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Formulation and Evaluation of Oral Dissolving Film Using Phyllanthus Amarus

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Abstract: Jaundice is a clinical condition characterized by elevated bilirubin levels, leading to yellow discoloration of skin and mucous membranes. Herbal remedies have gained significant importance due to their safety and therapeutic efficacy. Phyllanthus amarus, a medicinal plant widely used in traditional medicine, possesses hepatoprotective, antiviral, and antioxidant properties. The present study aims to develop and evaluate a fast dissolving oral film (ODF) containing methanolic extract of Phyllanthus amarus. Fast dissolving films are novel drug delivery systems that dissolve rapidly in the oral cavity without the need for water, improving patient compliance, especially in pediatric and geriatric populations. The films were prepared using the solvent casting method with suitable polymers such as HPMC, along with plasticizers, sweeteners, and flavoring agents.

The formulated films were evaluated for parameters including thickness, weight variation, folding endurance, disintegration time, and drug content uniformity. The results demonstrated rapid disintegration, good mechanical strength, and uniform drug distribution. Thus, Phyllanthus amarus oral films offer a promising herbal drug delivery system with improved bioavailability and patient acceptability.

Keywords: Phyllanthus amarus, Oral dissolving film, Jaundice, Herbal formulation, Fast dissolving system

1. INTRODUCTION

Jaundice is defined as the yellow discoloration of skin, sclera, and mucous membranes due to accumulation of bilirubin in the blood. It occurs when bilirubin levels exceed 2 mg/dL. Bilirubin is formed from the breakdown of heme, primarily derived from hemoglobin metabolism.

Jaundice is broadly classified into pre-hepatic, hepatic, and post-hepatic types depending on the underlying cause such as hemolysis, liver damage, or bile duct obstruction.

Medicinal plants play a vital role in treating liver disorders. Phyllanthus amarus, commonly known as “stone breaker,” is widely distributed in tropical regions and is traditionally used for liver diseases, viral infections, and kidney disorders. It contains bioactive compounds such as flavonoids, alkaloids, tannins, and lignans responsible for its pharmacological activities.

Recent advancements in drug delivery systems have led to the development of oral dissolving films (ODFs), which provide rapid drug release and improved bioavailability. These films dissolve quickly in the oral cavity, eliminating the need for water and enhancing patient compliance.

Plant Profile

Botanical Description:

Kingdom : Plantae

Division : Angiosperms

Class : Dicotyledonae

Order : malpighiales

Family : Phyllanthaceae

Genus name : Phyllanthus

Species name : Phyllanthus amarus

Common name : Stone breaker, gale of the wind, seed under leaf

Phyllanthus amarus known as "stone breaker" is a small erect annual herb (30-60 cm tall) with slender, branched stems, smooth pale green leaves arranged alternately (looking like a compound leaf), tiny greenish flowers (male & female separate) growing from leaf axils, and small, smooth, globose capsules that split to reveal small, warty seeds, widely distributed across tropical and subtropical regions globally, thriving in coastal areas and fields, especially in Asia, Americas, Africa..

Fig.1: *Leaves of Phyllanthus amarus*

2. MATERIALS AND METHODS

2.1. Drying of the Plant

The collected Phyllanthus amarus leaves were shade dried in a well-ventilated area at ambient temperature to preserve their bioactive constituents. This method was adopted to retain secondary metabolites and prevent the loss of active compounds. The samples were regularly monitored to avoid mold growth and insect contamination. Direct sunlight was avoided to prevent chemical degradation caused by ultraviolet radiation. Dry conditions were maintained throughout the process to minimize fungal contamination and microbial fermentation.

2.2. Grinding

The aim of grinding is to make fragments of the leaves into smaller particles and improves the subsequent extraction by rendering the sample more homogenous, increasing the surface area and facilitating the penetration of solvent into the cells. Mechanical grinder should be employed to shred the plant tissues to various particle sizes.

2.3. Preparation of plant extracts

The leaves of Phyllanthus amarus were collected and dried in shade. 300g of the powder was extracted with methanol. The Marc was extracted with methanol by cold extraction.

2.4. Cold Maceration Extraction

The coarsely powdered leaves of Phyllanthus amarus (300 g). Cold maceration is an extraction technique used to isolate bioactive compounds, essential oils, or flavors from plant materials by soaking them in a solvent (menstruum) at room or low temperatures.

3. PRELIMINARY PHYTOCHEMICAL SCREENING

Table 1: *phytochemical analysis of leaves of Phyllanthus amarus*

S. No	Phytochemical	Test Name	Procedure	Observation
1.	Alkaloids	Dragendroff's Test	Add 1 ml of Dragendroff's reagent to extract	Orange-red precipitate
2.	Flavonoids	Lead Acetate Test	Add few drops of 10% lead acetate solution	Yellow precipitate

3.	Saponins	Foam Test	Dilute 1 ml extract to 20 ml with water and shake for 15 min	1 cm foam layer
4.	Terpenoids	Chloroform + H_2SO_4 Test	Add chloroform, evaporate, add sulphuric acid, heat	Greyish color
5.	Tannins	Braymer's Test	Add water and ferric chloride solution	Blue-green color
6.	Carbohydrates	Molisch's Test	Add Molisch reagent and sulphuric acid	Violet ring
7.	Glycosides	Keller-Killani Test	Add acetic acid + ferric chloride, heat, then add H_2SO_4	Blue color
8.	Phenols	Ferric Chloride Test	Add ferric chloride solution	Bluish-black color
9.	Steroids	Liebermann-Burchard Test	Add chloroform, acetic anhydride, and H_2SO_4	Red → Blue → Bluish-green
10.	Proteins	Biuret Test	Add Biuret reagent, wait 5 minutes	Violet color

4. FORMULATION OF ORAL DISSOLVING FILM

4.1. Procedure

Oral dissolving films of Phyllanthus amarus was prepared by solvent casting method. Accurately weighed extract of Phyllanthus amarus was added to the prepared solution and stirred to get a clear solution. To the solution, HPMC 15 cps was added with continuous stirring to get a homogenous solution. Sucrose, Mixed vanilla and Glycerin were added to the above solution and mixed well. The solution was kept aside for the removal of air bubbles.

By using pipette, 5 ml of prepared solution was transferred to petri dish of 8 cm diameter and dried in micro wave oven at 50°C for 45 min. Further the film was dried in vacuum oven at 35°C. The prepared film was carefully removed from the petri dish, checked for imperfections and was cut into small circular films of 3 cm diameter to deliver the equivalent dose of 150 mg per ODF. The samples are kept in butter paper and sealed in Alu-Alu pouches. ODF with HPMC 15cps are taken in concentration of 150 mg, 200 mg per film. The prepared film was carefully removed from the petri dish, checked for imperfections and was cut into small circular films of 3 cm diameter to deliver the equivalent dose of 150mg 200mg per ODF. The samples were kept in butter paper and sealed with an Alu-Alu pouch".

5. RESULT AND DISCUSSION

- The plant ***Phyllanthus amarus*** was selected for **formulation of oral fast dissolving film for Jaundice disease.**
- The **Methanolic extract** of *Phyllanthus amarus* linn. Was prepared.

Fig: 2 *Formulation of Phyllanthus amarus ODF*

Table 2: *formulation of Phyllanthus amarus ODF*

S.NO	Ingredients	F1(150mg)	F2(300mg)
		Quantity	
1.	*Phyllanthus amarus*	150mg	150mg

2.	Hypromellose (hydroxypropyl methyl cellulose 15cPs)	150mg	300mg
3.	Sucralose	5mg	5mg
4.	Honey flavor	50mg	50mg
5.	Glycrin	0.5ml	0.5ml
6.	Distilled water	5ml	5ml

Table 3: *Physical Properties of Phyllanthus amarus Oral Dissolving Film*

Parameters	**Batch code**	
	F1(150mg)	**F2(300mg)**
Weight (mg)	38.11±0.79	45.46±0.76
Thickness (µm)	70.20±1.5	75.71±1.36
Folding endurance	≥300	≥300
Surface Ph	7	7
In vitro dispersion time(sec)	9.25±1.44	17.75±1.25
Disintegration time(sec)	6.75±4.0	15.25±2.5

Table 4. *Estimation of Drug Content*

Batch code	**F1 (150mg)**	**F2 (300 mg)**
Drug content (%)	99.49±0.45	100.59±0.52
Uniformity of dosage units (acceptance value)	1.49	2.11

Table 5: *In vitro drug release profile for Phyllanthus amarus ODF in simulated salivary fluid*

Time (in minutes)	**Cumulative % drug release**	
	Batch code	
	F1(150mg)	**F2(300mg)**
5min	90.81	91.17
10min	91.45	91.57
20min	93.43	93.55
30min	95.55	95.61
40min	98.03	99.39
50min	100.1	100.2

Report Drug Release Film Burst -Drug Film Burst1_FSR Texture Analysis Force (kg)

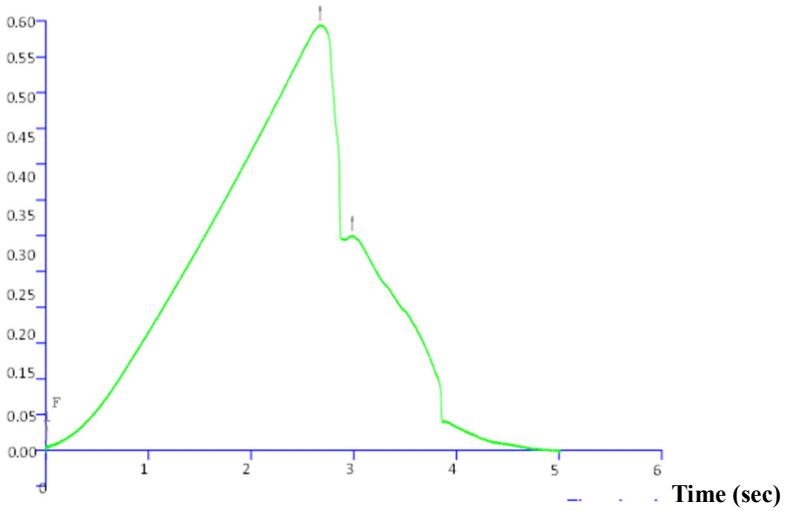

Fig: 3. *Phyllanthus amarus oral dissolving film*

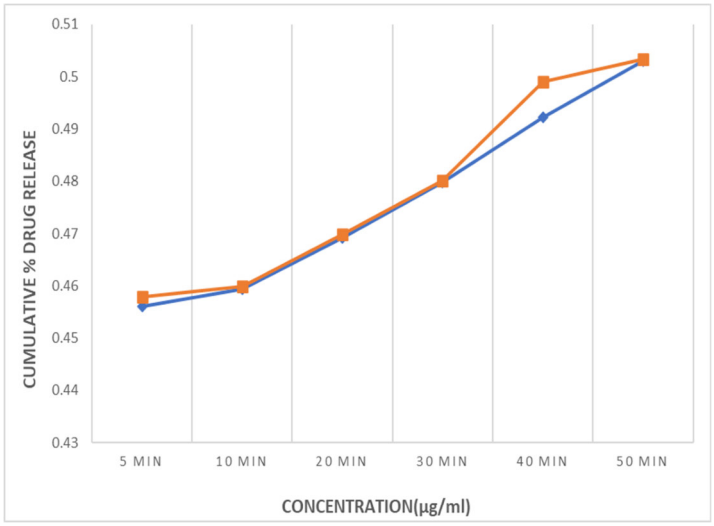

Fig: 4. *comparative in vitro drug release profile*

F1 (150mg)

F2 (300mg)

6. CONCLUSION

This study focused on developing and evaluating mouth dissolving films (MDFs) containing *Phyllanthus amarus*, a medicinal plant known for its hepatoprotective, antiviral, antioxidant, and anti-inflammatory properties. The aim was to create a patient-friendly oral dosage form with rapid drug release, improved bioavailability, and enhanced compliance, especially for pediatric and geriatric patients.

The plant extract was prepared and incorporated into films using the solvent casting method. Various formulations were designed using suitable polymers, plasticizers, and excipients to achieve optimal mechanical strength and fast disintegration.

The films were evaluated for multiple parameters, including physical appearance, thickness, weight uniformity, folding endurance, surface pH, moisture content, drug content, disintegration time, and in-vitro drug release. Results showed that the films were smooth, flexible, uniform, and free from defects, with a near-neutral pH indicating low irritation potential.

The optimized formulation demonstrated rapid disintegration and efficient drug release, confirming its effectiveness as a fast-dissolving delivery system.

In conclusion, the study successfully formulated MDFs of *Phyllanthus amarus* with desirable physicochemical properties and performance. These films offer advantages such as ease of administration, improved patient compliance, faster onset of action, and avoidance of first-pass metabolism, making them a promising alternative to conventional oral dosage forms.

The preliminary phytochemical screening of ***Phyllanthus amarus*** revealed the presence of

- Alkaloids
- Flavonoids
- Tannins
- Saponin
- Terpenoids
- Glycosides
- Phenols
- Steroids
- Proteins

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