



FORMULATION AND EVALUATION OF PHARMACEUTICAL POLYHERBAL PILL FOR THE TREATMENT OF MOUTH ULCER CONTAINING *GLYCYRRHIZAE GLABRA*, *FOENICULUM VULGARE* AND *CURCUMA LONGA*

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ABSTRACT

Oral health is a key indicator of overall health, well being and quality of life. Mouth ulcers are small sores that form on your lips, gums, inner cheeks, tongue or palate. They are painful and can be extremely uncomfortable and make it difficult for some people to eat, drink, and brush their teeth. They can be triggered by several different factors including minor injuries, hormonal changes, emotional stress, vitamin deficiencies, viral and bacterial infection. There are chances of occurrence of multiple mouth ulcers at same time at different locations. So the objective of this study was to develop and evaluate a herbal pill combining the powders of Licorice, Fennel and Turmeric to treat the mouth ulcers occurring at different location. Herbal pills were formulated using Hand Rolling method. While evaluating the pills weight variation, friability, hardness, disintegration and swelling index were determined. Herbs are a completely natural approach for prevention and treatment with lesser side effects.

KEYWORDS: Licorice, Fennel, Turmeric, Evaluation

INTRODUCTION

A mouth ulcer is the loss or erosion of the delicate lining tissue of the mouth (mucous membrane). They are small sores that form on gums, lips, inner cheeks or palate (roof of mouth). They're usually yellow or red, and they can be quite painful. Mouth ulcers are also called as aphthous ulcers. . They are painful and can be extremely uncomfortable and make it difficult for some people to eat, drink, and brush their teeth. They can be triggered by several different factors including minor injuries, hormonal changes, emotional stress, vitamin deficiencies, viral and bacterial infection.

Although many formulations like gels, creams, suspension, mouth wash, tablets are commercially available, no therapy can be said completely useful for the treatment of mouth ulcers. There are chances of occurrence of multiple mouth ulcers at same time at different locations. The herbal pills were formulated to treat the mouth ulcer. In comparison to different dosage forms the pills are cheap and can be easily formulated. Chitosan used in the formulation possesses antibacterial as well as mucoadhesive activity, which will facilitate rapid release of drugs at the site of absorption and hence the better bioavailability of drug.

Glycyrrhiza glabra, Foeniculum vulgare, Curcuma longa and Chitosan are known to have wound healing, anti-bacterial, soothing, cooling activities can be effective in the treatment of mouth ulcers. The more acceptable remedies are they are natural that they are safer and lesser side effect than the synthetic medicines. Now a day the demand of the herbal remedies have increasing in the world market. The aim of this study is to formulate and evaluate polyherbal pills for the treatment of mouth ulcers.



Fine powders of medicinal drugs are mixed with water or honey, to make a soft mass. Blending of this mass by mechanical machines or by hands in circular form is called as pills. Pills are cheap in comparison to different dosage form. Patients are more compliance because they are easy to carry.



FIG 1

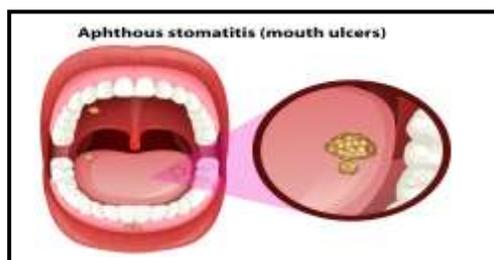


FIG 2

MATERIAL AND METHOD

TABLE 1: Formulation of pills

Sr. No	Each pill contains Components	Amount
1.	Liquorice powder	3 gm.
2.	Fennel powder	3 gm.
3.	Turmeric powder	1 gm.
4.	Chitosan	1 gm.
5.	Gum tragacanth	0.5 gm.
6.	Honey	qs.

Method

Weigh all the ingredients separately. Liquorice, Fennel, Turmeric, Chitosan, Gum tragacanth. Add them in the mortar and triturate them with the help of pestle until the fine powder is formed. Pass them through the sieve no. 80 sieve. Then collect the fine powder and add into the china dish. Mix honey according to the need, and form the dough The pills are prepared using mechanical machine or with the help of Hand Rolling method. Dry the pills under the sunlight. Store them in the well closed container.

TABLE 2: List of material and their purpose:

Materials	Purpose
Glycyrrhiza glabra (Liquorice)	Lubricate and sooth irritate mucous membrane
Foeniculum vulgare Miller (Fennel)	Cooling effect and helps in digestion
Curcuma longa (Turmeric)	Antimicrobial and Antiseptic
Chitosan	Mucoadhesion, antiulcer activity
Gum tragacanth	Antibacterial, binding agent
Honey	Wound healing property

TABLE 3: List of equipments:

Instrument
Weighing balance
Sieving machine
Monsanto Hardness Tester
Roche friabilator
Disintegration tester
Hot air oven



PREFORMULATION STUDIES

1. Organoleptic evaluation

Organoleptic characters such as colour, odour, taste was observed

2. Angle of repose

The flow properties of the powder in the formulation were determined by calculating the angle of repose by the fixed height method. A glass funnel with 10 mm in diameter of the bottom was fixed at the height of 2 on over the plain and smooth flat surface. About 10 gm. of a sample was passed from funnel until the tip of the pile formed and touches the bottom of the funnel. A rough circle drawn around the pile base, and the radius of the powder cone was measured. Θ was calculated by the average radius. Formula for the calculation of angle of repose is as follows:

$$\tan \Theta = h/r$$

Where,

Θ = Angle of repose

h = Height of the pile

r = Average radius of the powder cone

3. Bulk Density

The bulk density (BD) of the powder mixture was determined by pouring gently 8.5gm of sample mixture through a glass funnel into a 100 ml graduated cylinder. The initial volumes occupied by the sample were recorded. The bulk density was calculated by using the following formula given as:

$$\text{Bulk Density} = \frac{\text{Weight of the powder}}{\text{Volume of packing}}$$

4. Tapped density

The tapped density (TD) of the powder mixture was determined by pouring gently 8.5gm of sample mixture through a glass funnel into a 100 ml graduated cylinder. The cylinder was tapped from the height of 2 inches until a constant volume obtained and then the average value of all formulation reported. The final volumes occupied by the sample after tapping were recorded and tapped density calculated by using the formula given.

$$\text{Tapped Density} = \frac{\text{Weight of the powder}}{\text{Tapped volume}}$$

5. Hausner's ratio

The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material.

Hausner's ratio can be calculated by following formula

$$\text{Hausner's ratio} = \frac{\text{Tapped volume}}{\text{Bulk volume}}$$

6. Moisture content

2gm powder is weighed (w) and placed in porcelain dish. Weight of powder + porcelain is recorded (w_1). Porcelain containing powder is placed in hot air oven at 105° c. Weigh the porcelain with dried powder (w_2). % moisture content = $(w_1 - w_2) / w * 100$. Loss on drying is determined

EVALUATION OF PILLS

1. Morphological Evaluation

Colour, odour, taste was observed

2. Hardness

Monsanto hardness tester was used to evaluate hardness of pill. The tester consists of a barrel containing a compressible spring held between 2 plungers. The lower plunger was placed in with the tablet, and a zero reading was taken. The upper plunger was forced against a spring by turning a threaded bold until the pill fractures. As the spring compressed a pointer along with a gauge in the barrel to indicate the force. The force of fracture was recorded, and the zero-force reading was deducted from it. 10 pills of formulation are evaluated.



3. Friability

Roche friabilator was used to determine friability of the pills. Twenty prior weighed pills were placed in friabilator, which was then operated for hundred revolutions. The pills were then dedusted and reweighed. The friability was computed by formula as followed

$$F = \frac{(1-W_2) \times 100}{W}$$

4. Disintegration Time

From each formulation 3 pills were randomly selected to determine the disintegration time. The buffer (PH 6.8) was used as disintegration medium and temperature was maintained at normal body temperature that is 37 ± 0.5 °C. The disintegration time of 3 pills was noted down and average disintegration time was calculated.

∴ Avg disintegration time = 29 mins

5. Weight Variation Test

Twenty pills were selected randomly. Pills were weighed and average weight was calculated. The percentage deviation was computed.

Avg weight = 250mg

6. Mucoadhesion Test

Chitosan added in the formulation shows antibacterial activity as well as mucoadhesive activity. It inhibits the growth of both Gram-positive and Gram-negative bacteria. By using mucoadhesive approach the pills will produce prolong and local action. For the evaluation of mucoadhesive approach we determined swelling index of the pills.

Swelling index.

Method

Step1. Preparation of phosphate buffer of PH 6.8:

Step 2 Preparation of agar gel.

Step 3 Setting of agar gel.

Step4 Take the initial weight of the pill.

Step5 Place the pill in the agar gel.

Keep the pill on the surface of the gel for 60 min.

And then determine the final weight of the pill.

$$\text{Swelling index} = \frac{W_1 - W_2}{W_1} \times 100$$

RESULT AND DISCUSSION

W_2

TABLE 5

CHARACTERIZATION OF POWDER		
Sr.No	Parameter	Observation
1.	Organoleptic Character i. Colour ii. Odour iii Taste	Light brown Aromatic Aromatic
2.	Angle of Repose	Passable
3.	Bulk density	0.34gm/ml
4.	Tapped density	0.425gm/ml
5.	Hausner's ratio	1.25
6.	Moisture content	0.456%

**TABLE 6**

CHARACTERIZATION OF HERBAL PILL		
Sr. no.	Parameter	Observation
1.	Morphological evaluation i. Colour ii. Odour iii. Taste	Deep Brown Aromatic Aromatic
2.	Hardness	2kg/cm ²
3.	Friability	Passes
4.	Weight variation	4.44 %, pass
5.	Disintegration	29 mins
6.	Swelling index	162%

SUMMARY AND CONCLUSION

Herbal therapy is a Holistic therapy, integrating emotional, mental and spiritual levels. Life style, emotional, mental and spiritual considerations are part of any naturopathic approach. The use of herbs does not generally involve “drug” actions or adverse effects. Although medicinal plants are widely used and assumed to be safe, however, they can potentially be toxic. There are some “drug like” plant remedies that their actions approach that of pharmaceuticals. Modern medicines recognize herbalism as a form of alternative medicine. Modern medicine does make use of many plant derived compound as the basis for pharmaceutical drugs. Most herbs are safe to use but there are some herbs that should only be used by a professional practitioner. In this study, pills were formulated using powders of liquorice, fennel, turmeric using gum tragacanth and honey as binder. Chitosan shows antibacterial and mucoadhesive action. Also, the quality control tests of pills were done according to the set of criteria of IP and the obtained results were found to be within the specified limits of each test.

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