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Research Paper

Formulation Of Plecranthus Amboinicus Gummies as Respiratory Aid

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ABSTRACT

A simple and cost effective method has been developed for preparation of gummies using the extract of Plecranthus amboinicus. And validated according to the ICH guideline. The plant material was obtained and authenticated, after which the leaves were thoroughly washed and dried using IR lamp. The extraction was done by Soxhlet extraction method with maceration and the concentration of extract was done by rotary evaporator. Various evaluation test such as weight variation, swelling index, moisture content, pH determination and hardness test were done. Qualitative Test for the determination of phenol were conducted and the test were found to be positive. The results for the various qualitative test were found to be within the acceptance criteria.

INTRODUCTION

Commonly known as Mexican Mint or Indian Borage, 'Plecranthus amboinicus' is far more than just a hardy garden herb; it's a powerhouse in the world of traditional healing. Belonging to the mint family (Lamiaceae), this plant is packed with natural compounds like phenols and flavonoids that have made it a go-to remedy for respiratory issues across India and the tropics for generations. What makes it so effective is its high concentration of thymol. This specific element is a game-changer for lung health because it acts as a natural expectorant and anti-inflammatory. It's often

considered a safer, gentler alternative to many synthetic ingredients found on regulatory lists, making it ideal for low-dose treatments. Whether it's brewed into a soothing herbal syrup for a stubborn cough, used to ease the symptoms of asthma and bronchitis, or even utilized in treating digestive upset and epilepsy, this plant remains a staple of folkloric medicine. It is a perfect example of how traditional wisdom often aligns with modern science to provide relief where we need it most.[1]The therapeutic efficacy of the species is largely attributed to its dense concentration of specific flavonoids, including apigenin, luteolin,

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and salvigenin. These bioactive constituents are highly regarded in pharmacological research for their robust antioxidant profiles and systemic anti-inflammatory actions. Taxonomically, the plant is situated within the "Lamiaceae" family, a vast botanical group encompassing approximately 200 genera and upwards of 3,200 species. This family holds a distinguished place in both ethnobotany and gastronomy, as its members have been integrated into global medicinal practices and culinary traditions for millennia. The intersection of these diverse species highlights a long-standing human reliance on the Lamiaceae family for both physiological health and nutritional enrichment.[2] Historically identified as *Coleus aromaticus*, this plant is a member of the Lamiaceae family under the *Plectranthus* genus. It grows as a succulent perennial herb, reaching heights between 30 and 90 cm. The species is distinguished by its dense branching and thick, fleshy stems, which support leaves known for their potent and inviting fragrance. In addition to its therapeutic applications, the leaves are highly valued in the culinary arts. They are frequently used to season meat and fish, as their unique aromatic compounds improve flavor profiles while masking any natural odors. Because of this versatile combination of medicinal, aromatic, and culinary traits, *P. amboinicus* holds substantial promise for future advancements in both food science and pharmaceutical research.[3]

Hans Riegel invented the first gummy candy and was dissatisfied with his work in 1920 and made the decision to start his own company, which began with hard, colorless sweets.[4] [Hasibuan et al.(2013)] The research states the origin of the plant along with its phytochemistry was presented, The essential volatile composition of *P.amboinicus* plant extract obtained through the leaves and stems explant stated a total of 76 volatile constituents with presence of two major phenolic mainly monoterpene phenols like

Thymol and Carvacrol which were well appreciated in providing culinary properties and were directly related to biological functions of the plants. Study proved the significance of *Plectranthus Amboinicus* in various anti-bacterial, anti-fungal, anti-viral, anti-epileptic and anti-convulsive activities and also providing the health benefits in respiratory disorders and digestive problems. Thymol and Carvacrol belonging to the monoterpene phenolic class of *P.amboinicus* (Lour: Spreng) were found to be more promising to anti-microbial, anti-inflammatory, analgesic activities and major role in respiratory disease cure.[5] Burey et al. (2009) indicates that while newly developed gummy jellies received slightly lower sensory ratings than popular commercial brands, they were still well received by testers. Specifically, the ORH formulation achieved scores nearly identical to those of market leading products. Beyond their taste, these specialized gummies offered a superior nutritional profile, featuring fewer calories and a significantly higher antioxidant content than traditional candy. The study suggests that ORH and BEM gummies could serve as a viable, health conscious alternative for consumers. While substituting sugar with natural sweeteners like honey can be challenging, the research found that these adjustments did not significantly alter water content or increase the risk of microbial growth. However, to ensure consumer safety, any such changes to the recipe must be strictly monitored and validated according to HACCP protocols. This suggests that transitioning to healthier confectionery options is entirely possible without compromising shelf stability or safety standards.[6]. [Arumugam et al (2016)] the volatile profile of *P. amboinicus* extracts derived from leaf and stem samples, identifying a complex mixture of 76 unique constituents. The most prominent among these were the monoterpene phenols thymol and carvacrol. These specific compounds are not only



responsible for the plant's distinct culinary appeal but are also the primary drivers of its biological activity. The research further validated the broad therapeutic potential of *Plectranthus amboinicus*, highlighting its effectiveness against bacteria, fungi, and viruses, as well as its role in managing epilepsy and convulsions. Additionally, the plant was found to offer significant relief for gastrointestinal and respiratory issues. Specifically, thymol and carvacrol were identified as the most potent components for antimicrobial, anti-inflammatory, and pain-relieving treatments, playing a vital role in addressing respiratory health.[7][Phattayanon et al(2024)]

The NF- κ B proteins regulate the expression of numerous genes and play a central role in the body's defense against pathogens. These proteins are found in the cytoplasm of a cell and are activated by various stimuli, such as cellular danger signals. Problems with NF- κ B activity are associated with chronic inflammatory diseases and certain cancers. Thymol inhibits activation of the NF- κ B pathway, a key regulator of inflammatory gene transcription in airway epithelial and immune cells thereby decreasing the production of inflammatory cytokines like the tumor necrosis factor-alpha (TNF- α), Interleukin-1 beta (IL-1 β), Interleukin-6 (IL-6), Interleukin-8 (IL-8) MAPK-Mitogen-Activated Protein Kinase Inhibition Inhibition is carried through signalling modulation of MAPK and prevention of phosphorylation ERK, JNK, and p38 MAPKs, which are responsible for cytokine release and oxidative stress in inflamed lung tissue.[8][Chiu et al (2012)]

Plectranthus amboinicus offers significant protective benefits for the kidneys, specifically counteracting the damage often caused by acetaminophen while also acting as a potent natural diuretic. Scientific analysis of the plant's aqueous extracts shows a high concentration of carvacrol, measured at approximately 1.88 mg per gram of extract. This

compound is a primary driver behind the plant's ability to regulate the body's internal health.

Controlling the production of inflammatory cytokines is essential for managing chronic diseases. While many people rely on standard nonsteroidal anti-inflammatory drugs (NSAIDs), these often come with side effects like stomach ulcers, worsening asthma, or liver and kidney strain. This has led to a growing interest in natural alternatives like *P. amboinicus*. In laboratory studies using RAW 264.7 cells, extracts from this plant successfully blocked the production of nitric oxide and TNF-alpha, which are key triggers for inflammation. This effect is largely due to the plant's ability to suppress specific proteins like iNOS and COX-2. By tracking these proteins through Western blot analysis, researchers confirmed that the plant effectively interferes with the inflammatory process at a molecular level, offering a safer path toward treating inflammatory conditions.[9][Lukhoba et al (2006)]

This review involved the ethnobotanical use of *Plectranthus* species depicting the digestive conditions which were treated through the herbs in 21 *Plectranthus* species. They are used to treat stomach pain, nausea, vomiting, diarrhoea, mouth and throat infections and are used as purgatives, carminatives and as antihelmintics. *P. amboinicus* was found to be essential and popular in the treatment of dyspepsia, indigestion, diarrhoea and as a carminative in India and Africa. Fifteen species have been recorded for the treatment of infections and fever. *Plectranthus barbatus* is used to treat a range of infections including throat and mouth infections and *Plectranthus amboinicus* is stated important in Asia and South America for the treatment of fever. Six species of *Plectranthus* are used to treat musculo-skeletal conditions. *Plectranthus amboinicus* and *Plectranthus barbatus* are used for treating stiff neck and backaches as associated with Muscular-skeletal conditions. Species of *Plectranthus* are also used to



treat sensory disorders associated with ear and eye problems. For example, *Plectranthus amboinicus* seed oil is a treatment for acute edematous otitis acuta in Polynesia whereas in India its leaves are rubbed onto the eyes to alleviate conjunctivitis. *Plectranthus Amboinicus* have cytotoxic and anti-tumour promoting activity and can be used in the treatment of cancer. *Plectranthus barbatus* is reported to stimulate the immune system As food additives the three species of *Plectranthus* reported as food additives are *Plectranthus amboinicus*, *Plectranthus esculentus* and *Plectranthus crassus*. The leaves of *Plectranthus amboinicus* are used in food stuffing.[9]. [Yadav et al(2024)] The development of herbally fortified nutraceutical gummies offers a promising approach to pediatric supplementation by combining therapeutic efficacy with high palatability. This study utilized a gelatin matrix to ensure a consistent mass, incorporating a botanical blend of *Elettaria cardamomum*, *Amomum subulatum* Roxb, *Zingiber officinale*, and *Beta vulgaris*. Formulations were rigorously evaluated based on critical physicochemical parameters, including moisture content, pH, swelling index, viscosity, and dissolution rates. The results indicate that a base of 8% Type A gelatin provides the most stable and effective delivery system, meeting all structural requirements for an optimized nutraceutical product. This formulation represents a viable, high quality alternative for administering herbal benefits in a kid friendly format. [11]

Phytochemical Profile:



Plectranthus Amboinicus

Plectranthus Amboinicus (Lour.) Spreng also known as Mexican mint, Indian borage, Karpooravalli (Tamil), Patharchur (Hindi) is a aromatic perennial herbaceous plant belonging to the family Lamiaceae .Kingdom:-Plantae

Division (Phylum):- Magnoliophyta (Angiosperms)

Class:- Magnoliopsida (Dicotyledons)

Order:- Lamiales

Family:- Lamiaceae (Mint family)

Genus:- *Plectranthus*

Species:- *Plectranthus amboinicus* (Lour.) Spreng.[12]

Geographical Source:-

Plectranthus Amboinicus Formerly classified as *Coleus amboinicus*, this plant originated in the Paleotropics before its successful introduction to Brazil. As a member of the Lamiaceae family, it enjoys a broad geographic range that spans across Africa, Australia, and Asia. In India, the species thrives particularly well in the Western Ghats, where it is found at elevations ranging from 500 to 1000 meters. It grows in great abundance across southern states such as Kerala, Tamil Nadu, and Karnataka, and is also actively cultivated in regions like Andhra Pradesh and Odisha. Due to its wide distribution and cultural significance, *P. amboinicus* is known by a variety of common names that reflect its diverse utility and regional popularity

Kannada: Doddapatre, doddapatre soppu



Hindi: Patta ajavayin, Patharchur, Amroda, pathercheer

English: Country borage, Indian borage, Indian mint

Bengali: Amalkuchi

Malayalam: Panikoorka

Gujarati: Ovapan

Marathi: Pan ova

Sanskrit: Karpuravalli, Sugandhavalakam, Parnayavani

Marathi: Pathurchur [13]

Flower color: Pale purplish to lilac.

Inflorescence type: Slender raceme or spike (10–20 cm) with dense whorls of flowers.

Calyx: Bell-shaped (2–4 mm), hirsute and glandular.

Corolla: Bilabiate (8–12 mm); upper lip short and erect, lower lip longer and concave.

Stamens: Didynamous ; ovary four-partite, stigma bifid.

Fruit: Smooth nutlets (~0.7 × 0.5 mm), pale brownish colour.

Morphological Characteristics

Growth form: Often creeping or sprawling, many-stemmed, perennial, succulent herb or subshrub.

Stem: Fleshy, succulent, decumbent or spreading, 30–90 cm long, pubescent with glandular hairs.

Leaves: Arranged opposite on petioles (2–4.5 cm long).

Shape & size: Broadly ovate to suborbicular, 5–7 cm long × 4–6 cm wide.

Margin: Coarsely crenate to dentate-crenate.

Surface: Pubescent on both surfaces, glandular hairs prominent beneath

.Texture & aroma: Thick, fleshy, strongly aromatic (oregano-like scent).

Texture & aroma: Thick, fleshy, strongly aromatic (oregano-like scent).

Chemical Constituents:

Monoterpenoid phenols- Thymol(7.2%) Carvacrol(43.1%)[14,15]

Monoterpene hydrocarbon-γ-Terpinene,α-Humulene,α-Terpineol

Sesquiterpene -Caryophyllene oxide,β-Selinene[16]

Aldehyde-Undecanal

Monoterpene-α-Pinene,β-Pinene,Limonene

Carotenoids-Lutein, Zeaxanthin,α-Carotene,β-Carotene

Phenolicacids-Rosmarinic acid ,Caffeic acid,p-Coumaric acid,Gallic acid

Flavonoids-Cirsimariti,

Chrysoeriol,Salvigenin,Apigenin

Steroidal glycosides-Sitosterol[17]

Flowers:

MATERIALS AND METHODS

Table No. 1: Raw Material:-

Sr no	Raw Material	Uses/Role
1	Plectranthus Amboinicus	Respiratory Aiding Drug
2	Monoterpenes like Thymol	Anti-Inflammatory agent
3	Monoterpenes like Cavacrol	Bronchodilator

Table No. 2: Chemicals/ Reagents

Sr. No.	Chemicals/ Reagents
1.	Methanol
2.	Ethanol
3.	Pectin



4.	Agar
5.	Sucrose
6.	Citric acid
7.	Methyl paraben
8.	Sodium Benzoate
9	Distilled water
10	Thymol

Table No. 3: Instruments/ Accessories

Sr. No.	Instruments/ Accessories
1.	Electronic Balance
2.	Soxhlet Apparatus
3.	Water Bath
4.	Sonicator
5.	Hot Air Oven
6.	PH meter
7	Rotary Evaporator
8	Vernier calliper
9	UV Spectrophotometer

Methods Formulation -**A] Collection of plant material:**

The plant of *Plectranthus amboinicus* The Heritage Bistro, behind Campal Bridge, near Heritage Bistro, Panaji, Goa, India in JULY & AUGUST 2024.

B] Authentication of plant material:

The collected plant material was identified and authenticated by Dr. Uttam Dethé head PG Department of Botany Shri Pancham Khemraj College of Arts, Commerce, and Science, Sawantwadi, Sawantwadi India.

C] Processing of plant material:

1. The plant material was washed under running tap water and dried under IR lamp.
2. Dried plant material was coarsely powdered and stored in neatly labelled air tight container till the future use.

D] Extraction Method:

(a) Requirements: Soxhlet Apparatus, Beakers, Filter paper, Water bath, etc.

(b) Chemicals: Pectin, Agar, Sucrose, Citric acid, Methyl paraben, Sodium Benzoate, etc

(c) Procedure:

Dry leaves and grind into Coarse powder further coarse powder was subjected to the distillation flask

1. Weighed 50g leaves
2. Extract powder with 100 hexane in Soxhlet for 2-3 h(6-8 cycles).
3. Air dry before the methanol extraction.
4. Place the powder in the cellulose thimble
5. Add the methanol to 1L round bottom flask
6. Assemble Soxhlet with condenser, Check the water flow
7. Heat to reflux gently
8. Run the extraction for 8h
9. Cool and collect the extract
10. Place the powder in the cellulose thimble
11. Add the methanol to 1L round bottom flask
12. Assemble Soxhlet with condenser, Check the water flow
13. Heat to reflux gently
14. Run the extraction for 8hours
15. Cool and collect the extract.



Procedure for Formulation of Plecranthus Amboinicus gummies:

Two separate beakers were used for preparation

A] Pectin-agar base preparation:-

- Weight accurate amount of Pectin and agar in appropriate ratio in a beaker.
- Add methyl paraben and sodium benzoate in the pectin-agar mixture.

B] Preparation of a viscous sucrose syrup:-

- Sucrose and Citric acid were taken in appropriate ratio and in adequate amount of distilled water .
- The solution was mixed on a water bath at high temperatures (75-80°C)

C] Formulation of gummies with viscous sucrose syrup

- The viscous solution was mixed at constant stirring until a hot viscous sucrose syrup obtained .
- The mixture after heating for 5-10 mins at moderate flame was poured into the pectin-agar base and was stirred at the room temperature in order to activate the base resulting to proper bonding of the base with the solution.
- The API was added for the concentrated extract based on the literature into the gummy base.
- Formation of a hot gel was then stirred constantly until all the air bubbles were absent.
- The moulds were layered with glycerin to avoid the sticking of the gummy base to the moulds and to provide ease of removal
- The mixture was then poured in the moulds with caution.
- The mould filled with the gummy base formulation was subjected at room temperature 37°C -42°C for 30-45 mins.

□ Then the gummies were placed in refrigerator at 15°C-20°C for the enhancing affinity of the gel molecules in the gummies.

□ The gummies were stored at the room temperature in a dark place for determining the storage conditions and presence of any microbes causing degradation to the gummies at room temperature.

Method Validation

1.1 Physical Appearance:-

All the prepared gummies are visually observed for their colour, shape, odour, taste and texture.[18]



1.2. Thickness:-

The thickness of a gummy were measured using Vernier Calliper.

The thickness of 5 gummies were checked.



1.3. Weight Variation:-

A total of 10 gummies were weighed, with the average weight being determined after the total weight was added up.[19]

Weight variation = individual weight – average weight/ average weight×100

1.4 Moisture Content:-

Parameter	Symbol	Value (g)
Empty dish	W ₁	75.41
Dish + gummy before drying	W ₂	83.10
Dish + gummy after drying	W ₃	82.26

Acceptance criteria:-The acceptable percentage of moisture content should be in the range of 10-20% of the gummies.

1.5 PH determination :-

A pH meter with a glass combination electrode was used to monitor the pH. The materials were divided into thin slices, added to boiling water (1:3, w: w), and mixed continuously until completely dissolved. The pH was measured after the heated solution was tempered at 25°C. Each measurement was taken thrice times.

Acceptance criteria:-The acceptable pH range of chewable gummies is 5.69 to 6.40.[21]

1.8 Hardness Test

A Pfizer hardness tester crushed the gummies (one at a time) while keeping the force applied in the same direction. Higher hardness values may be taken into consideration if justified contact to simulated saliva.

Acceptance criteria:-According to the FDA guidance gummies, hardness must lie within a range of 1-5 kg/cm²[22]

Moisture Content=(Dry Basis): MCdb = ((W₂ - W₃) / (W₃ - W₁)) × 100

1. Weight of the empty porcelain dish (W₁)
2. Weight of the porcelain dish + gummy before drying(W₂)
3. Weight of the porcelain dish + gummy before drying(W₃)[20] The weights were determined on WENSAR weighing balance



1.9 Swelling index

By calculating gummy's starting weight, the development index was calculated. The amount of liquid in the gummy structure that can be absorbed is determined by the swelling index. Next, at a regulated room temperature of 25°C to 300C, gummy mixture was immersed in 100 millilitres of filtered water for 10 sec. Following soaking, a chewable gummy is taken out and cleaned with filter paper to remove any remaining water that may have stuck to the gummy's surface.

Ws=weight of chewable gummy after soaking.




Wd=weight of chewable gummy before soaking.

Acceptance criteria:-Swelling Index (SI) ≥ 0.8% and ≤ 3.0%



Tests for the detection of phenols (monoterpene phenols)

Sr No	Test for phenols	Observtion	Inference
1	Ferric chloride test	Appearance of a viole/ blue, green, coloration indicates the presence	Phenols are present
2	Vanillin sulphuric acid test	Appearance of green color indicates the presence of terpenoids or steroids	Phenols are present
3	Bromine water test	Decolorization of bromine water and formation of white precipitate.	Phenols are present

		
Ferric chloride test	Vanillin sulphuric acid test	Bromine water test

Physical Appearance:-

The physical appearance of the prepared gummies with respect to the color, shape, odour, taste, texture displayed through the table:-

Sr No.	Parameters	Observation
1	Colour	Golden Brown and yellow
2	Shape	Hexagonal
3	Odour	Fruity and Pleasant smell
4	Taste	Sweet
5	Texture	Soft and stretchy

The gummies prepared were appeared to be hexagonal golden brown and yellow with fruity and pleasant smell and sweet taste. The texture of the gummies was found to be soft and stretchy.

Weight Variation:-

The results displayed the average % deviation of 10 gummies formulated and the mean was determined

Sr.no	Weight(g)	% Deviation from Mean
1	8.573	+1.47%
2	8.451	+0.02%
3	8.122	-2.87%
4	8.461	+0.14%
5	8.610	+1.91%
6	8.277	-2.04%
7	8.277	+3.70%
8	8.762	-1.50%
9	8.322	+0.65%
10	8.504	-0.46%

The weight variation was calculated with the average % deviation is 1.58% which is under the acceptance criteria of $\pm 5\%$ for herbal gummies

Moisture Content:-

The results of the moisture content of the gummy by heating at 105 C in and hot air oven for 4 hours are displayed through calculation in table

Moisture Content	Formula	Result
Moisture content on dry basis	$\frac{((83.10 - 82.26))}{(82.26 - 75.41)} \times 100$	12.26%

As seen from the results the gummy sample has a moisture content of 12.26% on a dry basis which is in limits of the acceptance criteria. This moisture level is consistent with semi-dried gummy formulations, contributing to better shelf stability and a firm texture.

PH determination :-

Sr.no	PH of the gummies
1	6.35
2	6.24
3	6.30

The results of ph determination of the gummy by using a pH meter with a glass combination electrode and the measurement was taken three times displayed through the table

Because citric acid was used as a pH modifier to improve the gelling power of the pectin this is regarded as somewhat acidic.

As seen from the results the gummy sample has a pH of 6.30 on the measure taken three times through the pH meter

Hardness Test

Sr.no	Hardness (kg/cm ²)
1	0.75 \pm 0.054
2	0.73 \pm 0.053
3	0.75 \pm 0.051
Average	0.74 \pm 0.052



The results of the hardness test of the three gummies was found 0.74

± 0.052 (kg/cm²) and the average was in compliance with the acceptance criteria by the FDA guidance gummies, hardness must lie within a range of 1-5 kg/cm²

Swelling index

Sr.no		
1	W _s	7.59 g
2	W _d	7.51 g
3	Swelling index	1.065%

The results of the swelling index of the gummy was found and the average was in compliance with the acceptance criteria by the swelling must lie within a range of $\geq 0.8\%$ and $\leq 3.0\%$

RESULTS

Parameters	Observation
Colour	Golden Brown and yellow
Shape	Hexagonal
Odour	Fruity and Pleasant smell
Taste	Sweet
Texture	Soft and stretchy
Evaluation Parameters	
Weight Variation	1.58%
Moisture content	12.26%
PH determination	6.30
Hardness Test	0.74 \pm 0.052
Swelling index	1.065%

The herbal Plecranthus Amboinicus gummies were developed by using pectin-agar base and sucrose syrup mixture with essential additives was

method validated for the sensory evaluation and other evaluation parameters were carried out.

The gummies were found to be hexagonal golden-brown coloured gummies with fruit and pleasant smell with soft and stretchy texture. The weight variation was observed 1.58% .

The total moisture content of the gummy heated at 105°C for 4 hours

was observed 12.26% .The pH determined was observed 6.30 The gummies showed the hardness of

.The swelling ratio of the gummies subjected to the 100 millilitres was observed to be 1.065%

CONCLUSION

The development of Herbal gummies using Plecranthus Amboinicus extract successfully combines traditional herbal medicine with modern formulation techniques and in order to create a patient -friendly respiratory aiding formulation. The presence of active constituents such as thymol and carvacrol in the extract found to impart significant anti-inflammatory, antimicrobial, antioxidant, and bronchodilatory effects, contributing to improved respiratory function.

The importance of Thymol as an essential and active constituent of the P.amboinicus extract associated with the respiratory benefits through the inhibitory mechanism was stated

The method was validated in accordance to ICH guidelines and was found to comply with acceptance criteria for all parameters. The method was applied to Sensory evaluation and the gummies formulated were golden brown coloured hexagonal, the taste is sweet and soft in texture.

The gummy formulation enhances taste, ease of administration thus better compliance and overall acceptability, especially among children and geriatric patients. The developed method can serve as a safe, effective, and natural alternative for managing respiratory conditions while ensuring therapeutic efficiency and consumer satisfaction



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