

Formulation and Evaluation Syzygium Aromaticum Containing Nutraceutical Tablet Clove

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ABSTRACT: Today's age has anticipated the importance of herbal formulations in the treatment of various diseases comprising from major to minor ailments. The importance of these herbal development industries has immensely gained momentum due to the underlying side effects associated with allopathic medicines ranging from minor problems such as ulcerations to major life threatening problems such as growth retardation. In the present research studies the aim was to develop oral herbal tablets from Clove and cinnamon plant and perform its evaluation as per ICH guidelines. The eugenol was extracted by ethanol and water using assisted ultrasonication extraction process. Wet granulation method was used for the development of oral herbal tablets. The developed herbal tablets were evaluated by parameters such as general appearance, hardness, friability, disintegration time and dissolution profile as per ICH guidelines at different temperatures and humidity. The developed herbal tablets showed decent elegance and palatability followed by good hardness, friability, disintegration time and dissolution characteristics..

KEYWORDS: Clove, Cinnamon, nutraceutical, ICH Guideline.

I. INTRODUCTION

Traditional medicine has served as a folk medicine for Traditional healthcare medicine is a collection of knowledge, expertise, and practices based on indigenous concepts, opinions, and experiences from different cultures.

It is serves to maintain health, prevent, diagnose, improve, or treat physical and mental disorders, and is supported by literature and records of theoretical ideas and practical skills.⁽⁷⁾

Indian systems of medicine are unique and play an important role in the healthcare of the world

population. Indian physicians refer to medical practices that originated in India or were assimilated into Indian culture.

Oral route has been the most popular route of drug delivery because of its ease of administration, least sterility constraints patient compliance, and flexible design of dosage form.⁽¹³⁾

Tablets are well-defined as the unit dose, temper evident solid preparations containing one or more active ingredients with excipients.

Tablet is the most popular among all dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing.

There are novel types of dosage forms that act very quickly after administration.

Conventional drug delivery systems like tablets and capsules often dissolve quickly in the gastrointestinal tract for absorption into the bloodstream which gives rise to inordinately high drug concentrations in plasma.⁽²⁾

Natural components or health-promoting elements that may improve the body's health are found in nutraceuticals. A substance derived from food that is usually marketed in pharmaceutical forms unrelated to food is called a nutraceutical. Anything that benefits the body or guards against chronic illness is considered a nutraceutical.⁽³⁾

Nutraceuticals, a combination of the word's "nutrition" and "pharmaceuticals," refer to dietary supplements that provide medical or health benefits. The nutraceutical industry has experienced rapid growth in recent years, driven by increasing consumer demand for natural health products.⁽¹⁾

Depending on their focus, nutraceuticals typically include the necessary amounts of fats, protein, carbs, vitamins, minerals, and other essential nutrients. Both traditional and non traditional meals can be found in the market for nutraceuticals. The

nutrients in a supplement tablet must be broken down and absorbed by the body. Nutraceuticals can encompass a wide range of goods, such as processed foods, dietary supplements, herbal items, and isolated nutrients. Patients' increasing disdain of synthetic medicinal drugs and how they impact their toxicological profile created the "Dietary Supplements Health and Education Act" (DSHEA) in the United States of America in 1994. The idea behind the nutraceutical dosage form's mode of action is to increase the availability of natural building blocks in order to give functional benefits. It functions in two ways. That is, to reduce the symptoms of sickness or to enhance bodily functions.⁽⁶⁾

Herbs such as cloves & cinnamon have been traditionally used in Ayurvedic medicine to promote overall health and wellness. These herbs are rich in bioactive compounds, including alkaloids, glycosides, and phenolic acids, which have been shown to possess antioxidant, anti-inflammatory, and immunomodulatory properties.

Clove and cinnamon centuries, addressing both infectious and non-infectious diseases. Antioxidants are man-made or natural substances that may prevent or delay some types of cell damage. Antioxidants are found in many foods, including fruits and vegetables. The objective of this study is to formulate a nutraceutical tablet using a blend of herbal ingredients, including cloves, cinnamon and other excipients⁽⁸⁾

Herbal Formulation

We are using combination of herbal drugs which are clove and cinnamon.

Plant clove

Eugenia caryophyllus flower buds from the **Mortgagee** family are dried and used to make cloves. The cloves become a perfect red or brownish-black color after drying. Clove is used as a dental analgesic, stimulant, carminative, flavoring, and antimicrobial⁽⁶⁾

Synonyms : *Eugenia caryophyllus*

Chemical constituents:⁽⁶⁾

Clove buds contain 15–20% essential oil, which is dominated by eugenol (70–85%), eugenyl acetate (15%) and β -caryophyllene (5–12%). Other essential oil ingredients of clove oil are vanillin, crategolic acid, tannins, gallotannic acid, methyl salicylate, flavonoids eugenin, kaempferol.

Plant Cinnamon⁽³²⁾

Cinnamon is made from the dried inner bark of the coppiced Cinnamon zeylancium Nees tree shoots. Bark has mild carminative, stomachic, and astringent qualities. It has been used as an expectorant and a demulcent. Additionally, it has antispasmodic qualities. Diabetes, cancer, heart disease, and high blood pressure are among the major illnesses that nutraceuticals have been associated with preventing and/or treating.

Synoname : Cinnamon zeylancium

Chemical constituents:⁽³²⁾

Cinnamon's phytochemical composition :

1. **Cinnamaldehyde:** A key ingredient that gives cinnamon its flavor and scent.
 2. **Cinnamic acid:** An anti-inflammatory and antioxidant phenolic molecule.
 3. **Eugenol:** An antibacterial and anti-inflammatory phenolic molecule. Proanthocyanidins are a kind of flavonoid that has anti-inflammatory and antioxidant qualities.
- Flavonoids:** A group of substances that have anti-inflammatory and antioxidant qualities.

Material and their methods of extraction :

Clove Bud:



- Collect the dried clove bud from *Eugenia caryophyllus* flower
- Wash the clove bud thoroughly under running water to remove any dirt or debris.
- Pat the bud dry using clean towel or paper towel
- Using a clean and dry grinder grind the dried bud- into fine powder. You may need to grind it in batches if you have a large quantity.
- Sieve the powder using fine mesh sieve.
- Transfer the powder to an airtight container.

Extraction of Syzygium aromaticum from buds



FigureNo1.6:Extraction Of Syzygium aromaticum bud by Ultra-Sonication

Method

Fresh clove buds were collected, dried in sunlight and grinded into a powder form 50 gm clove powder was weighed and mixed with 100 ml ethanol in extraction vessel.

Mixture use kept on ultrasonic bath, temperature was maintained at 90 0 C.

The ultrasonic waves helped to breakdown the plant cells and release the desired

compound into the solvent. Process was carried out for 120 mins. Mixture was filtered to separate the solvent and extract. Clove oil was separated from the extract by using separating funnel.

II. EXPERIMENTAL WORK

Collection, Drying and Processing of Plant Material

Collection and Preparation of Plant Material

The fresh fruits of Syzygium aromaticum and Cinnamomum Zeylanicum were collected from the Sawantwadi local market in the month October-November 2024 and shade dried.

Drying and Cleaning

Plant material was dried at room temperature and clean the plant material to remove any debris or contaminants.

Morphological Characters of Plant Material

Morphological or organoleptic characters like shape, size, taste, odour, colour of the bud and powder of Syzygium aromaticum

SrNo	Materials Use	Roles	Quantity taken (for 500 mg)
1	Eugenol	API	0.3 ml
2	Cinnamon Powder	API	150 mg
3	Microcrystalline Cellulose	Binder	100 mg
4	Mannitol	Sweetner	10 mg
5	Starch	Disintegrant	100 mg
6	Crosspovidone	Disintegrant	50 mg
7	Talc	Lubricant	50 mg
8	Mg Sterate	Lubricant	10 mg

Preparation of granules⁽³³⁾

The wet granulation process was used to create the granules. By taking the proper amounts of Microcrystalline cellulose and dissolving it in distilled water, the slurry were made The drug powders i.e. Cinnamon powder and Mannitol, Starch, crosspovidone, powders—were put into a mortar along with the proper quantity of eugenol oil.

To make dough, the solution was added to the mixture and thoroughly combined. Then dough was passed through sieve number 10, which has a 710 µm mesh. Granules were then

dried in a hot air oven Granules were sized after drying by passing them through sieve number 18 then evaluate prepared granule

Evaluation of Powder blend

Precompression Parameters^(21,5)

a) **Bulk Density-** Bulk density is defined as the mass of the powder divided by the bulk volume and is expressed as gm/cm³.

Procedure: Accurately weighted amount of powder of 2.5cm at 2 second intervals on tapped density apparatus. The tapping was continued until no

further change in volume was noted. BD and TD were calculated using the following formulae

Bulk Density = Weight of Powder / Volume of Packing

Tap density is defined as mass of powder divided by tapped volume and is expressed as gm/cm³

b) Angle of repose -

Angle of repose is defined as the maximum angle possible between the surface of pile of sample and the horizontal plane. Inter particle force between particles are evaluated by angle of repose. It was measured by fixed funnel method.

Procedure: The fixed funnel method employs a funnel that was secured with its tip at height h, above graph paper that was placed on a flat horizontal surface. It was determined by allowing powder or granules to fall through funnel on to a paper to form a heap of height 1 cm, radius of circle considering approximately 90% of sample was drawn and it was calculated by following equation

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

Where;

h=height of the funnel

r= radius of the base of the pile

Table 1.6: Standard limit for Angle of Repose

Angle of repose	Powder flow
<25	Excellent
25-30	Good
>30-40	Passable
40	Very Poor

C) Compressibility Index

Compressibility index is an important measure. It is measured from bulk density and tapped density. It is the simplest measurement of flow property of the powder and indication of the ease with which a material can be induced to flow

is given by compressibility. The compressibility index of powder blend and granules was calculated by using following formula:

$$\% \text{ Compressibility index} = \frac{\text{tapped density} - \text{bulk density}}{\text{tapped density}} * 100$$

Table 1.7: Standard limit for Compressibility Index

% Compressibility Index	Type of Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-25	Poor
33-38	Very Poor
>40	Extremely Poor

d) Hausner's Ratio

Hausner's ratio is an indirect index of ease of powder flow. It is calculated by using following

formula.

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

Table 1.8: Standard limit for Hausner Ratio

Percent Compressibility	Flow of Powder
1 -1.2	Free Flow
1.2-1.6	Cohesive Flow

Preparation of tablet from granules⁽⁴⁾

Tablets were formulated as per the formulation is given in table. Each tablet was of 500 mg of the drugs and rest excipients.

The granules were mixed in appropriate quantities of magnesium stearate (as a lubricant & antiadherent) as given in Table These were then compressed into tablets by using Tablet punching machine. Three batches of tablets were obtained and subjected to evaluation.

Evaluation of prepared tablet^(29,5)

Prepared tablets were evaluated on the basis of following parameters

- a) **Thickness(mm)**-Tablet thickness is an important characteristic for size and appearance Thickness was measured using calibrated vernier calipers. Six tablets of each formulation were picked randomly and thickness was measured individually and average thickness was reported.
- b) **Weight Variation**-The tablet weight variation test was run by weighing 20 tablets individually. The average weight was calculated and compared with the individual tablet weight. The tablet meets the USP test, if not more than 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage.

Table 1.9: Standard limit for Average weight of a Tablet

Average weight of a Tablet	Percentage Deviation
130mg or less	±10
>130 mg or < 324mg	±7.5
324 mg or more	±5

b) Hardness(kg /cm²)

The tablet hardness, which is the force required to break a tablet. Barrel containing a compressible spring held between two plungers. The lower Hardness of tablets was tested using Monsanto hardness tester. The tester consists of a plunger is placed in contact with the tablet and a zero reading is taken. The upper plunger is then forced against a spring by turning a threaded bolt until the tablet fractures, and then the force of fracture was recorded. In all the cases average of six determinations were taken.

c) Friability (%)

Friability measures the tablet strength. Previously weighed 10 tablets were taken in a Roche friabilator and the friability was checked at 25 rpm for 4 minutes. Then the tablets were dusted and reweighed and the percentage of powder eroded during 4 minutes was recorded. Friability

was than calculated using the following equation,

F = (W (initial) – W (final) / W (initial) * 100 Where,
 W(initial) = Initial Weight of Tablet
 W (initial) = Final Weight of Tablet



c) Disintegration Test

The disintegration time was determined using disintegration test apparatus at 37±2°C. A tablet was placed in each of the six tubes of the apparatus and one disc was added to



Fig No :1.8 : Disintgression apparatus

III. RESULT AND DISCUSSION

The herbal tablet containing eugenol oil and cinnamon powder was prepared and evaluated. The formulation was prepared by wet granulation method were tested for pre- formulation studies for the effective evaluation of tablets. All The evaluated pre-formulation parameters are shown in table 2. Based on the pre-formulation study the flow property of granules was good. The physical parameters of compressed tablets were shown in table 3. The weight variation test, hardness, thickness, friability and disintegration time were shown in table 3.

Preformulation parameters for herbal tablet.

Sr. no.	Pre-formulation parameters	Result
1.	Bulk density	0.5gm/cm ²
2.	Tap density	0.54gm/cm ²
3.	Angle of repose	7.4
4.	Carr's Index	1.08%
5.	Hausner Ratio	22.29

Organoleptic characteristics of herbal tablet.

Sr. no.	Pre-formulation parameters	Result
1.	Colour	Dark Brown
2.	Odor	Woody Fragrance
3.	Taste	Spicy
4.	Appearance	Oily

physical parameters for herbal tablet.

Sr. no.	Pre-formulation parameters	Result
1.	Thickness	2mm
2.	Hardness	5.5kg/cm ²
3.	Weight variation	499 mg
4.	Friability	0.41%
5.	Disintegration	14.50 min
6.	Dissolution	86%

IV. CONCLUSION

Syzygium Aromaticum and Cinnamomum zeylanicum plant was selected for formulation and evaluation of tablet. Phytochemical investigation revealed that it contained carbohydrate, alkaloids, glycosides, flavonoids, tannins, steroids, triterpenoids and flavonol.

In which the Syzygium Aromaticum containing constituents like eugenol, eugenyl acetate, caryophyllene and Cinnamomum zeylanicum containing cinnamaldehyde cinnamic acid constituents having bio potentials to improve the anti-oxidant activity.

When the alcoholic extract of bud of *Syzygium Aromaticum* and powder of *Cinnamomum zeylanicum* were formed into the form of polyherbal tablets, it was discovered that the formulation produced effective anti-oxidatory effects.

The tablets that were produced had an appropriate level of hardness and a suitable rate of disintegration.

The B5 features a medication release that is both effective and promising.

B5 batch show the highest drug release about 86% in 2 Hrs. As a result of Anti-oxidant Activity of batch B5 came to the conclusion that the herbs that were chosen will have a significant impact on oxidation. And will serve as good nutraceutical supplements.

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