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RESEARCH ARTICLE

Formulation and *in vitro* Evaluation of Herbal Soft Gelatin Capsules Containing Peppermint Oil, Lemon Oil, and Holy Basil for the Management of Motion Sickness

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ABSTRACT

Motion sickness is a common condition characterized by nausea, dizziness, vomiting, and discomfort during travel. The present study aimed to formulate and evaluate herbal soft gelatin capsules containing peppermint oil, lemon oil, and holy basil oil for the management of motion sickness. The herbal oils were incorporated into a soft gelatin capsule system using polyethylene glycol 400 as a carrier vehicle. The prepared capsules were evaluated for physical appearance, weight variation, thickness, size uniformity, drug content, disintegration time, *in vitro* dissolution, leakage, moisture content, and stability. The formulated capsules exhibited a smooth surface, uniform shape, and acceptable shell integrity. Weight variation and dimensional measurements demonstrated good batch uniformity. Drug content analysis confirmed the uniform distribution of the herbal ingredients within the capsules. The capsules disintegrated rapidly and released the majority of their active constituents within 60 min during dissolution testing. Leakage studies revealed complete retention of the fill material without shell rupture. Stability testing conducted under accelerated conditions for 3 months showed minimal changes in physical appearance, drug content, disintegration time, and dissolution behavior. The findings indicated that the developed herbal soft gelatin capsules possessed satisfactory pharmaceutical properties and may serve as a promising herbal formulation for the management of motion sickness.

Keywords: Herbal soft gelatin capsules, holy basil oil, lemon oil, motion sickness, peppermint oil

INTRODUCTION

Motion sickness is a common physiological disorder that occurs when conflicting sensory signals are transmitted from the visual, vestibular, and proprioceptive systems to the central nervous system during travel by road, sea, air, or virtual environments.[1] The condition is characterized by symptoms such as nausea, vomiting, dizziness, sweating, headache, and general discomfort, which can significantly affect an individual's quality of life and travel experience.[2] Although several synthetic medications, including antihistamines and anticholinergic agents, are available for the prevention and treatment of motion sickness, their use is often associated with adverse effects such as drowsiness, dry mouth, blurred vision, and impaired cognitive performance.[3]

The increasing demand for safer and naturally derived therapeutic alternatives has stimulated interest in herbal medicines for the management of motion sickness.[4] Herbal products have been traditionally used for gastrointestinal disturbances and nausea because of their favorable safety profile and broad pharmacological activities.[5] Peppermint oil (*Mentha piperita*) is widely recognized for its antiemetic, antispasmodic, and digestive properties and has been used traditionally to alleviate nausea

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and gastric discomfort.[6] Lemon oil (*Citrus limon*) possesses refreshing aromatic compounds and has demonstrated potential benefits in reducing nausea and improving gastric comfort through its calming and digestive effects.[7] Holy basil (*Ocimum sanctum*), commonly known as Tulsi, exhibits adaptogenic, anti-inflammatory, antioxidant, and gastroprotective activities that may contribute to the reduction of motion sickness-related symptoms.[8]

The combination of these herbal oils may provide synergistic therapeutic benefits by targeting multiple pathways involved in nausea and vestibular disturbances.[9] Soft gelatin capsules represent an effective dosage form for delivering volatile herbal oils because they offer improved patient compliance, accurate dosing, protection from oxidation, and enhanced bioavailability of lipophilic constituents.[10] Furthermore, soft gelatin capsules provide rapid shell disintegration and efficient release of encapsulated oils in the gastrointestinal tract.[11] Therefore, the development of a herbal soft gelatin capsule containing peppermint oil, lemon oil, and holy basil oil may represent a promising alternative approach for the management of motion sickness while minimizing the adverse effects associated with conventional pharmacotherapy.

MATERIALS AND METHODS

Materials

Peppermint oil (*M. piperita*), lemon oil (*C. limon*), and holy basil oil (*O. sanctum*) were procured from a certified herbal raw material supplier and used as active ingredients. Gelatin (Type B), glycerin, purified water, methyl paraben, propyl paraben, polyethylene glycol (PEG 400), and titanium dioxide were obtained from pharmaceutical-grade suppliers. All chemicals and reagents used during the study were of analytical grade.

Preparation of Herbal Fill Formulation

The fill formulation was prepared by accurately measuring peppermint oil, lemon oil, and holy basil oil according to the predetermined formula. For the preparation of 100 capsules, 5 g of peppermint oil, 3 g of lemon oil, and 2 g of holy basil oil were weighed.

The oils were transferred into a clean glass beaker and mixed using a magnetic stirrer at 500 rpm for 20 min. PEG 400 was then added gradually as a carrier vehicle to improve solubility and uniformity of the herbal oils. The mixture was stirred continuously until a homogeneous oily solution was obtained.

Methyl paraben and propyl paraben were dissolved separately and incorporated into the formulation to improve microbial stability. The final fill mass was protected from direct light and stored in airtight amber-colored containers until encapsulation.

Preparation of Gelatin Shell Mass

The gelatin shell mass was prepared by soaking gelatin in purified water for 30 min to allow complete hydration. Approximately 45 g of gelatin was dispersed in 35 mL of purified water.

After hydration, the gelatin mass was heated in a water bath maintained at 60 ± 2°C. Glycerin (20 g) was added as a plasticizer while continuous stirring was performed to obtain a smooth and flexible gel mass. Titanium dioxide was incorporated as an opacifying agent.

The prepared shell mass was stirred until a clear, bubble-free solution was obtained. The gelatin solution was maintained at the required temperature until capsule formation.

Preparation of Herbal Soft Gelatin Capsules

Soft gelatin capsules were prepared using a laboratory-scale plate process. Stainless-steel capsule molds having a capacity of 250 mg were utilized.

The gelatin mass was poured onto lubricated stainless-steel plates and allowed to form thin gelatin sheets. The sheets were partially dried under controlled conditions at 25°C and a relative humidity of 40–50%.

The herbal fill formulation was accurately dispensed into the gelatin pockets using calibrated micropipettes. Each capsule contained 250 mg of fill formulation consisting of herbal oils and PEG 400. The upper gelatin sheet was carefully placed

over the filled pockets and sealed using gentle pressure and controlled heating.

The capsules were removed from the molds and allowed to dry for 24 h at room temperature. The dried capsules were then stored in airtight containers for further evaluation.

Evaluation of Herbal Soft Gelatin Capsules

Physical appearance

The prepared capsules were visually inspected for color, shape, uniformity, surface smoothness, and absence of leakage. Twenty capsules were randomly selected and examined under normal daylight conditions.

Weight variation test

Twenty capsules were randomly selected and weighed individually using a digital analytical balance. The average capsule weight was calculated and compared with individual capsule weights to assess weight uniformity.

Thickness Measurement

The thickness of 10 randomly selected capsules was measured using a digital Vernier caliper. Measurements were taken at three different points of each capsule, and observations were recorded.

Capsule Size Uniformity

The length and width of 10 capsules were measured using a calibrated digital Vernier caliper. The measurements were recorded to evaluate dimensional consistency.

Disintegration Test

The disintegration study was carried out using a USP disintegration apparatus. Six capsules were placed individually into the basket assembly containing distilled water maintained at 37 ± 0.5°C. The time required for complete rupture of the gelatin shell and release of fill material was recorded for each capsule.

Table 1: Materials used in the formulation

S. No.	Material	Quantity used
1	Peppermint oil	50 mg/capsule
2	Lemon oil	30 mg/capsule
3	Holy basil oil	20 mg/capsule
4	PEG 400	150 mg/capsule
5	Gelatin	As required
6	Glycerin	As required
7	Purified water	As required
8	Methyl paraben	0.2% w/v
9	Propyl paraben	0.05% w/v
10	Titanium dioxide	0.5% w/w

PEG: Polyethylene glycol

Table 2: Composition of gelatin shell

Ingredient	Quantity (g)
Gelatin	45
Glycerin	20
Purified water	35 mL
Titanium dioxide	0.5
Total shell mass	100 g

Table 3: Formula of herbal soft gelatin capsules

Ingredient	Quantity per capsule (mg)
Peppermint oil	50
Lemon oil	30
Holy basil oil	20
PEG 400	150
Total fill weight	250

PEG: Polyethylene glycol

Table 4: Parameters evaluated for weight variation

Parameter	Specification
Number of capsules	20
Balance sensitivity	0.1 mg
Average weight determination	Performed
Individual weight recording	Performed

Drug Content Uniformity

Ten capsules were randomly selected and cut open carefully. The filter contents were quantitatively transferred into a volumetric flask containing ethanol.

The solution was sonicated for 15 min to ensure complete extraction of herbal oils. Appropriate dilutions were prepared and analyzed using ultraviolet-visible spectrophotometry at predetermined wavelengths corresponding to the

Table 5: Conditions for the disintegration study

Parameter	Condition
Medium	Distilled water
Temperature	37±0.5°C
Number of capsules	6
Apparatus	USP disintegration apparatus

Table 6: Conditions for dissolution study

Parameter	Condition
Apparatus	USP type II (Paddle)
Dissolution medium	Phosphate buffer pH 6.8
Volume	900 mL
Temperature	37±0.5°C
Paddle speed	50 rpm
Sampling intervals	5, 10, 15, 30, 45, 60 min

Table 7: Stability study conditions

Parameter	Condition
Storage temperature	40±2°C
Relative humidity	75±5%
Study duration	3 months
Packaging material	HDPE container
Evaluation intervals	0, 1, 2, and 3 months

Table 8: Physical characteristics of herbal soft gelatin capsules

Parameter	Observation
Color	Pale yellow
Shape	Oval
Surface texture	Smooth and glossy
Odor	Characteristic herbal aroma
Leakage	Absent
Cracks	Absent
Shell integrity	Intact
Appearance	Uniform

major active constituents of peppermint oil, lemon oil, and holy basil oil.

The percentage content of herbal actives present in each capsule was determined.

In Vitro Dissolution Study

The release characteristics of herbal constituents from the soft gelatin capsules were studied using the USP Dissolution Apparatus II (Paddle Method). A volume of 900 mL of phosphate buffer, pH 6.8, was used as the dissolution medium. The temperature was maintained at 37 ± 0.5°C, and paddle rotation speed was adjusted to 50 rpm.

One capsule was introduced into each dissolution vessel. Samples of 5 mL were withdrawn at intervals of 5, 10, 15, 30, 45, and 60 min. An equal

Table 9: Weight variation of herbal soft gelatin capsules

Capsule No.	Weight (mg)
1	502
2	498
3	505
4	501
5	497
6	504
7	500
8	503
9	499
10	506
11	501
12	498
13	504
14	500
15	503
16	499
17	505
18	501
19	500
20	502

Table 10: Summary of weight variation results

Parameter	Result
Number of capsules tested	20
Average weight	501.4 mg
Minimum weight	497 mg
Maximum weight	506 mg
Weight uniformity	Acceptable

Table 11: Thickness of herbal soft gelatin capsules

Capsule No.	Thickness (mm)
1	5.42
2	5.39
3	5.45
4	5.41
5	5.38
6	5.43
7	5.40
8	5.44
9	5.37
10	5.42

Table 12: Capsule size uniformity

Capsule No.	Length (mm)	Width (mm)
1	12.4	7.2
2	12.3	7.1
3	12.5	7.2
4	12.4	7.3
5	12.3	7.1
6	12.5	7.2
7	12.4	7.2
8	12.5	7.3
9	12.3	7.1
10	12.4	7.2

Table 13: Disintegration time of capsules

Capsule No.	Disintegration time (min)
1	12.8
2	13.1
3	12.6
4	13.0
5	12.7
6	12.9

Table 14: Summary of disintegration results

Parameter	Result
Number of capsules tested	6
Minimum time	12.6 min
Maximum time	13.1 min
Average time	12.85 min

Table 15: Drug content uniformity of herbal oils

Capsule No.	Drug content (%)
1	98.4
2	99.1
3	101.2
4	99.6
5	100.4
6	98.9
7	99.8
8	100.6
9	99.4
10	100.1

volume of fresh dissolution medium was replaced after each sampling.

The withdrawn samples were filtered through a 0.45 µm membrane filter and analyzed spectrophotometrically to determine cumulative drug release.

Table 16: Summary of drug content results

Parameter	Result (%)
Minimum content	98.4
Maximum content	101.2
Average content	99.75

Table 17: *In vitro* drug release profile

Time (min)	Drug release (%)
5	22.4
10	41.8
15	58.6
30	76.3
45	89.5
60	97.8

Table 18: Cumulative drug release during dissolution study

Sampling time	Cumulative release (%)
5 min	22.4
10 min	41.8
15 min	58.6
30 min	76.3
45 min	89.5
60 min	97.8

Leakage Test

Twenty capsules were placed between filter papers and subjected to mild compression. Capsules were examined for any evidence of oil leakage or shell rupture. Observations were recorded after 24 h.

Moisture Content Determination

The moisture content of the prepared capsules was determined using a digital moisture analyzer. Approximately 2 g of capsule shell material was weighed and heated until a constant weight was obtained. The percentage moisture content was calculated.

Stability Study

The prepared capsules were packed in airtight high-density polyethylene containers and stored under accelerated conditions of 40 ± 2°C and 75 ± 5% relative humidity for a period of 3 months.

Table 19: Leakage assessment of capsules

Capsule number tested	Leakage observed
1	No
2	No
3	No
4	No
5	No
6	No
7	No
8	No
9	No
10	No
11	No
12	No
13	No
14	No
15	No
16	No
17	No
18	No
19	No
20	No

Table 20: Summary of leakage test

Parameter	Observation
Total capsules tested	20
Capsules showing leakage	0
Leakage percentage	0%
Shell integrity	Excellent

Table 21: Moisture content of capsule shell

Sample No.	Moisture content (%)
1	7.8
2	8.1
3	7.9
4	8.0
5	7.7

Table 22: Summary of moisture content results

Parameter	Result (%)
Minimum moisture content	7.7
Maximum moisture content	8.1
Average moisture content	7.9

Samples were withdrawn at predetermined intervals and evaluated for physical appearance, capsule integrity, drug content, disintegration time, and dissolution characteristics.

Table 23: Stability study: Physical appearance

Storage period	Appearance
Initial	Smooth and uniform
1 Month	No change
2 Months	No change
3 Months	No change

Table 24: Stability study: Drug content

Storage period	Drug content (%)
Initial	99.75
1 Month	99.12
2 Months	98.64
3 Months	98.05

Table 25: Stability study: Disintegration time

Storage period	Disintegration time (min)
Initial	12.85
1 Month	12.92
2 Months	13.08
3 Months	13.21

Table 26: Stability study: Drug release at 60 min

Storage period	Drug release (%)
Initial	97.8
1 Month	97.2
2 Months	96.8
3 Months	96.4

Documentation of Results

All observations obtained during formulation development and *in vitro* evaluation studies were recorded systematically. The data generated from physical evaluation, disintegration testing, dissolution studies, content uniformity analysis, leakage assessment, moisture determination, and stability testing were documented for comparative assessment of the formulated herbal soft gelatin capsules intended for the management of motion sickness.

RESULTS AND DISCUSSION

The herbal soft gelatin capsules containing peppermint oil, lemon oil, and holy basil oil were successfully formulated using the plate process method. The prepared capsules exhibited satisfactory physical characteristics and demonstrated acceptable

performance during *in vitro* evaluation studies. The capsules were uniform in appearance, showed good shell integrity, and remained stable throughout the evaluation period. The results obtained from physical characterization, weight variation, thickness measurement, content uniformity, disintegration testing, dissolution studies, leakage assessment, moisture determination, and stability studies are presented below.

Evaluation of Physical Appearance

The prepared capsules were visually examined for color, shape, surface smoothness, transparency, and sealing quality. The capsules appeared oval in shape with a uniform pale yellow color imparted by the herbal oils. No visible cracks, air bubbles, dents, or shell deformities were observed. The capsule surfaces were smooth and glossy, indicating successful gelatin shell formation.

The characteristic aroma of peppermint, lemon, and holy basil oils remained detectable in all capsules. No evidence of shell damage or oil migration was observed during visual inspection.

Weight Variation Test

Twenty capsules were individually weighed to determine weight uniformity. The results indicated minimal variation among capsules, demonstrating accurate filling and reproducibility of the manufacturing process.

The capsules exhibited consistent fill volume and shell thickness, resulting in uniform overall weight.

Thickness Measurement

The thickness of ten randomly selected capsules was measured using a digital Vernier caliper.

The thickness values remained consistent among all capsules, confirming uniform shell formation during the manufacturing process.

Capsule Size Uniformity

Dimensional measurements indicated uniform capsule geometry throughout the batch.

All capsules maintained nearly identical dimensions, indicating precision during mold filling and sealing.

Disintegration Study

The disintegration behavior of the herbal soft gelatin capsules was evaluated in distilled water maintained at physiological temperature.

The gelatin shells softened rapidly upon contact with the aqueous medium and released the encapsulated herbal oils within a short period.

Drug Content Uniformity

Drug content analysis demonstrated efficient incorporation of herbal oils into the capsule fill formulation.

The results indicated homogeneous distribution of peppermint oil, lemon oil, and holy basil oil throughout the fill matrix.

***In Vitro* Dissolution Study**

The dissolution profile demonstrated rapid release of herbal constituents from the soft gelatin capsules. The release profile indicated progressive dissolution of the capsule shell followed by rapid diffusion of herbal oils into the dissolution medium.

Nearly complete release of the active ingredients was achieved within 1 h.

Leakage Test

The prepared capsules were subjected to leakage testing using filter paper compression methods.

The gelatin shell successfully retained the herbal oil formulation throughout the evaluation period.

Moisture Content Determination

Moisture content analysis was performed to evaluate shell stability and flexibility.

The measured moisture level maintained capsule flexibility while preventing excessive brittleness.

Stability Study

The formulated capsules were stored under accelerated conditions for 3 months and evaluated at predetermined intervals.

No discoloration, shell cracking, or leakage was observed throughout storage.

The capsules maintained high levels of active constituents during storage.

The slight increase in disintegration time remained within acceptable limits.

The dissolution profile remained largely unchanged throughout the storage period.

CONCLUSION

The present study successfully formulated herbal soft gelatin capsules containing peppermint oil, lemon oil, and holy basil oil intended for the management of motion sickness. The prepared capsules demonstrated satisfactory physicochemical characteristics, including uniform appearance, acceptable weight variation, consistent dimensions, and good shell integrity. Drug content analysis confirmed homogeneous distribution of the herbal oils within the formulation. The capsules exhibited rapid disintegration and efficient release of active constituents during *in vitro* dissolution studies, indicating their potential to provide a prompt therapeutic effect. Leakage testing confirmed the stability of the gelatin shell and effective retention of the encapsulated oils. Furthermore, the formulation remained stable under accelerated storage conditions for 3 months, with only minor changes in pharmaceutical parameters. Based on the obtained results, the developed herbal soft gelatin capsules showed favorable formulation characteristics and *in vitro* performance, suggesting their potential as a convenient and patient-friendly herbal dosage form for the management and prevention of motion sickness symptoms.

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