may help reduce asthma symptoms triggered by allergens.
  - Lifestyle modifications: Maintaining a healthy lifestyle, avoiding tobacco smoke, exercising regularly, and managing stress can help improve asthma control.
- Action Plan:- Many people with asthma benefit from having an asthma action plan, which

outlines steps to take based on asthma symptoms and peak flow measurements to manage exacerbations effectively.

Asthma is a chronic condition that requires on going management and monitoring. With proper treatment and self-management strategies, most people with asthma can lead active lives with minimal symptoms. Regular follow-up with healthcare providers is essential to adjust treatment as needed and monitor lung function.

II. LITERATURE REVIEW

1. Moritz Rosch (2021):-Hydrogen, as a medical gas, is a promising emerging treatment for many diseases related to inflammation and oxidative stress. Molecular hydrogen can be generated through hydrogen ion reduction by a metal, and magnesium-containing effervescent tablets constitute an attractive formulation strategy for oral delivery. In this regard, selected for the optimized tablet, due to regulatory considerations. {5}
2. Jan Lenz (2021):-The functional behaviour of tablets is strongly influenced by their manufacturing process and the choice of excipients. Water uptake and swelling are prerequisites for tablet disintegration, dispersion and hence active pharmaceutical ingredient (API) dissolution. The application of lubricants slows down the analysed processes. Water uptake and swelling data are fitted to an empirical model obtaining four characteristic parameters to facilitate the simple quantitative assessment of varying tablet formulations and structural properties. {6}
3. Nabin Poudel (2014):-Effectiveness of medication administered through oral route is determined by several factors that affect the overall bioavailability of the drug. The efficacy of oral drug is further reduced in patients suffering with gastrointestinal diseases. A series of physiochemical parameters together with force of mucoadhesion and in vitro dissolution profile were studied. The highest force of mucoadhesion was found in formulation with 40% CBP while drug was almost completely released after 8 hr of dissolution study in formulation with 10% and 20% of CBP. {7}
4. Neeta Kushwaha (2022):-Nothing in this world is stable and ever accepted. Change is the requirement of nature for the sake of adaptability. However, the pharmaceutical world is also not far off from this change. Technical advancement in pharma world also leads to the development of new dosages forms. This leads to the replacement of the older dosages forms with the newer once. But for the tablet dosages forms this replacement is substituted with modifications. we discussed about the manufacturing techniques and evaluation tests for tablets.{9}
5. Devendra Sharma (2017):-Tablet is a unit solid dosage form containing active ingredient with or without suitable excipient. These are most widely used dosage form.[1] The main objective of the design and manufacture of the compressed tablet is to deliver orally correct amount of drug in the proper form over proper time and at desired location, so as to have suitable chemical integrity protected at the point of its action. The main focus on moisture activated dry granulation method is better than other granulation method in case of poorly soluble drug tablets. {10}
6. Abishek J.(2023):-Tablets are the most commonly prescribed dosage form as offer a convenient form of drug administration provides dosage uniformity from tablet to tablet. Among the various step involved in tablet manufacturing granulation is one of the most important until operation in the production of pharmaceutical tablet dosage form. The present work aims to comprehensively review the advantages disadvantages, formulative ingredients preparation methods, applications and evaluation of tablets. {11}
7. Shanu B. Sahu (2024):-Solid dosage forms, such as tablets, are widespread in practice. This is due to the ease of administration and capability of mass production by the pharmaceutical industry. Tablets are the most popular dosage form, accounting for some 70% of all ethical pharmaceutical preparations produced. Tablets may be defined as solid pharmaceutical dosage forms containing drug substances with or without suitable excipients and prepared by either compression or moulding methods. The excipients include diluents, binders and adhesives, disintegrants etc.{13}
8. Dijana Jelić (2021):- Ambroxol hydrochloride

(AMB), used as a broncho secretolytic and an expectorant drug, is a semi-synthetic derivative of vasicine obtained from the Indian shrub Adhatoda vasica. It is a metabolic product of bromhexine. At the same time, lactose monohydrate contributes to faster degradation of AMB and change in decomposition mechanism. It was found that the n^{th} order kinetic model mechanistically best describes the decomposition process of pure AMB and in Flavamed® tablets. {16}

9. Celine Ollier (2020):- Ambroxol is used in the treatment of acute and chronic respiratory conditions characterized by abnormal mucus secretion and impaired mucus transport and is available in a variety of formulations. This study aimed to compare the steady-state (SS) pharmacokinetic characteristics of extended-release (ER) 75-mg retard capsules with two immediate release (IR) formulations (60-mg effervescent tablets and 30-mg tablets) over a 24-h period. {17}
10. Ahmad Kantar (2020):- Ambroxol (2-amino-3,5-dibromo-N-[trans-4- hydroxycyclohexyl] benzylamine), an over-the-counter product, is a mucoactive agent and has been used widely to treat both acute and chronic respiratory diseases since 1978. Furthermore, efficacy findings were consistent irrespective of age, including for patients as young as 1 month old. Additionally, the majority of studies found ambroxol to be well tolerated in children. {19}
11. Ved Parkash (2011):- Fast disintegrating tablets (FDTs) have received ever- increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. Oral drug delivery remains the preferred route for administration of various drugs. Recent developments in the technology have prompted scientists to develop FDTs with improved patient compliance and convenience. Upon introduction into the mouth, these tablets dissolve or disintegrate in the mouth in the absence of additional water for easy administration of active pharmaceutical ingredients. The popularity and usefulness of the formulation resulted in development of several FDT technologies. FDTs are solid unit dosage forms, which disintegrate or dissolve rapidly in the mouth without chewing and water. {28}
12. Dragana Gaji´c (2021):- Ambroxol hydrochloride (AMB), used as a broncho secretolytic and an expectorant drug, is a semi-synthetic derivative of vasicine obtained from the Indian shrub Adhatoda vasica. It is a metabolic product of bromhexine. At the same time, lactose monohydrate contributes to faster degradation of AMB and change in decomposition mechanism. It was found that the n^{th} order kinetic model mechanistically best describes the decomposition process of pure AMB and in Flavamed® tablets. {18}

III. NEED OF WORK

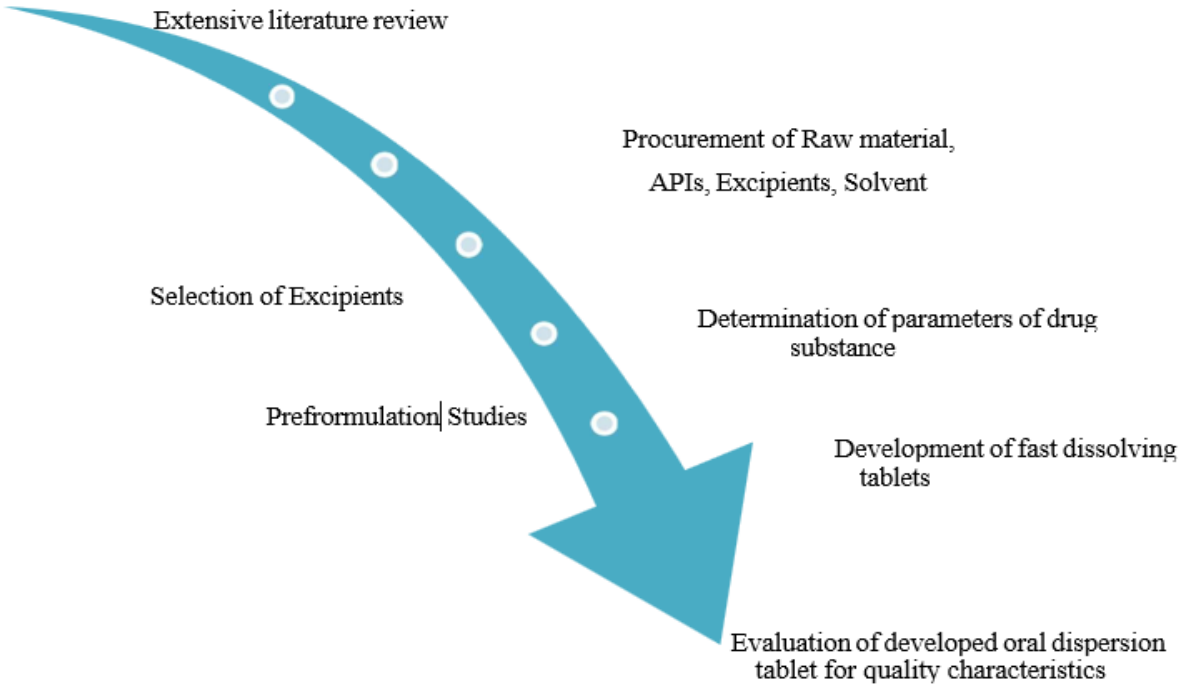
Ambroxol is a drug primarily used for its mucolytic properties, which means it helps to break down and clear mucus from the respiratory tract. Here are its key importance and benefits:

- Mucolytic Action:- Ambroxol helps to thin and liquefy thick and sticky mucus in the airways, making it easier to cough up and clear from the lungs. This action is particularly beneficial in conditions where there is excessive mucus production, such as respiratory tract infections (e.g., bronchitis, pneumonia) and chronic obstructive pulmonary disease (COPD).
- Expectorant Effect:- By facilitating the removal of mucus, ambroxol aids in relieving congestion and cough associated with respiratory illnesses. This can help improve breathing and reduce discomfort.
- Anti-inflammatory Properties:- Ambroxol also exhibits mild anti-inflammatory effects, which can contribute to reducing inflammation in the respiratory tract and easing symptoms like coughing and throat irritation.
- Protection and Repair of Lung Tissue:- It has been suggested that ambroxol may stimulate the production of pulmonary surfactant, a substance that coats the inside of the lungs and helps prevent collapse of the air sacs (alveoli). This can potentially protect and promote healing of lung tissue damaged by infections or other respiratory conditions.
- Additional Uses:- Ambroxol has been explored for its potential benefits in other conditions such as acute respiratory distress syndrome (ARDS), asthma, and even neurodegenerative diseases due

to its antioxidant properties, although more research is needed in these areas.

Overall, ambroxol plays a crucial role in respiratory care by alleviating symptoms related to excessive mucus production and supporting the natural mechanisms of lung clearance and healing. It is widely used and generally well-tolerated when used according to medical guidelines.

IV. PLAN OF WORK



V. DRUG PROFILE

Ambroxol Hydrochloride:-

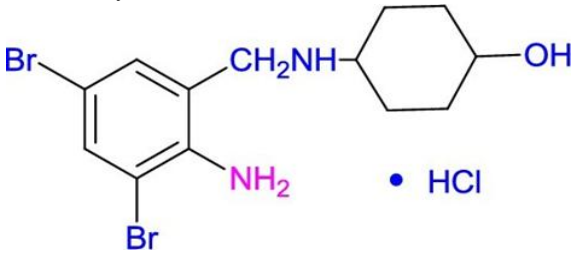
Ambroxol hydrochloride is a medication primarily used to treat respiratory conditions characterized by excessive mucus production, such as acute and chronic bronchitis, asthma, and chronic obstructive pulmonary disease (COPD). It belongs to the class of drugs known as mucolytics, which work by thinning and loosening mucus in the airways, making it easier to cough up and clear from the respiratory tract.

Here's a detailed overview of ambroxol hydrochloride:-

V.1. Mechanism of Action:- Ambroxol hydrochloride exerts its therapeutic effects by:

- Stimulating the production and secretion of pulmonary surfactant, a substance that helps maintain the elasticity of lung tissue and reduces surface tension in the airways.
- Enhancing the activity of ciliary epithelial cells in the respiratory tract, which helps to facilitate the movement of mucus and foreign particles out of the airways.
- Modulating the rheological properties of mucus, making it less viscous and easier to expel from the lungs.

V.2. The chemical structure of Ambroxol Hydrochloride is as follows:-



The molecular formula for Ambroxol Hydrochloride is C13H18Br2N2O2·HCl. Ambroxol hydrochloride is a bromhexine metabolite and is commonly used as a mucolytic agent to treat respiratory conditions characterized by excessive mucus production. It helps to thin and loosen mucus in the airways, making it easier to cough up and clear from the respiratory tract.

V.3. Pharmacodynamics effects of drug:- Ambroxol hydrochloride is primarily used as an expectorant to treat respiratory conditions such as bronchitis, asthma, and other conditions where there is an excessive buildup of mucus in the airways. Its pharmacodynamics effects include:

- Expectorant Action:- Ambroxol facilitates the clearance of mucus from the respiratory tract by reducing its viscosity. It does this by altering the structure of mucus molecules, making them less sticky and easier to cough up.
- Mucociliary Clearance:- It enhances the function of cilia in the respiratory epithelium, which helps in moving mucus out of the lungs and airways more effectively.
- Anti-inflammatory Properties:- Ambroxol has shown some anti-inflammatory effects in preclinical studies, which can help reduce inflammation in the respiratory tract.
- Antioxidant Activity:- It has been suggested that ambroxol may have antioxidant properties, which could protect lung tissues from oxidative stress and damage.
- Local Anesthetic Effects:- In addition to its mucolytic properties, ambroxol has weak local anesthetic effects which may contribute to its ability to alleviate throat irritation and cough.

Overall, ambroxol hydrochloride is valued for its ability to improve the clearance of respiratory secretions, reduce cough severity, and facilitate easier breathing in conditions characterized by excessive mucus production. These pharmacodynamics effects make it a commonly used medication in the management of respiratory disorders.

V.4. Pharmacokinetics effects of drug:- Pharmacokinetics refers to how a drug is absorbed, distributed, metabolized, and excreted in the body. Here are the pharmacokinetic effects of Ambroxol Hydrochloride:

- Absorption:- Ambroxol is well absorbed from the gastrointestinal tract after oral administration. Peak plasma concentrations typically occur within 1-3 hours after ingestion.
- Distribution:- Ambroxol has a moderate volume of distribution, indicating that it distributes fairly widely throughout the body's tissues. It crosses the blood-brain barrier to a limited extent.
- Metabolism:- Ambroxol undergoes extensive first-pass metabolism in the liver. The primary metabolic pathway involves conjugation with glucuronic acid to form inactive metabolites, which are then excreted in the urine.
- Excretion:- The elimination half-life of ambroxol is relatively short, typically around 7-12 hours in healthy individuals. It is primarily excreted via the kidneys, with approximately 90% of the administered dose eliminated in the urine within 24 hours.
- Special Populations:- In patients with impaired renal function, the elimination half- life of ambroxol may be prolonged, necessitating dosage adjustment to prevent drug accumulation.
- Drug Interactions:- Ambroxol is not known to have significant interactions with other drugs that affect its pharmacokinetics. However, caution should be exercised when co- administering with other medications that are extensively metabolized by the liver or excreted renally.

Overall, understanding the pharmacokinetic profile of Ambroxol Hydrochloride is crucial for determining appropriate dosing regimens and ensuring effective therapeutic outcomes in patients with respiratory conditions.

V.5. Uses:- Ambroxol hydrochloride is used primarily as a mucolytic agent to treat respiratory conditions associated with excessive mucus production. Here are some common uses of ambroxol hydrochloride:

- Acute and Chronic Bronchitis:- Ambroxol hydrochloride is frequently prescribed for the treatment of acute and chronic bronchitis, which are characterized by inflammation of the bronchial tubes and excessive mucus production. By

thinning and loosening mucus in the airways, ambroxol helps to alleviate coughing and facilitate the clearance of mucus from the respiratory tract.

- Chronic Obstructive Pulmonary Disease (COPD):- Ambroxol hydrochloride may be used as an adjunctive therapy for patients with COPD, including chronic bronchitis and emphysema. It helps to reduce the viscosity of mucus, making it easier to expectorate and improving airflow in the lungs.
- Asthma:- While ambroxol hydrochloride is not typically used as a primary treatment for asthma, it may be used as an adjunctive therapy in some cases to help alleviate symptoms such as coughing and mucus production.
- Respiratory Tract Infections:- Ambroxol hydrochloride may be used to alleviate symptoms associated with respiratory tract infections, such as the common cold or influenza. It helps to loosen and expel mucus from the respiratory tract, making breathing easier and relieving coughing.
- Preoperative Respiratory Care:- Ambroxol hydrochloride may be administered before certain surgical procedures to help reduce the risk of postoperative respiratory complications, such as atelectasis (partial collapse of the lung) or pneumonia. By promoting the clearance of mucus from the airways, ambroxol can help to maintain optimal lung function following surgery.
- Cystic Fibrosis:- Ambroxol hydrochloride may be used as part of the treatment regimen for patients with cystic fibrosis, a genetic disorder characterized by thick, sticky mucus that clogs the airways and leads to respiratory infections and other complications.

V.6. Indications:- Ambroxol hydrochloride is indicated for the treatment of various respiratory conditions associated with excessive mucus production, including:

- Acute and chronic bronchitis: Inflammation of the bronchial tubes characterized by coughing, mucus production, and difficulty breathing.
- Chronic obstructive pulmonary disease (COPD): A group of lung diseases, including chronic bronchitis and emphysema, characterized by airflow limitation and respiratory symptoms.
- Asthma: A chronic respiratory condition characterized by inflammation and constriction of the airways, leading to wheezing, coughing, and shortness of breath.
- Other respiratory tract infections: Ambroxol hydrochloride may also be used to alleviate symptoms associated with respiratory infections, such as the common cold or influenza.

V.7. Dosage Forms:- Ambroxol hydrochloride is available in various dosage forms for oral and inhalation administration, including:

- Oral tablets and capsules: These are taken by mouth and are available in different strengths.
- Syrups: Liquid formulations suitable for patients who have difficulty swallowing tablets or capsules.
- Solutions for inhalation: Ambroxol can be administered via inhalation using a nebulizer device, delivering the medication directly to the lungs.

V.8. Dosage and Administration:- The dosage and frequency of administration of ambroxol hydrochloride depend on the patient's age, the severity of the condition, and other factors. It is essential to follow the dosage instructions provided by a healthcare professional or as indicated on the medication label.

V.9. Side Effects:- Common side effects of ambroxol hydrochloride may include:

- Gastrointestinal disturbances such as nausea, vomiting, diarrhea, and abdominal pain.
- Allergic reactions such as rash, itching, or hives.

Serious side effects are rare but may include severe allergic reactions or bronchospasm (difficulty breathing). If you experience any severe or persistent side effects, it is essential to seek medical attention promptly.

V.10. Precautions and Contraindications:- Ambroxol hydrochloride should be used with caution in patients with a history of gastric ulcers or gastrointestinal bleeding. It is not recommended for use in pregnant or breastfeeding women unless the potential benefits outweigh the risks. Patients with a known allergy to ambroxol or other similar

medications should avoid its use.

V.11. Interactions:- Ambroxol hydrochloride may interact with certain medications, such as antibiotics (e.g., erythromycin, amoxicillin), antitussive agents (e.g., dextromethorphan), and medications that affect liver enzymes. It is essential to inform your healthcare provider about all medications you are taking before starting ambroxol therapy.

In summary, ambroxol hydrochloride is a mucolytic medication used to treat respiratory conditions associated with excessive mucus production. It works by thinning and loosening mucus in the airways, making it easier to clear from the respiratory tract. It is essential to use this medication as directed by a healthcare professional and to report any adverse effects promptly.

VI. EXPERIMENTAL WORK

VI.1. Methods:-

Optimization of Concentration and Excipient Selection The disintegration time is the most crucial characteristic that must be optimized in the creation of rapid dissolving tablets. Prior to determining the optimal combination for the formulation of fast dissolving tablets, a variety of excipients, including binders and super disintegrants, were used to manufacture the tablets. These excipients were then analyzed for numerous criteria, such as friability, hardness, and disintegration time. For more research, the combination that had the shortest disintegration time and the best hardness and friability was chosen.

Enhancement of Sodium Starch Glycolate Super disintegrant (Primogel, Explotab) The presence of the appropriate super disintegrant in its optimal concentration is a necessity for good bioavailability in tablets and capsules that need to dissolve quickly. Super disintegrants speed up the pace at which drugs dissolve by reducing the disintegration time. For this reason, selecting the right super disintegrant and ensuring its consistent performance are crucial for creating dosage forms that dissolve quickly.

Formulation F1-F6 was prepared to study the effect of type and concentration of super disintegrant given in (Table 1). The direct compression method was used to make the tablets. In a dry, clean mortar, weighed amounts of ambroxol hydrochloride with varying super disintegrant concentrations and excipients were combined in a geometric sequence. The mixture was then put through sieve number 60 in order to compress it directly. After that, the powder mixture was crushed into tablets using a multi-punch tablet compression machine (Dhiman Industries, India) using an 8mm punch.

Table 1: Formula for 1 tablet (30 mg) of Different Concentration of SSG

Ingredients	F1	F2	F3	F4
Ambroxol Hydrochloride	30	30	30	30
SSG	4	8	12	16
PVP	5	5	5	5
Sodium Stearyl Fumarate	3	3	3	3
Talc	3	3	3	3
Sodium Saccharin	5	5	5	5

By using a direct compression process, optimized concentrations of superdisintegrant tablets and Polyvinylpyrrolidone (PVP) or Microcrystalline Cellulose as binder were created. In a dry, clean mortar, a weighed amount of ambroxol hydrochloride was combined with an optimum concentration of sodium starch glycolate, varying concentrations of binders like polyvinylpyrrolidone (PVP) or microcrystalline cellulose, and excipients in a g metric progression. After that, the mixture was sent through sieve number 60 to compress it directly.

After that, the powder mixture was crushed into tablets using a multi-punch tablet compression machine (Dhiman Industries, India) using an 8mm punch. Ambroxol Hydrochloride Fast Disintegrating Tablets: Complete Formulation Using the Direct Compression Method Ambroxol hydrochloride fast-disintegrating tablets are made using the direct compression method. In a dry, clean mortar, weighed amounts of ambroxol hydrochloride,

optimal concentrations of superdisintegrant and binder, and excipients were combined in a geometric succession.

VI.2. Evaluation Parameters:

VI.2.1. Weight Variation:- Twenty tablets were selected, weighed on Digital Weighting Balance (Ohaus, USA) and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight.

VI.2.2. Thickness:- Vernier Cali was used to measure the thickness of the tablets (Indiancaliper industries, Ambala, India). For every batch, three tab lets were utilized, and the average value was determined.

VI.2.3. Hardness:- A Monsanto Hardness Tester (Perfit) was used to determine the tablets' crushing strength. Each formulation batch's three tab lets were randomly tested, and the average reading was recorded. In kg/cm2, the hardness is expressed.

VI.2.4. Friability:- A Roche Friabilator (Veego, India) was filled with ten weighted pills and turned at 25 rpm for four minutes. The pills were removed, cleaned, and weighed again. The following formula was used to calculate the tablets' % friability.

VI.2.5. In-vitro Disintegration:- Examine Using a Digital Tablet Disintegration Tester (Veego, India), six tablets were tested. As a disintegration medium, distilled water at 37 oC ± 2 oC was utilized. The amount of time in seconds required for the tablet to completely dissolve and leave no discernible mass inside the device was calculated.

VI.2.6. Wetting Time:- Six milliliters of distilled water were taken out of a Petridis. On top of this was a tablet with a tiny amount of amaranth colour on it. It was noticed how long it took for the tablet's top surface to turn completely crimson.

VI.2.7. Drug Content Uniformity:- The mix, which equated to 7.5 mg of ambroxol hydro chloride, was weighed and dissolved in 100 ml of 6.8 pH phosphate buffer solutions after ten tablets (200 mg) were ground up in a mortar and pestle. After sonicating the mixture, whatman filter paper was used to filter it, 6.8 pH phosphate buffer was used to dilute it appropriately, and a Double Beam UV Spectrophotometer (UV-1800 Shimadzu) was used to measure the drug concentration at 244 nm. Every sample was examined three times.

VI.2.8. In-vitro Dissolution Study:- Using the paddle technique (USP eight stage dissolving testing apparatus-2), the release from compounded FDTs was ascertained (Lab, India). 500 milliliters of pH 6.8 phosphate buffer solution were used for the dissolving test, which was conducted at 37 ± 0.5°C and 50 rpm. At predetermined intervals, a five milliliter sample of the solution was removed from the dissolving device and replaced with new dissolving media. Whatman filter paper was used to filter the samples. These solutions' absorbance was measured at 244 nm using a UV-1800 Shimadzu Double Beam UV Spectrophotometer. Drug release cumulative percentage (%) was computed using a conventional Ambroxol Hydrochloride plot.

VI.2.9. Drug-Excipient Compatibility Studies:- The purpose of these investigations was to validate the drug-excipient interaction. FTIR spectroscopy is usually used in these investigations. Using an FTIR Spectrophotometer (Bruker, USA), the FTIR spectra of both pure drug and drug-containing compounded FDT were recorded. The resolution was 1 cm-1 and the scanning range was 4000 to 600 cm-1. The main drug peaks, drug peaks that were moving or masking, and novel peaks that appeared as a result of excipient interaction were all assessed in the scans. The spectral analysis was utilized to verify if the medications and excipients were compatible.

VI.2.10. Accelerated Stability Studies:- Accelerated stability investigations are carried out at room temperature, ambient humidity, and an oven temperature of 40 ± 2o C. The most crucial factors for quickly dissolving tablets are hardness, friability, homogeneity of drug content, and in-vitro disintegration time, which were measured after the pills were taken out on days 15 and 30.

VII. RESULTS AND DISCUSSION

The goal of the current study was to create and assess Ambroxol Hydrochloride fast- disintegrating tablets utilizing a direct compression approach. To improve palatability, sodium saccharin was added, and sodium starch glycolate was utilized as a superdisintegrant and directly compressible diluent. The formulation contained Avicel PH 102 as a binder and disintegrant. Due to its granular form, this grade of microcrystalline cellulose has outstanding flow properties. Sodium saccharin, which is 400 times sweeter than sucrose, was used as a sweetening ingredient to provide a pleasing flavor and enhance mouth feel. Magnesium stearate has a metallic taste, thus sodium stearyl fumarate was used as a lubricant instead of it because of its water solubility and immediately compressible properties.

Evaluation Parameters for Ambroxol Hydrochloride Fast Disintegrating Tablet:-

After passing every official test, the final Ambroxol Hydrochloride Fast Disintegrating Tablet formulation was determined to be within the specified bounds. The percentage weight fluctuation was well within the Indian Pharmacopoeia's allowed bounds for uncoated tablets. Scientists who study formulation are well aware that tablets with higher hardness levels have longer breakdown times. The hardness of the tablets was measured as mechanical integrity is crucial to the proper formulation of FDTs.

Ambroxol Hydrochloride FDT's friability of less than 1% suggested that the tablets' composition provided acceptable mechanical strength. The produced Ambroxol Hydrochloride FDT's content homogeneity complies with IP specifications. Out of 10 pills, none fall outside of the 85–115% range specified on the label. These findings showed that the active component was distributed uniformly and at the right amount in the dosage form. Practically speaking, the disintegration and wetting times were ideal for formulation. The Fast Disintegrating Tablets are supposed to dissolve in three minutes, according to EP, yet the formulation of the FDTs showed low DT, suggesting that the formulation was appropriate for an oral disintegrating tablet.

Accelerated Stability Studies:- Stability tests on formulated Ambroxol Hydrochloride FDTs (formulated in three primary batches) were conducted in this study. The formulation was wrapped in aluminum foil to shield it from light, simulating the aluminum packaging, or Alu Alu packing, of drug products. The formulation was then stored in airtight containers that

are impermeable to solids, liquids, and gases under the conditions listed below for a month, as required by ICH guidelines for accelerated study. The product is subjected to standard humidity and temperature conditions during the stability studies. It would be more convenient to do accelerated stability experiments, in which the product is stored under severe humidity and temperature conditions, as the studies will take longer.

The stability study's findings showed that, before and after the storage period at room temperature and ambient humidity, there were not many differences in hardness, dis integration time, drug content uniformity, or friability. However, at 40°C ± 2°C and at ambient humidity, hardness increased over time and prolonged the tablet's dryness time (DT), most likely due to moisture loss from the tablets. In all cases, however, DT was within the designated EP limit (within 3 minutes). This suggests that the formulation is reasonably stable under both kinds of storage.

VIII. CONCLUSION

It was determined that a fast-disintegrating tablet of ambroxol hydrochloride for pediatric use in respiratory disorders could be successfully formulated with the desired characteristics, including rapid disintegration, rapid onset of action, and improved patient convenience and compliance. This was achieved by using readily available pharmaceutical excipients, such as superdisintegrants, hydrophilic and swellable excipients, and appropriate filler.

A fast-disintegrating tablet is a potentially useful strategy for achieving a quicker onset of pharmacological action and would be superior to the liquid dosage forms that are already on the market. The mechanical strength and disintegration time of the FDT dos age form were well-balanced. The main goal of the research was to create a fast-disintegrating tablet of ambroxol hydrochloride utilizing standard technologies and readily accessible excipients. The aforementioned study concluded that a fast-disintegrating tablet of ambroxol hydrochloride for

pediatric use in respiratory disorders was successfully formulated with the desired characteristics, which included rapid disintegration, rapid onset of action, and improved patient convenience and compliance. These excipients included superdisintegrants, hydrophilic and swellable excipients, and appropriate filler.

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