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Research Article

Formulation and Evaluation of Ashwagandha Hard Candy Lozenges for Reducing Anxiety

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ABSTRACT

The oral route remains the most preferred method for drug administration due to its convenience, cost-effectiveness, and patient compliance. However, conventional oral dosage forms often pose challenges such as pill-swallowing difficulties and poor taste, particularly in pediatric, geriatric, and dysphagic patients. To overcome these limitations, the present study focuses on the formulation and evaluation of Ashwagandha (Withania somnifera) hard candy lozenges aimed at anxiety relief. Ashwagandha is a well-known adaptogen with proven anxiolytic properties. The lozenges were formulated using the heating and congealing technique, incorporating excipients like sucrose, liquid glucose, citric acid, and menthol to enhance palatability and stability. The final product aims to offer advantages such as ease of administration, rapid onset of action, improved bioavailability, and better patient compliance. Among the tested formulations, Batch F2 showed optimal results in terms of taste, texture, and drug uniformity. This study concludes that Ashwagandha hard candy lozenges provide a natural, effective, and patient-friendly alternative for managing anxiety, especially for those with swallowing difficulties.

INTRODUCTION

Oral Drug Delivery

Oral drug delivery is the most widely preferred route for administering therapeutic agents, owing to its affordability, ease of administration, and high patient compliance. Oral dosage forms are widely preferred due to their convenience of use, precise measurement of doses, suitability for self-administration, avoidance of discomfort, and promotion of patient adherence. Moreover, oral dosage forms are convenient, cost- effective, and non-invasive, making them an attractive option for patients. However, oral delivery faces challenges

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such as pill-swallowing difficulty, delivering unpalatable drugs, and reducing dosing frequency. Pill-swallowing difficulty affects patients with dysphagia in geriatric and pediatric populations, and those undergoing radiation therapy. To address these issues, fast-dissolving tablets (FDTs) or orally disintegrating tablets (ODTs) have been developed. These tablets have optimal mechanical strength and disintegrate within 60 seconds in the oral cavity. ODTs are gaining popularity due to their convenience, suitability for patients with dysphagia, and no requirement for water to swallow. They are ideal for geriatric, pediatric, and traveling patients. Orally disintegrating tablets (ODTs) offer several advantages, such as increasing patient adherence to medication regimens, minimizing the risk of dosing errors, and significantly improving the overall experience for patients during administration. In today's pharmaceutical industry, consumer satisfaction is key. Factors such as taste, smell, texture, and after taste play a vital role in developing dosage forms and influencing consumer preferences. Pleasant flavors and textures are key contributors to a product's market success, while unpleasant tastes pose significant challenges in formulation. As a result, key organoleptic attributes, such as appearance, color, odor, and taste, play a crucial role and must be carefully evaluated. Taste masking plays a crucial role in pharmaceutical development, focusing on minimizing unpleasant flavors while preserving the overall integrity of the formulation. Although the ideal solution a universal inhibitor that neutralizes bitterness without other tastes like sweetness remains undiscovered, ongoing efforts focus on improving these aspects. Researchers are actively exploring new technologies and ingredients to address this challenge and improve patient compliance.[13] (Jain and Choubey.,2017)To make medicines taste better, scientists use special techniques. These techniques stop the medicine from tasting bitter or unpleasant. A possible approach involves incorporating specific ingredients into the medication. Even with all the advances in medicine, taking medicine by mouth is still the most popular way to take medicine. This is because patients like it, and it's easy to use. In fact, about 60% of all medicines are taken by mouth. However, some patients have trouble swallowing pills, or they don't like the taste. To help these patients, companies have created other ways to take medicine, like liquids or injections. But these methods have their own problems. Liquids can be hard to measure correctly, and injections can be painful. This is why many patients don't take their medicine as prescribed. Oral drug delivery formulation and technologies are mainly focused on the following areas of gastrointestinal tract (GIT).

Many patients have trouble swallowing tablets and capsules, which can lead to not taking their medication as prescribed. This problem, known as dysphagia, affects about 35% of people. It's especially common among those with mental health conditions, disabilities, and certain medical conditions like stroke, Parkinson's disease, and HIV-AIDS. Some situations, like motion sickness or sudden allergic attacks, can also make swallowing difficult. To help these patients, scientists have created new and innovative ways to deliver medication, making it easier to take and more effective.[14](Gupta et al. 2009).

Anxiety

Fear is an instinctive physiological reaction to actual or perceived threats, commonly activating the body's fight-or-flight response. Anxiety, while related, is a future-oriented state involving emotional, cognitive, and physical responses to anticipated threats.

Pathological anxiety arises when individuals overestimate danger, leading to excessive or inappropriate reactions. Although anxiety disorders are among the most common psychiatric conditions, their true prevalence is unclear due to underreporting and missed diagnoses.[25][26][27]

Stress results from physical or mental overload, leading to feelings of nervousness, anxiety, and reduced coping ability. Anxiety, while similar, is marked by persistent worry even without external triggers.[28] Though their symptoms overlap, prolonged stress can severely impact health, causing conditions like hypertension, metabolic syndrome, hormonal imbalances, and anxiety. Adaptogens are natural herbal substances that enhance the body's ability to cope with stress and promote physiological balance. They are safe, non-addictive, and support the body's adaptive response. One such adaptogen is Ashwagandha (Withania somnifera), known in Ayurveda for boosting energy, endurance, and overall well-being. The plant's key active compounds, withanolides (steroidal lactones and glycosides), have shown anxiolytic, antidepressant, and neuroprotective effects in animal models. Clinical studies also report that Ashwagandha root extract (ARE) can reduce stress, anxiety, and cortisol levels in individuals under chronic stress, including those with obesity.[29]

Herbal lozenges:[18]

Herbal lozenges are sweet confections made from natural ingredients like herbs, spices, and essential oils. They offer health benefits such as soothing sore throats, reducing inflammation, suppressing coughs, and boosting immunity. Available in various flavors and blends, popular brands include Halls, Ricola, and Luden's. While generally safe, individuals with allergies or health conditions should consult a healthcare provider before use.

Hard Candy Lozenges[18]

Hard candy lozenges are solid mixtures of sugar and other carbohydrates in an amorphous or glassy state, functioning as solid syrups. Traditionally used for sore throat relief, they also serve as delivery systems for topical anesthetics and antibiotics. These solid dosage forms dissolve slowly in the oral cavity (5–10 minutes), providing localized or systemic effects while masking the drug's taste. Lozenges retain a smooth texture and resist disintegration due to their moisture content ranging from 0.5% to 1.5%. A major drawback is the high temperature required for preparation. They generally weigh between 1.5 and 4.5 grams. Excipients like sorbitol and sugar act as demulcents, soothing irritation from cough and sore throat. Some of the active drug may be absorbed through the buccal mucosa, bypassing first-pass metabolism. Hard candy lozenges are prone to crystallization over time, with the rate and occurrence of this process influenced by their ingredient makeup. Corn syrup solids (>50%) slow crystallization but increase moisture absorption, leading to stickiness. Conversely, sucrose solids (>70%) accelerate crystallization. A balanced formulation (55–65% sugar, 35–45% corn syrup) optimizes stability, minimizes graining, and ensures manageable preparation times. Flavor enhancement and medication stabilization through pH control are achieved with acidulents like citric, tartaric, fumaric, and malic acid. Regular hard candy has a pH of 5.0–6.0, but acidulents can lower it to 2.5–3.0. Alkalizing agents like calcium carbonate, sodium bicarbonate, and magnesium trisilicate can raise pH to 7.5–8.5, further modifying the final lozenge characteristic.

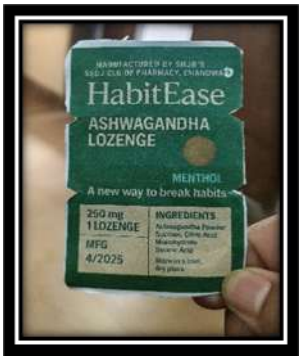
2. Related Work

MATERIAL AND METHODS

Sr. No	Ingredient	Quantity (F2)	Role of Ingredients
1	Ashwagandha (gm)	1	Antianxiety
2	Sucrose (gm)	19	Sweetener
3	Liquid glucose (gm)	4	Binder
4	Citric acid monohydrate (gm)	0.3	Acidulant
5	Stearic acid (mg)	0.5	Lubricant
6	Amaranth	0.1	Color
7	Menthol	0.1	Flavor

Formulation of Ashwagandha Hard Candy lozenges:

Heating and congealing technique: A syrupy base was prepared in a beaker by dissolving the required amounts of sugar in water and kept for heating on a hot plate. Temperature was maintained at 105-110 °C till it became thick. The drug and other excipients were added manually and mixed thoroughly after 30 min with a continuous process of heating. The prepared mass was further heated for 45 minutes, and then plasticizer was added to it. Then above syrupy base was poured into the pre-cooled and pre-lubricated mold, and the mold was kept aside for 10-15 min. Lozenges were removed from the mold and were kept for air drying.



3. Proposed of work:

Classification of lozenges:

A) According to the site of action: -

1. Local effect
2. Systemic effect

B) According to texture and composition: -

1. Chewy or caramel based medicated lozenges
2. Compressed tablet lozenges
3. Soft lozenges
4. Hard candy lozenges
5. Centre filled hard candy lozenges[17] (Shinde et al., 2014)

Advantages: -

1. Ease of administration to pediatrics and geriatrics patients.
2. Local and systemic effect through oral cavity.
3. Prolonged drug action.
4. Avoid first pass metabolism of drugs.
5. Do not require water for intake.
6. Suitable for patients having difficulty in swallowing (dysphagia).
7. Increase in bioavailability.
8. Reduced dosing frequency.
9. Improve onset of action.

Disadvantages: -

1. Children having above 6 years of age can use lozenges safely.
2. Drugs having minimum bitter taste are suitable.
3. High temperature is required for the preparation of lozenges.
4. Hard lozenges become grainy.
5. The non-ubiquitous distribution of drug within saliva for local therapy.
6. Possible draining of drug from oral cavity to stomach along with saliva.

Characterization of Optimized Lozenges Batch:

Sr. No.	Visual evaluation Parameter	Results
1	Shape	Circular
2	Surface	Dry, not sticky, Smooth Solid Surface
3	Color	Redish brown
4	Odor	Menthol Flavor Observed

Results of optimized batch (F2) Visual inspection

Evaluation of Optimized batch of Lozenges (F2)

Sr. No.	Evaluation Parameter	Results
1	*pH*	4.9
2	Weight Variation (gm)	2.52
3	Hardness (kg/cm^2)	6.2
4	Thickness (mm)	8.76
5	Diameter (size)	17.9
6	% Friability	0.70
7	% Moisture Content	2.32
8	Disintegration Time (min)	22.7
9	Mouthfeel	+
10	Palatability	AAA

NOTE-

- **Mouthfeel test:** No metallic test+, slight metallic test++, strong metallic test+++
- **Palatability:** Average: A, Good :AA, Very Good: AAA

4. Benefits:

Aim: Aim of the present work is the Formulation and Evaluation of Ashwagandha Hard Candy lozenges for reducing anxiety.

Objective:

1. Develop a stable and effective hard candy lozenge incorporating Ashwagandha powder.
2. To design the sweetened candy based medicated hard candy lozenges for anxiety treatment.
3. To design a dosage form that is more effective and acceptable than the existing marketed formulations for ashwagandha.
4. To help achieve rapid onset of action.
5. Conduct test masking studies to improve patient compliance and acceptance.
6. Ensure uniformity of Ashwagandha powder within the lozenges.

CONCLUSION

The preparation and evaluation of herbal lozenges using Ashwagandha (Withania somnifera) demonstrated promising results for anxiety relief. The lozenges were successfully formulated using a combination of Ashwagandha powder, sweeteners, and flavoring agents. Here we can conclude that all the objectives are fulfilled. The F2 batch shows optimized results of the Formulation. The development of Ashwagandha lozenges offers a promising alternative for anxiety management, providing a natural, convenient, and effective treatment option.

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