

Available online on 15.04.2019 at <http://jddtonline.info>

Journal of Drug Delivery and Therapeutics

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Research Article

Formulation and evaluation of Vasaka granules for asthma

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ABSTRACT

Asthma is a chronic disease of bronchi which usually requires continuous medical care. Approaches for drug formulation that easy to administer especially for chronic diseases can form valuable therapy. Adhatoda vasica is a plant believed to have several therapeutic effects including antiasthmatic properties. It is the leaves, which are of great importance for asthma. Adhatoda vasica belongs to the family Acanthaceae, it is found mainly in India. It is also called as vasaka. Vasaka herb is used for treating cold cough and asthma. It is a well-known ayurvedic medicine for expectorant and helps to ease out the phlegm. Vasaka leaves contain quinazoline alkaloids such as vasicinone, vasicine, vasicinol, vasicol. Granules can be used for the treatment of asthma as they offer advantages such as faster disintegration and dissolution as compared to tablet capsules.¹

Keywords: vasicinone, vasicine, vasicol, Acanthaceae, Adhatoda

Article Info: Received 24 Feb 2019; Review Completed 30 March 2019; Accepted 05 April 2019; Available online 15 April 2019



Cite this article as:

Bangar MS, Balsaraf CD, Ms. Dhamdhare SK, Patel SG, Jadhav SL, Gaikwad DD, Formulation and evaluation of Vasaka granules for asthma, Journal of Drug Delivery and Therapeutics. 2019; 9(2-s):296-299
<http://dx.doi.org/10.22270/jddt.v9i2-s.2526>

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1. INTRODUCTION

Asthma is thought to be caused by a combination of genetic and environmental factors. Diagnosis is usually based on the pattern of symptoms, response to therapy over time, and spirometry. There is no cure for asthma. Symptoms can be prevented by avoiding triggers, such as allergens and irritants, and by the use of inhaled corticosteroids. Asthma attacks all age groups but often starts in childhood. Asthma is a chronic disease characterized by recurrent attacks of breathlessness and wheezing, which vary in severity and frequency from person to person.^{1,2,3}

Bronchodilators are recommended for short-term relief of symptoms. In those with occasional attacks, no other medication is needed. If mild persistent disease is present (more than two attacks a week), low-dose inhaled corticosteroids or alternatively, a leukotriene antagonist or a mast cell stabilizer by mouth is recommended. During an asthma attack, the lining of the bronchial tubes swells, causing the airways to narrow and reducing flow of air into and out of the lungs.



Figure 1: Vasaka leaves

The medicinal herb expands the airways and provides great relief to the bronchitis patients. The active chemical constituents present in vasaka leaves are quinazoline, vasicinone, vasicine, vasicinol, vasicol, vasicinone, adhatodine and 6-hydroxyl vasicine¹ as they offer advantages such as faster disintegration and dissolution as compared to tablets and capsules, palatable as compared to syrups and decoctions, greater acceptability in pediatrics

and geriatrics due to lesser risk of choking, time and cost required for their manufacture is lesser as compared to tablets.

2. MATERIALS AND METHODS

2.1 Preparation of Vasaka powder

Vasaka leaves were collected and authenticated from Botanical Survey of India (BSI). Leaves were chopped and subjected to grinder and finely powdered and passed through sieve no.44. The fine powder is then used for preparation of granules by wet granulation method.

2.2 Selection of excipients

Starch was chosen as disintegrant, calcium phosphate dibasic and talc as bulking agent, magnesium stearate as antiadherent, coloring agent to impart colour, PVP-K 30 as a binder and methyl and propyl parabens as preservatives. To

mask the extreme bitter taste of Vasaka, sodium saccharine and mannitol was used as sweetener, citric acid as taste masker and for flavoring raspberry flavor was used. The coloring and flavoring agents used were of food grade quality.^{4,5}

2.3 Preparation of Granules

Formulation Table

Granules were prepared by using wet granulation technique. Vasaka powder and citric acid were mixed in a mortar to which sodium saccharine, mannitol and Raspberry flavor were added. This was followed by subsequent addition of starch, talc, calcium phosphate dibasic and the parabens. Sufficient quantity of distilled water was added to form a lumpy mass which was then passed through sieve no. 22 to form granules. Granules were dried in the oven. Magnesium stearate was added at the end.⁶

Table 1: Formulation

S.N.	Ingredients	Category	F1(mg)	F2(mg)	F3(mg)	F4(mg)
1	Vasaka	Antiasthmatic	125	125	125	125
2	Starch	Disintegrant	150	150	150	150
3	Magnesium stearate	Antiadherent	2.5	2.5	2.5	2.5
4	Calcium phosphate dibasic	Bulking agent	250	250	250	250
5	Mannitol	Bulking agent	300	300	300	300
6	Citric acid	Taste masker, Sialagogue	110	110	110	110
7	Methyl paraben	Preservative	3	3	3	3
8	Propyl paraben	Preservative	0.5	0.5	0.5	0.5
9	Raspberry flavor	Flavoring agent	0.01	0.01	0.01	0.01
10	Sodium saccharine	Sweetening agent	1.49	1.49	1.49	1.49
11	Talc	Sweetening agent	30	31	35	34
12	Color	Coloring agent	2.5	2.5	2.5	2.5
13	PVP-K-30	Binder	25	24	20	21
TOTAL			1000 mg	1000 mg	1000 mg	1000 mg

Table 2: Formulation

S. N.	Ingredients	F5(mg)	F 6(mg)	F 7(mg)	F 8(mg)	F 9(mg)
1	Vasaka	125	125	125	125	125
2	Starch	150	150	150	150	150
3	Magnesium stearate	2.5	2.5	2.5	2.5	2.5
4	Calcium phosphate dibasic	250	250	250	250	250
5	Mannitol	300	300	300	300	300
6	Citric acid	110	110	110	110	110
7	Methyl paraben	3	3	3	3	3
8	Propyl paraben	0.5	0.5	0.5	0.5	0.5
9	Raspberry flavor	0.01	0.01	0.01	0.01	0.01
10	Sodium saccharine	1.49	1.49	1.49	1.49	1.49
11	Talc	38	40	36	33	32
12	Color	2.5	2.5	2.5	2.5	2.5
13	PVP-K-30	17	15	19	22	23
TOTAL		1000 mg	1000 mg	1000 mg	1000 mg	1000 mg

2.4 Evaluation of granules

2.4.1. Angle of Repose

The angle of repose is the angle formed by the horizontal base of the bench surface and the edge of a cone-like pile of granules. After the cone from 5 g of sample was built, height of the granules forming the cone (h) and the radius (r) of the base were measured. The angle of repose (θ) was calculated as follows:

$$\theta = \tan^{-1} (h/r)$$

$$\theta = \tan^{-1} (1.2/3.1)$$

$$\theta = 21.15^\circ$$

Results were only considered valid when a symmetrical cone of powder was formed. The funnel method was used to perform the test⁶. (Table 3)

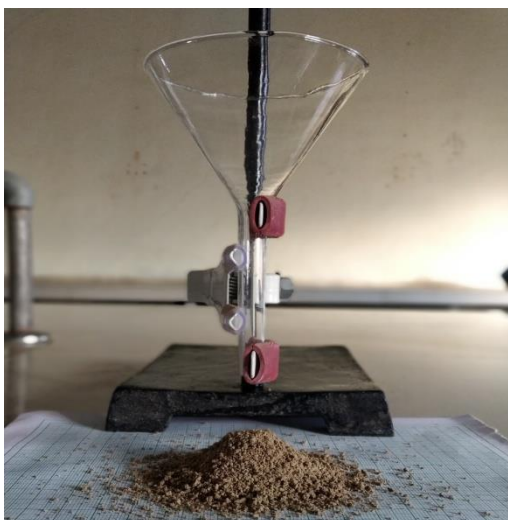


Figure 2: Angle of repose

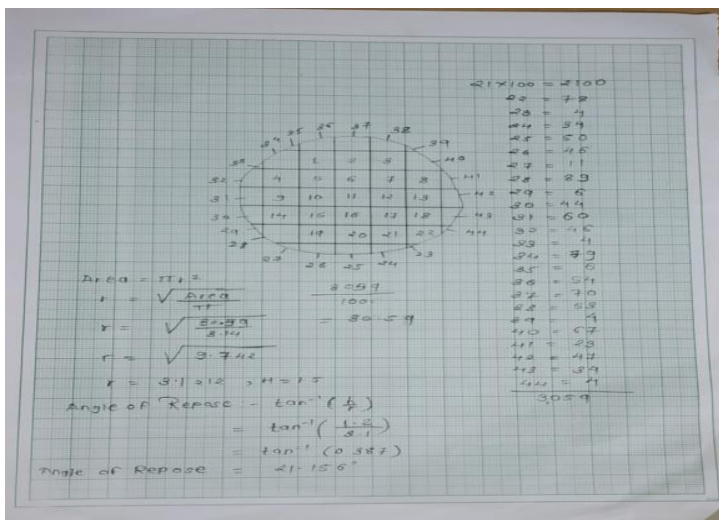


Figure 3: Angle of repose (θ)

2.4.2. Bulk density

It is the ratio of total mass of powder to the bulk volume of powder.

$$D_b = m / V_o$$

Where, m: Mass of the blend=20gm

V_o: Untapped Volume=45ml

A graduated glass cylinder was used to perform the test 7. (Table 3)



Figure 4: Bulk density

2.4.3. Tapped Density

Tapped density is the ratio of mass of powder to the tapped volume. Tapped volume is the volume occupied by the same mass of the powder after a standard tapping of a measure.

$$D_t = m / V_i$$

Where, m: Mass of the blend.=20gm

V_i: Tapped Volume=40ml

Graduated glass cylinder was used for the test which was subjected to 50 tappings and the volume was noted (Table 3)



Figure 5: Tapped density

2.4.4. Loss on drying

This test was performed by drying a weighed quantity of the product in the oven at 105 °C until constant weight was obtained. (Table 3)

Table 3: Results for angle of repose, bulk and tapped density, % LOD.

Formula	Angle of repose	Bulk Density	Tapped density	% of LOD
F9	21.15°	0.444gm/ml	0.5gm/ml	0.12

3.1 Drug profile

Vasaka was chosen as the drug as it is easily available, perennial plant and the collection is easier. It also has a well-established pharmacological profile proving its antiasthmatic activity. Vasicine (quinazoline alkaloid) is mainly responsible for the bronchodilatory and mucolytic effects of the drug. This formulation is mainly intended for pediatric and geriatric use hence, the dose of the drug is taken to be 125 mg. The dose has been fixed in reference to commercially available dosage forms of Vasaka which recommends number of tablets or teaspoons of syrup that correspond to 125mg of the drug for pediatric use.

3.2 Excipient profile

Starch takes up water from the body fluids which cause it to swell and thereby leading to disintegration of the granules. Calcium phosphate dibasic and mannitol were used as bulking agents. Mannitol also aids in faster disintegration and acts as a non-calorific sweetening agent. Magnesium stearate helps to prevent attrition between the granules and formation of fines. Methyl and propyl parabens are nontoxic, non-irritating and are used in combination to prevent decomposition of the formulation. Citric acid helps to stimulate salivary secretions and hence leading to disintegration of the granules in the oral cavity, thereby obviating the need to consume water along with the formulation. Hence, it can be conveniently used by travelling patients. Sodium saccharine and the flavoring agent help to mask the bitter taste of Vasaka.

3.3 Angle of repose, bulk and tapped density and % LOD

The values of angle of repose are below 30° thereby indicating excellent flow properties. Lower values of bulk and tapped density indicate higher porosity. % LOD test values comply with the official limits and indicate lower moisture content in the formulation.

RESULTS AND DISCUSSION

Table 4: Results

S. N.	Parameters	Observation
1	Appearance	Solid
2	Colour	Brick red
3	Odour	Pleasant
4	Shape of granules	Spherical
5	Bulk Density	0.444gm/ml
6	Tapped density	0.5 gm/ml
7	Hausners ratio	1.13
8	Carrs compressability index	12.1%
9	Angle of repose	21.15°
10	%LOD	0.12%

4. CONCLUSION

Drugs like Vasaka have proven bronchodilatory activity. According to Ayurveda, the swarasa or juice of Vasaka leaves is administered for respiratory conditions. Many liquid oral formulations such as syrups and other formulations such as tablets, capsules and lozenges of Vasaka are available in market. The solid oral formulations are not readily accepted by pediatric and geriatric patients due to the fear of choking whereas the variation in dose and sugar content in liquid formulations is of concern. Thus, herbal granules formulated from dried aqueous extract of Vasaka have good flow properties, greater palatability and disintegrate within 20 seconds in the oral cavity without the use of water. Hence, it can be widely accepted by pediatric and geriatric patients. It can also be an ideal choice for travelling patients as it obviates 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.

ACKNOWLEDGEMENT

Authors are thankful to Principal Dr. S.L. Jadhav, Dr. D.D. Gaikwad, Mr. S.G. Patel and VJSM'S Vishal Institute of Pharmaceutical Education And Research, Ale, Pune for providing all the necessary facilities and guidance to conduct the said work.

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