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FORMULATION AND EVALUATION OF FAST DISSOLVING TABLETS OF THEOPHYLLINE

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Abstract:
Fast dissolving tablets are modern approach that focuses on helping the tablets disintegrate faster in mouth without water. Asthma and COPD are major illness that millions of people are facing these days, hence to overcome this problem Theophylline is used as second line bronchodilator. Our study aims on formulating and evaluating fast dissolving tablets of theophylline using natural polymers as superdisintegrants. Natural polymers like plantago ovata and fenugreek mucilage are used to reduce the risk caused by the synthetic ones. They are non-toxic and biodegradable which are nature friendly. These polymers exhibit rapid swelling and water absorption that leads to fast disintegration and quicker drug release. Our project mainly focuses on using advanced approaches for dosage forms using natural superdisintegrants.
Along with formulating the FDT's we are also focusing on evaluating them for better patient safety and convenience. It consist of pre compression (Angle of repose, Bulk density, Tapped density, Carr's index, Hausner's ratio) and post compression parameters (Weight variation, Thickness, Friability, Wetting time) to evaluate drug safety. The tablets were formulated along with other excipients that contributes to longer shelf life and stability of the tablet. Four type of formulations(F1 –F4) with different concentrations were formulated to check which formulation exhibits quick disintegration with faster drug release.
The results conclude that F4 formulation with high percentage of fenugreek mucilage showed shortest disintegration time with more drug release (98.9% in 25 minutes) when compared to F1, F2 & F3.
KEYWORDS: *Fast dissolving tablets, Plantago ovata, Fenugreek mucilage, Pre compression parameters, Formulation, Post compression , Evaluation.*

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INTRODUCTION:

Respiratory diseases are among the leading causes of illness and reduced quality of life across the world. Conditions such as bronchial asthma and Chronic Obstructive Pulmonary Disease (COPD) affect millions of people every year and place a significant burden on healthcare systems. These disorders mainly involve inflammation and narrowing of the airways, making it difficult for patients to breathe normally. Theophylline is a methylxanthine derivative that has been used for several decades in the management of asthma and COPD. It acts mainly by relaxing the smooth muscles surrounding the bronchial airways, thereby widening the air passages and improving airflow to the lungs. In addition to its bronchodilator action, theophylline possesses mild anti-inflammatory properties and enhances the contractility of the diaphragm, making breathing more efficient. Although many newer bronchodilators are available, theophylline continues to play an important role as an adjunct therapy, particularly in patients with persistent respiratory symptoms. Because the drug has a narrow therapeutic index, maintaining an appropriate dosage and ensuring rapid yet controlled drug release are essential for achieving maximum therapeutic benefit while minimizing adverse effects.

Conventional oral tablets are the most common dosage form because they are easy to manufacture, stable during storage, and convenient to transport. However, many patients experience difficulty swallowing these tablets, especially children, elderly individuals, bedridden patients, and those suffering from neurological disorders or dysphagia. Fast Dissolving Tablets (FDTs) have emerged as an innovative oral drug delivery system designed to overcome the limitations of conventional tablets. These tablets rapidly disintegrate when placed on the tongue and dissolve in the saliva within a short period, usually without requiring water.

CLASSIFICATION:

Classification of Anti-asthmatic Drugs:

Asthma is a chronic inflammatory disease of the airways that requires both immediate symptom relief and long-term control. The drugs used in its management are broadly classified into bronchodilators, anti-inflammatory agents, leukotriene modifiers, mast cell stabilizers, and biological agents. Bronchodilators such as β_2-adrenergic agonists, anticholinergic drugs, and methylxanthines rapidly relax bronchial smooth muscles and relieve airway obstruction. Anti-inflammatory medications, mainly corticosteroids, reduce airway inflammation and help prevent recurrent asthma attacks. Leukotriene receptor antagonists inhibit inflammatory mediators responsible for bronchoconstriction, while mast cell stabilizers prevent the release of substances that trigger allergic reactions.

Classification of Drugs Used in COPD:

Chronic Obstructive Pulmonary Disease (COPD) is a progressive respiratory disorder characterized by irreversible airflow limitation. The main objective of treatment is to relieve symptoms, improve exercise tolerance, reduce exacerbations, and enhance the patient's quality of life. Bronchodilators remain the cornerstone of COPD therapy and include short-acting and long-acting β_2-agonists, muscarinic antagonists, and methylxanthines such as theophylline. Inhaled corticosteroids are prescribed for patients with frequent exacerbations to control airway inflammation. Phosphodiesterase-4 inhibitors are beneficial in selected patients with severe COPD associated with chronic bronchitis.

ETIOLOGY:

Etiology of asthma:

Environmental pollution, cigarette smoke, occupational dust, chemical fumes, cold air, and physical exercise are additional factors that may provoke asthma symptoms. Emotional stress and anxiety can worsen airway constriction in some patients. During an asthma attack, inflammatory cells release various chemical mediators that cause swelling of the bronchial lining, contraction of smooth muscles, and excessive mucus secretion. These changes narrow the airways, making breathing difficult and producing symptoms such as wheezing, coughing, chest tightness, and shortness of breath.

Etiology of COPD:

Cigarette smoking is considered the leading cause of COPD worldwide, accounting for the majority of reported cases. Long-term exposure to biomass fuel smoke, industrial pollutants, dust, and toxic chemicals also contributes significantly to the development of the disease, especially in developing countries. Repeated exposure to these irritants causes chronic inflammation of the lungs, resulting in structural damage to the airways and destruction of the alveoli. Individuals with a genetic deficiency of alpha-1 antitrypsin are at increased risk of developing COPD even in the absence of smoking.

TREATMENT:

The selection of therapy depends on the severity of the disease, frequency of symptoms, and overall health status of the patient. Bronchodilators are the primary medications used to relieve airway obstruction by relaxing bronchial smooth muscles. Short-acting bronchodilators provide rapid symptom relief during acute attacks, whereas long-

acting bronchodilators help maintain prolonged airway dilation and improve disease control.
Anti-inflammatory agents, particularly inhaled corticosteroids, play an important role in reducing airway inflammation and preventing disease exacerbations. Leukotriene receptor antagonists, phosphodiesterase inhibitors, and biological therapies may also be prescribed for selected patients with severe or poorly controlled disease. Oxygen therapy, pulmonary rehabilitation, breathing exercises, smoking cessation, vaccination against respiratory infections, and avoidance of environmental triggers further improve treatment outcomes.

MECHANISM OF ACTION:

Theophylline exerts its therapeutic effects through multiple mechanisms that contribute to improved respiratory function. Its principal action involves inhibition of phosphodiesterase enzymes, leading to an increase in intracellular cyclic adenosine monophosphate (cAMP). Elevated cAMP levels promote relaxation of bronchial smooth muscles, resulting in bronchodilation and easier airflow through the respiratory tract.

Another important mechanism is antagonism of adenosine receptors. By blocking these receptors, theophylline reduces bronchoconstriction and suppresses the release of inflammatory mediators such as histamine. This action decreases airway hypersensitivity and contributes to better control of respiratory symptoms.

MATERIALS & METHODS:

Materials & equipments:

S.no	Materials	Manufacturer
1	Theophylline.	Sdfine.
2	Plantago ovatum.	Paradise Exim, Mandsaur.
3	Fenugreek mucilage.	Local market.
4	Microcrystalline cellulose.	Accord labs
5	Mannitol.	Accord labs.
6	Aspartame.	Accord labs.
7	Magnesium stearate.	Accord labs.
8	Talc.	Accord labs.

Table no.1- Materials used.

S.no	Equipments	Manufacturer
1.	Weighing Balance	CONTECH.
2.	Monsanto Hardness Tester	Ketan.
3.	Vernier Calliper	Venkateshwara scientific trades.
4.	Tablet Dissolution Test Apparatus	Mkowoptik
5.	Friabilator	Venkateshwara scientific trades.
6.	UV Spectrometer	Fisher scientific.
7.	Melting Point Apparatus	Eisco labs.
8.	Thermometer	Mextech.
9.	Rotary Punching Machine	Cadmack
10.	Glassware	Borosil
11.	Hot Air Oven	Biotechnics India

Table no.2 – Equipments used.

CALIBRATION CURVE OF THEOPHYLLINE:

PREPARATION OF 0.1N HCL BUFFER:
Weigh 3.5g of potassium chloride in a beaker and make it up to 250ml with distilled water. In another beaker take 4ml of HCL and dissolve it in 500 ml of distilled water. Take a 1000ml volumetric flask and add both the solutions and make it up to 1000ml with distilled water.

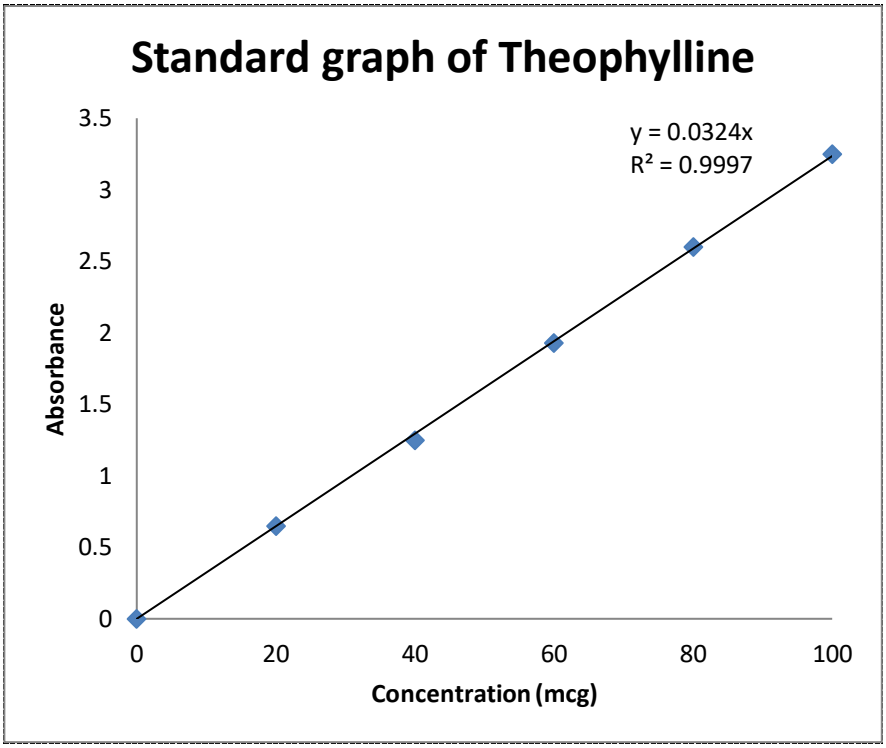
PREPARATION OF PRIMARY STOCK SOLUTION:
Add 100mg of theophylline in a beaker. Then make it up to 100ml with 0.1N HCL buffer.

PREPARATION OF SECONDARY STOCK SOLUTION:
Pipette out 10ml of primary stock solution in 100 ml beaker. Make it up to 100ml with 0.1N HCL buffer.

SERIAL DILUTION:
Take a clean test tube to that add 2ml of secondary stock solution and make it up to 10 ml with 0.1N HCL buffer solution (8ml). In another test tube add 4ml of secondary stock solution and make it up to 10ml with 0.1N HCL buffer (6ml). In another test tube add 6ml of secondary stock solution and make it up to 10ml with 0.1N HCL buffer (4ml).In another test tube add 8ml of secondary stock solution and make it up to 10 ml with 0.1N HCL buffer (2ml). In another test tube add 10ml of secondary stock solution. Take a test tube and add 10ml of 0.1N HCL buffer for blank. Observe it under UV spectrophotometer to check the absorbance.

Concentration**(µg/mL):**	Absorbance**(A):**
0	0
20	0.65
40	1.25
60	1.93
80	2.6
100	3.25

Table no.3



Formulation:
Preparation of Theophylline Fast dissolving Tablets :
All excipients and a precisely weighed quantity of Theophylline were passed through a 60-mesh sieve separately to obtain uniform particle size. The required quantities of Theophylline, Plantago ovata mucilage/Fenugreek mucilage, Microcrystalline Cellulose (MCC), Mannitol, Aspartame, Magnesium stearate, and Talc were accurately weighed and mixed in a mortar and pestle for 20–30 minutes to achieve a uniform blend.

The natural superdisintegrants (Plantago ovata mucilage and Fenugreek mucilage) were incorporated in varying con
concentrations according to the formulation design.

Magnesium stearate and Talc were added at the final stage and blended gently for 2–3 minutes to avoid over-lubrication.

The prepared powder blend was evaluated for pre-compression parameters and then compressed into tablets using a single-punch tablet compression machine by the direct compression method. The tablet weight was maintained constant for all formulations.

S.No	Ingredients	F1	F2	F3	F4
1.	Theophylline	50	50	50	50
2.	Plantago ovata	20	40	-	-
3.	Fenugreek Mucilage	-	-	20	40
4.	MCC	52	32	52	32
5.	Mannitol	20	20	20	20
6.	Aspartame	3	3	3	3
7.	Magnesium Stearate	2	2	2	2
8.	Talc	3	3	3	3
		150	150	150	150

Table no.4- Formulation design.

8. RESULTS AND DISCUSSION:

I. Determination of Standard Calibration Curve:

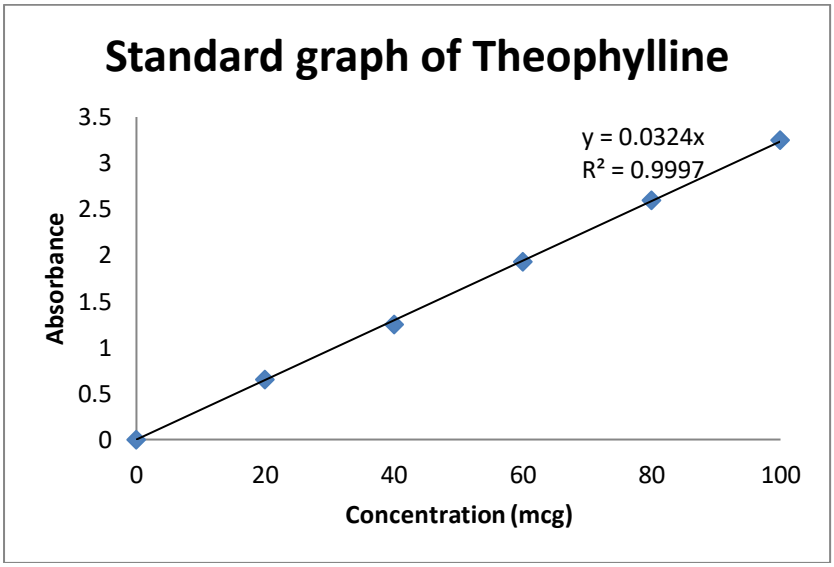
a) Determination of λ_{max}:

The absorption maximum (λmax) of Theophylline was estimated by scanning the drug solution (10 µg/mL) between 200–400 nm using a UV-Visible spectrophotometer.

The λmax was found to be 272 nm in 0.1 N HCl.

Table 6: Calibration Curve of Theophylline in 0.1 N HCl:

Concentration(µg/mL)	Absorbance (A)
0	0
0.2	0.65
0.4	1.25
0.6	1.93
0.8	2.6
1	3.253



EVALUATION

II. Pre Compression Parameters:

Parameter	F1	F2	F3	F4
Bulk Density	0.35	0.31	0.39	0.33
Tapped Density	0.55	0.52	0.53	0.59
Hausner ratio	1.4	1.31	1.41	1.39
Compressibility index	27.36	27.28	27.50	27.25
Angle of Repose	37.64	37.5	37.71	36.96

III. Post Compression Parameters:

The results of post-compression evaluation revealed that all the prepared fast dissolving tablets showed satisfactory physical characteristics. The tablets exhibited uniform weight, acceptable thickness, and adequate hardness. Friability was below 1%, indicating good mechanical strength. The wetting time was found to be low, confirming the fast-dissolving nature of the tablets.

Formulation	F1	F2	F3	F4
Weight Variation	200 ±2.10	200 ±1.95	200 ±2.04	200 ±1.88
Hardness	3.12 ±0.10	3.28 ±0.08	3.41 ±0.12	3.56 ±0.09
Thickness	3.21 ±0.03	3.24 ±0.04	3.26 ±0.03	3.28 ±0.02
Friability	0.48	0.44	0.40	0.36
Wetting Time	38.4 ±0.62	34.6 ±0.54	30.2 ±0.48	26.8 ±0.41

IV. In-Vitro Disintegration Time:

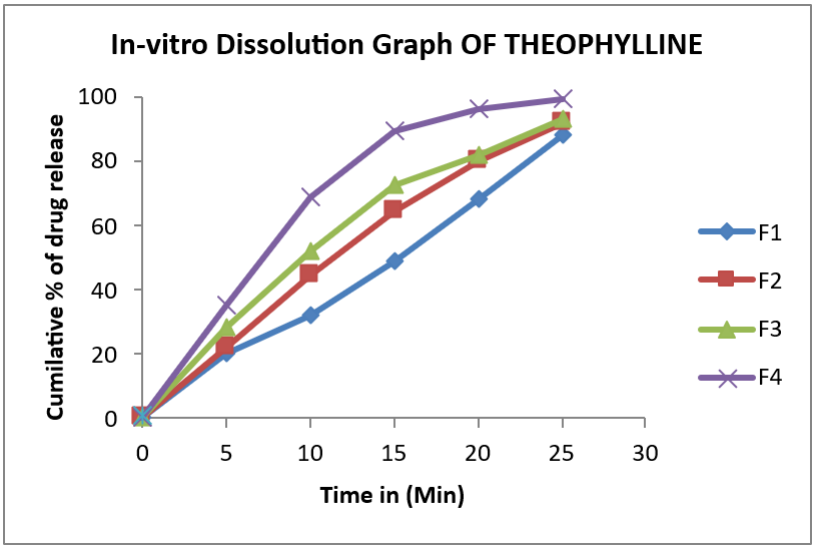
The in-vitro disintegration study showed that increasing the concentration of the superdisintegrant decreased the disintegration time. Among all formulations, F4 showed the shortest disintegration time (23.4 ± 0.38 sec), while F1 showed the longest (34.8 ± 0.52 sec).

Formulation	Disintegration Time
F1	34.8 ± 0.52
F2	26.5 ± 0.48
F3	31.2± 0.44
F4	23.4± 0.38

V. In -Vitro Drug Release Study:

The in-vitro drug release study was carried out using USP Type II (Paddle) dissolution apparatus containing 900 mL of 0.1 N HCl at 37 ± 0.5°C and 50 rpm. The samples were analyzed at λmax = 272 nm. Among all formulations, F4 exhibited the highest drug release (98.9% at 25 min), while F1 showed the lowest (88% at 25 min). The results indicate that increasing the concentration of the natural superdisintegrant enhanced the drug release of theophylline fast dissolving tablets.

Time (min)	F1(%)	F2(%)	F3(%)	F4(%)
0	0	0	0	0
5	20	22	28	35
10	32	44.3	51.7	68.9
15	48.9	64.2	72.5	89.3
20	68	80	82	96
25	88	91.4	92.8	98.9



CONCLUSION:

In the present study successfully formulated and evaluated fast dissolving tablets of Theophylline using the natural superdisintegrants Plantago ovata mucilage and Fenugreek mucilage by the direct compression method. F1- F4 showed satisfactory pre-compression and post-compression characteristics within acceptable limits. The tablets exhibited rapid disintegration and good drug release. Among all formulations, F4 Fenugreek mucilage showed the best performance with the shortest disintegration time and the highest drug release (98.9% in 25 minutes).When compared to F1, F2 &F3, Fenugreek mucilage was found to be the most effective natural superdisintegrant for preparing fast dissolving tablets of Theophylline. This maybe due to presence of higher concentrations of superdisintegrating agents of Fenugreek mucilage, Hence, F4 is optimum formulation for fast dissolving tablets of theophylline.

REFERENCES:

1.Pacifici GM. Clinical pharmacology of theophylline in preterm infants: effects, metabolism and pharmacokinetics. Curr Pediatr Rev. 2014;10(4):297-303.

2. Mannino DM, Homa DM, Akinbami LJ, Moorman JE, Gwynn C, Redd SC. Surveillance for asthma--United States, 1980-1999. MMWR Surveill Summ. 2002 Mar 29;51(1):1-13.

3.Centers for Disease Control and Prevention (CDC). Vital signs: asthma prevalence, disease characteristics, and self-management education: United States, 2001--2009. MMWR Morb Mortal Wkly Rep. 2011 May 06;60(17):547-52.

4.Maio S, Baldacci S, Carrozzi L, Pistelli F, Angino A, Simoni M, Sarno G, Cerrai S, Martini F, Fresta M, Silvi P, Di Pede F, Guerriero M, Viegi G. Respiratory symptoms/diseases prevalence is still increasing: a 25-yr population study. Respir Med. 2016 Jan;110:58-65.

5.Weiss ST, Gold DR. Gender differences in asthma. Pediatr Pulmonol. 1995 Mar;19(3):153-5.

6.Burrows B, Martinez FD, Halonen M, Barbee RA, Cline MG. Association of asthma with serum IgE levels and skin-test reactivity to allergens. N Engl J Med. 1989 Feb 02;320(5):271-7.

7.Gilliland FD, Islam T, Berhane K, Gauderman WJ, McConnell R, Avol E, Peters JM. Regular smoking and asthma incidence in adolescents. Am J Respir Crit Care Med. 2006 Nov 15;174(10):1094-100.

8.Camargo CA, Weiss ST, Zhang S, Willett WC, Speizer FE. Prospective study of body mass index, weight change, and risk of adult-onset asthma in women. Arch Intern Med. 1999 Nov 22;159(21):2582-8.

9.Harsh Mohan, Textbook of pathology, Jaypee Brothers Medical Publishers (P) Ltd, 6th Edition, 2010;477-478.

10.KD Tripathi, Essentials of medical pharmacology, Jaypee Brothers Medical Publishers (P) Ltd,7thEdition,2013;232