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Formulation and evaluation of Adhulsa lozenges for pediatric patients

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ABSTRACT

WHO estimates that 235 million people currently suffer from asthma. WHO has recognized herbal medicines as an essential building block for primary health care of vast countries like India. In India the number of children suffering from asthma is increasing. Asthma is the chronic diseases of the bronchi which require continuous medical care. Appropriate management of asthma can enable people to enjoy a good quality of life. Many synthetic and traditional medicines are used in the treatment. Herbal formulations have been used by mankind for the cure and treatment of various diseases and are still popular to a large extend. *Justicia adhatoda* has been used to treat respiratory and other allergic conditions since years. Vasicine is the main active ingredient of *Justicia adhatoda*. It has been used in the ayurvedic system of medicine in the treatment of various ailments of respiratory tract both in children and adults. Juice of Adulsa is generally recommended for use. Formulations containing *Justicia adhatoda* are available in the market, which are syrups or liquid orals. Lozenges are palatable solid unit dosage form administrated in the oral cavity. The study aims in formulation and evaluation of sweet hard candy lozenges using medicinal plant extract especially for administration to pediatric patients for better patient compliance using juice of vasaka leaves.

Keywords: Asthma, Traditional medicines, *Justicia adhatoda,* Vasicine

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INTRODUCTION

WHO estimates that 235 million people currently suffer from asthma. Asthma is the most common chronic disease among children. Ashtma is a public health problem not just for high-income countries; it occurs in all countries regardless of the level of development. Most asthma-related deaths occur in low and lower-middle income countries. India has an estimated 15-20 million asthmatics and between 10% and 15% in 5-11year old children. Herbal medicines remain the major source of health care for the world's population. WHO has recognized herbal medicine as an essential building block for primary health care for vast countries like India. A large population in India suffers from asthma, concerning is the population of children that suffer. Appropriate management of asthma can enable people to enjoy a good quality of life.

Ayurveda is a long standing tradition that provides a systematic approach to asthma management through proper medication and care. Ayurveda refers to bronchial asthma as *Tamaka Swasa* and contributes several modalities of treatment for the same. Polyherbal combinations are well-accepted, safe and effective in asthma. Ayurveda prescribes various herbs and minerals in the form of various formulations like asava arishta, churna, paka, arka, leha, avaleha, gutika, vati, taila, ghrita, bhasma, etc.

Many pediatric and geriatric patients are unwilling to take conventional solid preparations like tablets and capsules due to fear of choking because of its bigger size, swelling discomfort, in case of dyspepsia and because of the need of water for administration. In case of liquid oral preparations, there is high incidence of noncompliance and ineffective therapy in pediatic patients. Intravenous route is highly non acceptable to pediatric patients due to pain during administration. Pediatric and geriatric patients differ from adults in many aspects of pharmacotherapy, including capabilities for drug administration, medicine related toxicity, and taste preferences. Hence, pediatric and geriatric medicines are formulated to best suit the patients age, size, physiologic condition, and treatment requirements.

In spite of all its disadvantages, oral route still remains the most preferred route because of ease of ingestion, pain avoidance and versatility ease of administration to pediatric, geriatric and neurodegenerative disease patients, local action, rapid release products and buccoadhesive systems -to release drug in controlled fashion. Novel drug formulations that can be administered orally include lozenges, granules, oral dispersible tablets, oral film strips etc. Such developments have enabled greater dose flexibility, easier administration, and better acceptance of drug formulations in children for various chronic conditions

Approaches in formulating novel herbal drug formulations that are easy to administer for chronic use that overcome side effects of synthetic drugs is the need of time. Appropriate management of asthma can enable people to enjoy a good quality of life. Asthma is treated with short acting (Salbutamol/Albuterol, Terbutaline, Aminophylline, Theophylline) and long acting reliever medication (Salmeterol, Formoterol, Tiotropium) specifically designed to relieve asthma symptoms by relaxing the muscle cells that surround the airways and preventer medications (Beclomethasone, Montelukast, Fluticasone, Mometasone, Zafirlukas, Cromoglycate, Cromogen, Nedocromil) most commonly steroid inhalers. Inhalers, nebulizers, steroid tablets are the mode of drug delivery to asthmatics which are not convenient to pediatric and geriatric patients to handle, also dose variation may occur if not monitored properly. Many herbal drugs and herbal preparations have been used in the treatment of asthma. Other antiasthamtic herbal drugs *include Tylophora indica, Allium cepa, Bacopa monniera,Butea frondosa, Adhatoda vasic, Tinospora cordifolia, Vitex nigundo* etc.

Justicia adhatoda has been used to treat respiratory and other allergic conditions since years. It has been shown to treat many other diseased conditions like diabetes, ulcer etc. Vasicine is the main active ingredient of *Justicia adhatoda*. It has been used in the Ayurvedic system of medicine in treatment of various ailments of respiratory tract both in children and adults. All parts of the plant have been used for its therapeutic beneficiary effect from ancient times T he invention aims in formulation of sweet hard candy lozenges using medicinal plant extract/s especially for administration to pediatric patients for better patient compliance using juice of vasaka leaves. There are different kinds of Lozenges like

1. Medicated lozenges

Based on manufacturing

A) Hard candy lozenges

i) Center filled hard candy lozenges: Liquid filled/Fruit centers/Paste centers/Fat centers

ii) Chewy or caramel base medicated tablets: Caramels/Toffees

B) Compressed lozenges

i) Tablets compressed in weight range of 1.5- 4 g

Large in diameter and having desired area of activity on mucous membrane and mouth.

2. Non medicated lozenges

i) Sugar candies,

ii) Lollypops

METHODOLOGY AND RESULTS

Dosage formulation-

Melting and Molding technique was used for the preparation of lozenges. Sugar and corn syrup were melted and mixed with other ingredients like PEG 400 which resulted in formation of a homogenous mixture. Adulsa aqueous extract was poured into it along with ginger juice as flavouring and taste masking agent. Finally, this mixture was poured into the silicone mould.

S.N.	Ingredients	Quantity for one lozenge
1	Sugar	69%
2	Corn Syrup	23%
3	Adulsa aqueous extract	5 %
4	Ginger juice	2%
5	PEG	1%

Macroscopical evaluation-

For determination of organoleptic properties of the formulation, it was evaluated based on its visual observation.

S.N.	Parameters	Observations
1	Colour	Dark Brown
2	Odour	Ginger flavour
3	Taste	Sweet and spicy
4	Texture	Smooth and transparent
5	Shape	Round

Evaluation of lozenges:

Average weight and Weight variation test: Twenty lozenges were weighed collectively and individually on a pan balance and average weight was calculated. Not more than two lozenges deviated from the standard weight of 2500 mg. Weight variation was found to be 2.46±0.002%

Hardness: To evaluate the diametrical crushing strength, 3 lozenges from each formulation were tested using a MAC hardness tester Hardness was found to be 11.04± 0.115 Kg/cm2

Friability: The friability of the 20 lozenges from each batch was tested, at a speed of 25 rpm for 4 min. The lozenges were then de-dusted, reweighed and percentage weight loss was calculated by the equation. % friability was 2.87±0.055%.

% Friability = (initial Wt.- Wt. after friability) × 100 / initial Wt

Determination of Physical parameters of Vasaka

Measurement of the total amount of substance remaining after its ignition is known as the total ash method which includes physiological ash (obtained from plant tissue) and non- physiological ash (derived from extraneous matter residue like sand), extractive value, foreign organic matter etc

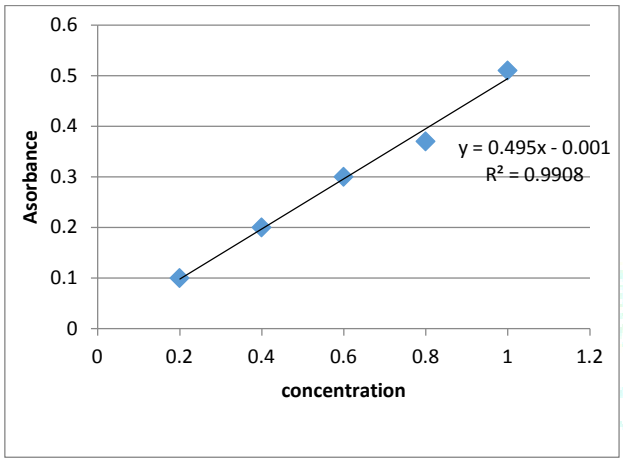
Physical Parameter	Observation
Colour (Extract)	Yellowish brown
Odour (Extract)	Characteristic bitter
Ash values (%)	
Total ash	17
Acid insoluble ash	0.93
Water soluble ash	4
Extractive values (%)	
Water soluble	23
Alcohol soluble	3.6
Chloroform soluble	1.2
Petroleum ether soluble	0.91
Total contents	
Foreign Matter	0.6 %
Total yield of extract	13.4%
Qt. Of Jucie obtained	26ml/100g
Total alkaloids	5.23 ± 0.25 mg/ml

Determination of moisture content:

Moisture content is the ratio of mass of water in a sample to the mass of solids in the sample expressed as a percentage. For the determination of this parameter, the weighed amount of the formulation was kept in hot air overnight at 110 degree centigrade and calculation of moisture content was carried out.

S.N.	Dosage form	Moisture content
1	Lozenges	3.2%

Total Alkaloid content: The total alkaloids are responsible for the anti-asthmatic and mucolytic activity and hence total alkaloid concentration is crucial. The total alkaloid content was estimated using vasicine as standard. Calibration curve was obtained by serial dilution of vasicine in saline and noting the absorbance at 281nm for standard as well a sample. The Total Alkaloid content was found to be 5.23 ± 0.25 mg/ml of the juice of vasaka

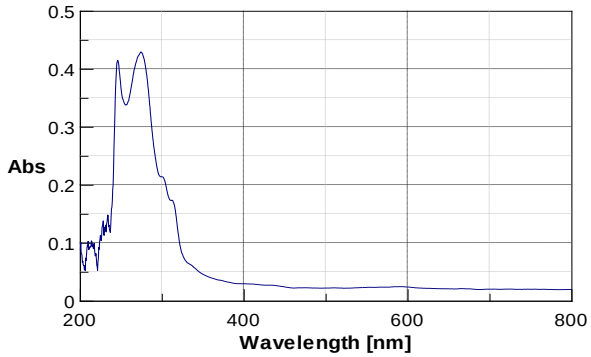


Thin-Layer Chromatography (TLC)-

TLC is a method of separation or identification of a mixture of components into individual components by application of finely divided adsorbent. This technique is widely used for evaluation of herbal materials as the instruments required are inexpensive and it is easy to perform. Rf values of 0.7 and 0.8 confirm presence of Vasicine and Vasicinone respectively.

UV Spectrophotometry-

The total alkaloids liberated after extraction using an aqueous base was screened to detect the presence of vasicine at 276 nm



CONCLUSION

Vasaka has proven bronchodilator activity. In Ayurveda, the *swarasa* or juice of Vasaka leaves are administered for respiratory conditions. There are many liquid oral formulations available in market containing Vasaka and other related compounds. But, the solid oral formulations are still the most preferred formulation. Variation in dose is the major drawback of liquid oral syrups. Also, they are messy to administer and self administration is difficult. Thus, herbal lozenges are formulated from aqueous extract of Vasaka with bitter taste masked with sugar and flavoured with ginger extract, easy for paediatric patients to administer. It can also be an ideal choice for travelling patients as it eliminates the need of water for its administration. As Vasaka is a single component in the formulation, the standardization is easier. The cost of the formulation is reduced as it is easy to manufacture this formulation on a large scale.

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Conflicts of interest

The authors confirm that this article content has no conflicts of interest.

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