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Research Paper

Formulation and Evaluation of Herbal Pastilles for Tobacco and Smoking De-addiction

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ABSTRACT

Tobacco addiction is a critical global health emergency, particularly in India, which is the second-largest consumer of tobacco products globally. While the necessity for quitting is well recognized, current cessation treatments like Nicotine Replacement Therapy (NRT) often face low success rates due to high costs, potential side effects, and the fact that they merely substitute one form of nicotine for another. This research focuses on the formulation development and evaluation of polyherbal pastilles specifically designed to aid in smoking and tobacco de-addiction. These medicated pastilles are solid oral dosage forms intended to dissolve slowly in the mouth, extending the duration of medicinal contact with the oral mucosa to satisfy the "oral fixation" that often triggers relapseThe formulation utilizes a synergistic blend of four standardized herbal extracts: Ashwagandha (Withania somnifera), Curcumin (Curcuma longa), Ginger (Zingiber officinale), and Clove (Syzygium aromaticum). Ashwagandha is incorporated for its adaptogenic properties to reduce withdrawal-related stress, while Ginger helps alleviate nausea. Clove provides a strong aromatic sensation to satisfy oral fixation, and Curcumin offers potent antioxidant benefits to facilitate the healing of tobacco-related oral lesions. The pastilles were prepared using a heating and congealing technique with a gelatin-glucose base. Rigorous quality control testing confirmed a near-neutral pH of 5.5, uniform weight (average 1.50 g), and a controlled dissolution profile where nearly 95–100% of the drug was released within 30 minutes. This project provides a palatable, nicotine-free alternative to traditional pharmacotherapies, aiming to improve patient compliance and support a healthier lifestyle.

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INTRODUCTION

The Global Crisis of Tobacco and Smoking,
Tobacco addiction is a critical global health em+ergency and the leading cause of preventable death and disease worldwide. India currently stands as the second-largest manufacturer and consumer of tobacco products globally. Chronic tobacco use, whether through smoking or smokeless forms, is a primary predisposing factor for life-threatening conditions, including various malignant neoplasms (cancers), cardiovascular diseases, and chronic respiratory tract infections such as COPD, emphysema, and bronchiti
The addictive nature of tobacco is driven by nicotine, which creates both a physical and psychological dependency. While many users express a desire to quit, the sudden cessation of tobacco leads to debilitating withdrawal symptoms. These symptoms include intense cravings, irritability, anxiety, restlessness, insomnia, and nausea [1-4]

Limitations of Current Treatments

Currently, several medicinal and behavioral methods are used to aid cessation, but they often face significant challenges:

- Nicotine Replacement Therapy (NRT): Options like patches, gums, and sprays provide a controlled dose of nicotine but often fail to achieve long-term success for the majority of smokers.
- Pharmacological Treatments: While effective in alleviating withdrawal, prescription drugs are frequently expensive and carry a risk of numerous potential side effects.
- Therapeutic Non-compliance: Many patients fail to follow treatment regimens due to the unpleasant taste of medications, adverse effects, or difficulty swallowing pills.

There is a clear and urgent need for a nicotine-free, cost-effective, and palatable formulation that not only helps in de-addiction but also treats the physical ailments, such as oral lesions, caused by tobacco use.[5-8]

The Proposed Solution: Polyherbal Pastilles

This project proposes the formulation of medicated herbal pastilles as a patient-friendly and effective alternative for de-addiction. Pastilles are solid oral medications designed to dissolve slowly in the buccal cavity (mouth).
The use of a pastille dosage form offers several strategic benefits for a person trying to quit tobacco:

- **Oral Fixation:** By dissolving slowly (averaging 10 ± 2 minutes), the pastille satisfies the "hand to mouth" urge and oral cravings that smokers experience.
- **Local and Systemic Healing:** The pastille provides a topical effect to promote the healing of oral mucosal lesions while also delivering systemic benefits through absorption.
- **Convenience:** Pastilles are non-invasive, portable, and do not require water for ingestion, which significantly increases patient compliance. [9-10]

Rationale for Ingredient Selection

Our formulation utilizes a synergistic blend of four standardized herbal extracts, each chosen for a specific pharmacological role in the de-addiction process

Table no.1: List of Crude drugs with its Benefit

Ingredient	Role in Deaddiction	Scientific Benefit
Ashwagandha	Stress & Withdrawal Management	Acts as an adaptogen to reduce cortisol, anxiety, and restlessness during nicotine withdrawal.

Clove	Oral Fixation & Throat Hit	Provides a strong aromatic sensation to distract from cravings and freshens breath.
Ginger	Nausea & Digestive Support	Combats the gastrointestinal distress and nausea commonly associated with quitting tobacco.
Curcumin	Tissue Repair & Antiinflammation	Potent antioxidant that helps heal oral lesions and reduces lung inflammation caused by smoke.

All these 4 ingredients were used to replace the nicotine [11-15]

MATERIALS AND METHODS

Study Rationale and Delivery System

A **medicated pastille** (similar to a gummy lozenge) was chosen as the best way to deliver this treatment because it works in two ways at once: it treats the mouth directly and enters the bloodstream for overall relief.

- **Long-Lasting Effect**: While pills are swallowed quickly, these pastilles stay in the mouth for about **10 minutes**.
- **Satisfies Cravings**: This long "staying time" helps smokers who miss the habit of having something in their mouth (known as **oral fixation**).
- **Direct Healing**: Because the pastille dissolves slowly, ingredients like **Clove and Curcumin** have more time to directly coat and heal mouth sores or lesions caused by tobacco use.

Formulation Composition

The formulation utilizes a synergistic polyherbal blend consisting of Ashwagandha (adaptogen), Ginger (anti-emetic), Clove (sensory substitute), and Curcumin (mucosal repair). These active extracts were incorporated into a candy-like matrix.

Table 1: List of Ingredients and Their Pharmaceutical Roles

Sr. No.	Ingredient	Scientific Name / Category	Role in Formulation
1	Ashwagandha Extract	*Withania somnifera*	Adaptogen; stress and withdrawal reduction
2	Curcumin Extract	*Curcuma longa*	Anti-inflammatory; mucosal healing
3	Ginger Extract	*Zingiber officinale*	Anti-nausea; digestive support
4	Clove Extract	*Syzygium aromaticum*	Oral fixation; aromatic “throat hit”
5	Sucrose (Sugar)	Sweetening agent	Bulk-forming agent; base medium
6	Liquid Glucose	Binding agent	Provides texture; prevents crystallization
7	Gelatin	Gelling agent	Forms matrix; provides chewy consistency
8	Citric Acid	Acidulant	Taste enhancer; maintains stability
9	Orange Oil/Color	Organoleptic agents	Improves flavor and aesthetic appearance
10	Liquid Paraffin	Lubricant	Mould release agent



Ashwagandha



Clove



Curcumin



Ginger

Manufacturing Process

The "Heating and Congealing" technique was employed for manufacturing. This method creates a stable, palatable matrix that ensures uniform drug distribution and high patient compliance without requiring water for administration.

Instrumentation and Evaluation

The formulation and evaluation were conducted using standardized laboratory equipment:

- Formulation: Beakers, glass rods, and temperature-controlled water baths were used for the indirect heating of the gelatin-sucrose base.
- **Evaluation:**
  - Analytical Balance: Used for precision weighing of extracts. o pH Meter: Calibrated to ensure compatibility with oral mucosa (pH ~5.5). o Dissolution Tester:

Employed to determine the drug release profile in phosphate buffer.

  - UV-Spectrophotometer: Used for quantitative analysis and concentration determination at λ_{max} 325nm.

Extraction of Bioactives

To maximize the concentration of secondary metabolites, a two-step exhaustive extraction process was utilized:

- **Maceration:** Ground herbal materials were soaked in a hydroalcoholic solvent (Ethanol/Methanol) for three days to facilitate cell swelling and the slow diffusion of active compounds like withanolides and gingerols.
- **Soxhlet Extraction:** Continuous extraction was performed using a Soxhlet apparatus, a standard technique for recovering phytochemicals from ginger, ashwagandha, turmeric, and clove.
- **Methodology:** Dried powder was placed in a thimble and processed with appropriate solvents (ethanol, methanol, or acetone) through 10–20 siphon cycles over 2–4 days at boiling temperature.

- **Concentration:** The resulting solvent was evaporated to obtain the final concentrated extracts and essential oils.

Maceration

Formulation of Herbal Pastilles

The pastilles were manufactured using the heating and congealing method according to the following standardized procedure:

1. **Base Preparation:** 20 mL of distilled water was heated under continuous stirring to form a thick paste.
2. **Matrix Incorporation:** Liquid glucose, gelatin, and citric acid were added to the mixture to establish the gelling matrix.
3. **Additive Addition:** After partial cooling, orange oil, peppermint oil, and food-grade color were incorporated.
4. **Moulding:** The mixture was poured into moulds pre-coated with liquid paraffin to prevent sticking.
5. **Setting:** The units were allowed to set at room temperature for 20–30 minutes, resulting in the formation of 10–14 jelly-like pastille units.

Table no.: Formulation Table of Pastilles (Batches):

Batch No.	Distilled Water (mL)	Liquid Glucose (g)	Gelatin (g)	Sucrose (g)	Observation
P1	30	5	10	10	Evaporation occurred; batch failed
P2	20	5	8	10	Jelly formation not achieved
P3	20	5	8	15	Became hard after 1–2 days
P4	20	5	6	6	Uneven texture formed
P5	20	5	11	7	Becomes hard Batch failed
P6	20	5	9	12	Uneven texture formed
P7	20	5	13	10	Jelly formation not achieved
P8	20	5	12	8	Smooth, uniform, stable pastilles formed
P9(optimize)	20	5	12	8	Smooth, uniform, stable pastilles formed

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Table no.5: optimization Observations

Batch No.	Parameter	Observation	Conclusion
P1	Moisture	Evaporation	Excess water
P2	Gel formation	No jelly	Low gelatin
P3	Hardness	Too hard	Excess sugar
P4	Texture	Uneven	Improper ratio
P5	Overall	Smooth & stable	Optimized formula
P6	disintegration	With in 15 to 30 min	ideal for pestilles
P7	Surface ph	5.2 to 5.4	Compatible with oral mucus
P8	Content uniformity	Uniform content	Uniform distribution
P9	Stability	Robust formulation	Robust formulation

RESULTS AND DISCUSSION

The polyherbal pastilles were evaluated for physicochemical and phytochemical parameters to ensure quality, stability, and therapeutic efficacy.

Physicochemical Evaluation

- **pH Stability:** The pastilles maintained a pH of **5.5**, which is ideal for the oral mucosa and prevents irritation during consumption.
- **Dissolution Profile:** In-vitro drug release reached **96% within 30 minutes**, confirming a consistent and controlled release of active constituents.
- **Weight & Thickness:** The average weight was **2.36 g** and average thickness was **3.2 mm**, demonstrating uniform drug distribution and batch consistency.
- **Stability:** Under accelerated conditions (40°C), the formulation remained robust with drug content held between **95%–100%** after 30 days.

Table 1: Stability and Physical Parameters Summary

Parameter	Result/Observation	Conclusion
Appearance	Yellowish white; smooth and glossy	Aesthetically acceptable
pH Evaluation	5.5	Compatible with oral cavity
Average Weight	2.36 g	Uniform distribution
Dissolution (30 min)	96% Drug Release	Efficient release profile

Phytochemical Screening and Therapeutic Role
Phytochemical analysis confirmed the presence of key secondary metabolites in all herbal extracts, which are essential for treating nicotine dependence.

Table 2: Phytochemical Profile and Clinical Rationale

Test (Reagent)	Results (All Extracts)	Role in Tobacco De-addiction
Flavonoids	Positive (Pinkred/Orange)	Antioxidant; reduces oral irritation and modulates dopamine to suppress cravings.
Terpenoids	Positive (Reddishbrown)	Provides masking aroma; antimicrobial protection for the oral cavity.
Phenols	Positive (Bluish/Greenish)	Free-radical scavengers; protects tissues from carcinogen-induced oxidative damage.
Tannins	Positive (Except Curcumin)	Astringent; forms a protective coating on the mucosa to heal tobacco-induced lesions.

Analytical Calibration
The UV-Spectrophotometric analysis at **λ_{max} 325nm** yielded a regression equation of $y = 0.00005x + 0.076$ with a correlation coefficient (R^2) of **0.998**, indicating a highly linear and accurate analytical method for drug quantification.

CONCLUSION

The present study successfully developed a nicotine-free polyherbal pastille for tobacco deaddiction. The formulation showed acceptable pH, uniformity, stability, and controlled drug release. Herbal ingredients like Withania somnifera, Zingiber officinale, Syzygium aromaticum, and Curcuma longa provided synergistic therapeutic effects. The slowdissolving nature enhances drug action and helps reduce oral cravings. The formulation is safe, cost-effective, and patient-friendly. Overall, it offers a promising natural alternative for tobacco cessation and improving oral health.

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