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Formulation and quality assessment of a polyherbal capsule (gas relief pro) for gastrointestinal discomfort

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Abstract
This study presents the formulation and quality assessment of a polyherbal capsule (Gas Relief Pro) designed for gastrointestinal discomfort. The capsule combined extracts of *Trachyspermum* Ammi, *Mentha spicata* leaf powder, *Mentha spicata* extract, *Cyperus rotundus* extract, *Zingiber officinale* extract, *Asafoetida oleogum* resin, *Piper nigrum* extract, *Cuminum cyminum* powder, and *Cassia fistula pods* extract. Preformulation parameters showed bulk density 0.47-0.52 g/ml, tapped density 0.51-0.56 g/ml, Carr's index 7.8-8.8%, Hausner ratio 1.08-1.09, and angle of repose 20-23°, confirming excellent flowability. Capsule evaluation revealed an average weight of 588-635 mg, a fill weight of 458-505 mg, a moisture content of 5.1-5.2%, and a disintegration time of 5 minutes. HPLC quantification of thymol confirmed content uniformity (28-30 mg/capsule), with method validation showing linearity (20-100 ppm; $r^2 = 0.999$), precision (RSD <1.2%), LOD 5 ppm, LOQ 5 ppm, and recovery 98.5-100.2%. The capsule exhibited acceptable stability and reproducibility, supporting its potential as a standardized herbal alternative for gastrointestinal discomfort.

Keywords: Polyherbal capsule, gastrointestinal discomfort, thymol, HPLC, quality assessment

Introduction
Gastrointestinal discomfort, such as flatulence, bloating, abdominal pain, and indigestion, is one of the most common functional disorders globally. Conventional drugs, including antacids, prokinetics, and proton pump inhibitors, provide symptomatic relief but can lead to long-term adverse effects. Herbal medicine presents safer and multi-targeted approaches with minimal side effects. Polyherbal formulations combine multiple herbs to enhance therapeutic efficacy. In *Gas Relief Pro*, Trachyspermum ammi provides carminative action, Mentha spicata serves as a digestive stimulant, Zingiber officinale acts as an antiemetic and prokinetic, Asafoetida reduces flatulence, Piper nigrum enhances bioavailability, Cuminum cyminum supports digestion, and Cassia fistula acts as a mild laxative.
Together, these ingredients address multiple pathways of gastrointestinal discomfort. This study aimed to develop and evaluate a polyherbal capsule for gastrointestinal relief (*commercial name: Gas Relief Pro*), assess its pre-formulation and post-formulation parameters, and validate an analytical method for quantifying a marker compound to ensure quality and consistency.

Materials and Methods
Materials and Reagents
All reagents used in the study were of either HPLC or AR grade and were used according to the analytical requirements. The HPLC-grade Thymol standard was procured from Natural Remedies Pvt. Ltd. All experimental analyses were performed at the Research and Development Centre of Suwasthi Intense Health Care Pvt. Ltd. Gas Relief capsules were obtained from the in-house production department.

Preparation of Capsules
The powdered ingredients—*Trachyspermum ammi* extract, *Mentha spicata* leaf powder,

Mentha spicata extract, *Cyperus rotundus* extract, *Zingiber officinale* extract, *Asafoetida oleogum* resin, *Piper nigrum* extract, *Cuminum cyminum* powder, *Cassia fistula pods* extract, and excipients—were passed through a 40-mesh sieve to obtain a uniform particle size. The sieved powders were accurately weighed and blended in the proportions specified in Table 3. The resulting polyherbal formulation was encapsulated into size "00" hard HPMC capsules (brown color) using an automatic capsule-filling machine with a production capacity of 150,000 capsules per batch. Encapsulation was carried out under controlled environmental conditions (25 ± 2°C temperature and relative humidity below 60%).

For weight variation compliance, under pharmacopeial limits, capsules containing 480 mg or more of fill material were evaluated to ensure that no more than two units deviated by over 5% from the mean weight, and none deviated by more than 10%. The filled capsules were subsequently de-dusted, securely sealed, and packaged in moisture-resistant bottles containing silica gel desiccant packets to maintain stability during storage.

Table 1: Composition of Polyherbal Gas Relief Capsules

S. No.	Ingredient	Quantity (MG)
1.	*Trachyspermum ammi* extract	50
2.	*Mentha spicata leaf* powder	100
3.	*Mentha spicata* extract	50
4.	*Cyperus rotundus* extract	50
5.	*Zingiber officinale* extract	50
6.	*Asafoetida oleogum* resin	20
7.	*Piper nigrum* extract	10
8.	*Cuminum cyminum* powder	100
9.	*Cassia fistula pods* extract	50

Pre-formulation Studies

The evaluation included the assessment of bulk density, tap density, Carr's index, Hausner's ratio, and angle of repose to determine the flow properties of the polyherbal powder from three different batches of Gas Relief capsules.

Bulk density

Bulk density was determined by gently transferring 25 g of the sample through a glass funnel into a 100 mL graduated cylinder, and the volume occupied by the sample was recorded. Bulk density (g/mL) was calculated using the formula:

Bulk density (g/ml) = weight of sample in gm/volume occupied by the sample

Tapped density

Tapped density was determined by gently transferring 25 g of the sample through a glass funnel into a 100 mL graduated cylinder. The cylinder was then tapped 50 times, and the resulting volume occupied by the sample was recorded. Tapped density (g/mL) was subsequently calculated based on the recorded values.

Tapped density (g/ml) = weight of sample in gm/ volume occupied by the sample

Compressibility index

This method is among the simplest and most convenient approaches for evaluating the flow properties of powders, based on a comparison of bulk density and tapped density. Carr's compressibility index provides a valuable empirical measure for this assessment.

Carr's index TD-BD / TD X 100

Hausner ratio

It indicates the extent of densification that may occur as a result of vibration within the feed hopper.

Hausner ratio = Tapped density/ Bulk density.

Angle of Repose

The flow properties of the physical mixtures for all formulations were assessed by determining the angle of repose using the fixed-height method. A funnel with a 10 mm inner stem diameter was positioned at a height of 2 cm above the platform. Approximately 10 g of the sample was allowed to flow slowly along the inner wall of the funnel until the tip of the formed powder pile touched the funnel stem. A rough circle was drawn around the base of the pile, and the radius of the powder cone was measured. The angle of repose was then calculated from the average radius using the following formula:

$\tan \theta = h/r$

Where, θ = Angle of repose, h = Height of the pile,
r = Average radius of powder cone

Capsule Evaluation Parameters

The organoleptic characteristics, average weight, weight variation, drug content, disintegration time, and moisture content of the capsules were evaluated as part of the quality control assessment.

Organoleptic characters

The polyherbal formulation, encapsulated in hard HPMC capsules, was subjected to organoleptic evaluation, including assessment of colour, odour, and taste.

Average weight of capsules

The average weight of 20 capsules was calculated using a digital weighing balance.

Weight variation

Twenty capsules were weighed individually, and the weight of each capsule was compared with the calculated mean weight. Compliance was confirmed if the individual capsule weights were within **±5%** of the average weight.

Disintegration time

The disintegration test for the polyherbal capsules was performed using a disintegration test apparatus (LabIndia DT 1000). One capsule was placed in each tube of the basket, and a disk was inserted into each tube. The basket assembly was immersed in a 1000 mL beaker containing 800 mL of distilled water, maintained at 37 ± 2°C. The apparatus was operated, and the time required for the capsules to completely disintegrate and pass through a 10-mesh screen was recorded.

Moisture content

The moisture content of the formulation was determined using an automatic Karl Fischer titration apparatus.

Drug Content

Ten capsules of the polyherbal formulation were carefully opened, and the contents were collected in a clean Petri dish. An accurately weighed portion (~20 mg) of the capsule

powder was used for the determination of drug content by high-performance liquid chromatography (HPLC).

Instrumentation and Chromatographic Conditions

Thymol quantification was performed using High-Performance Liquid Chromatography (HPLC) with a Shimadzu P-Series UV system (LC-20AD, Japan) equipped with an autosampler (SIL-20ACHT) and a UV detector. Data acquisition and processing were carried out using the LC Solution Administrator software (Shimadzu, Japan). Chromatographic separation was achieved on a Shimadzu C18 column (250 mm × 4.6 mm, 5 µm) under isocratic conditions, and employing a mobile phase of acetonitrile (99.9%) and water containing 0.1% glacial acetic acid (80:20, v/v). The mobile phase was filtered through a 0.45 µm Millipore membrane filter and degassed via sonication for 30 minutes before use. The flow rate was maintained at 1.0 mL/min, with an injection volume of 20 µL, and detection was performed at a wavelength of 274 nm.

Preparation of Standard Solution

Standard solution of Thymol was prepared by dissolving 50 mg in 50 ml methanol (1000 ppm) then took 5 ml of this solution was diluted to 50ml methanol (100 ppm) in a volumetric flask (stock solution). 2 ml of the stock solution was diluted to 10 ml methanol (20 ppm), 4 ml of the same stock solution was diluted to 10 ml methanol (40 ppm), 6 ml of the same stock solution was diluted to 10 ml methanol (60 ppm) and 8 ml of the same stock solution was diluted to 10 ml methanol (80 ppm) for linearity study.

Preparation of Sample Solution

Ten Gas Relief capsules were opened, and the contents were collected in a sterile Petri dish. An accurately weighed portion of approximately 50 mg of the powdered sample was transferred to a volumetric flask and dissolved in 50 mL of methanol. The solution was sonicated for 20 minutes to ensure complete extraction, after which the volume was adjusted to 100 mL with methanol. The resulting solution was filtered through a 0.45 µm membrane filter before analysis.

Calibration Curve

Five different concentrations of stock solution after dilution (20, 40, 60, 80, 100 ppm) with mobile phase were injected in triplicate. The regression equation and coefficient of correlation (r2) were derived (Table 1).

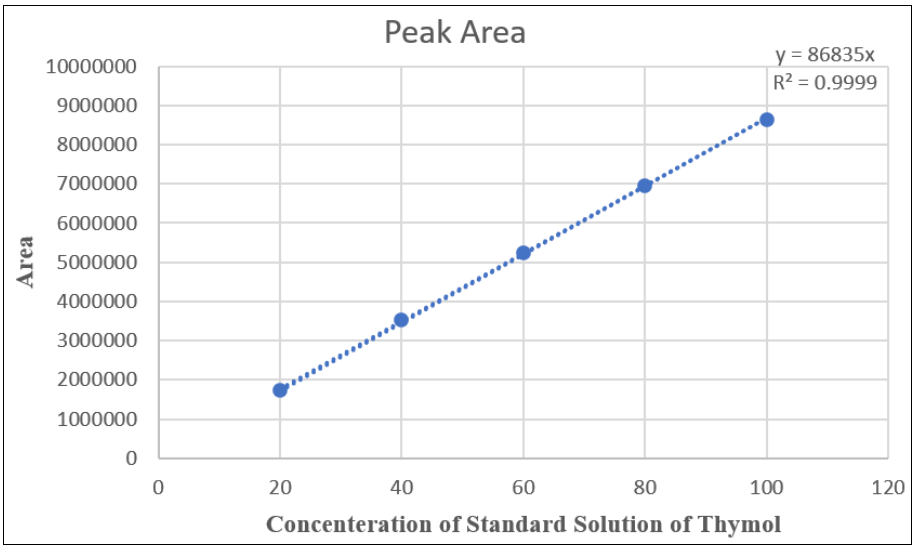


Fig 1: Thymol calibration curve

Range of Linearity

Standard calibration curves were prepared daily over three consecutive days using five Thymol standard concentrations (20, 40, 60, 80, and 100 ppm). The linearity of the peak area response relative to concentration was assessed with linear least-squares regression analysis, resulting in the regression equation y = 86835x. The linearity parameters are shown in Table 1, and the calibration curve is displayed in Figure 2.

Table 1: Validation Parameters of the Developed HPLC Method for Thymol Quantification

S. No.	Validation Parameters	Results
1.	Linearity range (ppm)	20-100 ppm
2.	Correlation coefficient (r2)	0.99
3.	Regression equation	y = 86835x
4.	LOD (ppm)	5.0 ppm
5.	LOQ (ppm)	5.0 ppm
6.	Method precision (RSD%)	0.71
Intermediate precision (RSD%)		
7.	Interday (%)	0.88
8.	Intraday (%)	1.25
9.	RSD% (Linearity of the method)	1.29

Limits of Detection (LOD) and Quantification (LOQ)

The Limit of Detection (LOD) is the smallest concentration that can be detected but not necessarily quantified as an exact value. The LOD value is 5ppm. The Limit of Quantification (LOQ) is the lowest amount of analyte in the sample that can be quantitatively determined with suitable precision and accuracy. LOQ observed is 5 ppm, and the values are given in Table 1.

Accuracy (recovery)

The method's accuracy was evaluated through recovery studies by spiking pre-analysed samples with known amounts of Thymol standard solution at three concentration levels: 50%, 100%, and 150% of the target concentration. Recovery tests were performed at 20 ppm, 40 ppm, and 60 ppm, with three replicate samples prepared and analyzed for each level. The average percentage recovery was calculated by applying the measured peak area values to the regression equation of the calibration curve. The results are shown in Table 2.

Recovery	Conc. of Std.	Amount of Std Spiked in mg	Amount Recovered in mg	% of recovery
50%	20 ppm	2.08 mg	2.05 mg	98.56%
100%	40 ppm	4.02 mg	4.00 mg	99.50%
150%	60 ppm	6.07 mg	6.07 mg	100%

Method precision (repeatability)

Instrument precision was evaluated by repeatedly injecting and analysing a 60 ppm Thymol standard solution (n = 6), with results expressed as the relative standard deviation (RSD). Method precision, including intraday and interday variability, was assessed by analysing standard solutions at five concentration levels (20, 40, 60, 80, and 100 ppm) in triplicate within a single day (intraday) and across three consecutive days (interday). The precision results are expressed in terms of RSD.

Results and Discussion

Preformulation studies

Preformulation parameters, including bulk density, tap density, Carr's index, Hausner's ratio, and angle of repose, were studied. The results are presented in Table 2.

Table 2: Preformulation Study of Polyherbal Powder of 3 batches of ArthoCalm Capsules

S. No.	Parameter	Standard Limit	Gas Relief Pro Capsules Batch Number		
			SHUSGR-00001	SHUSGR-00002	SHUSGR-00003
1.	Bulk density	0.45 - 0.55gm/ml	0.4706 gm/ml	0.5207 gm/ml	0.4765 gm/ml
2.	Tapped density	0.50 - 0.60gm/ml	0.5164 gm/ml	0.5655 gm/ml	0.5221 gm/ml
3.	Carr's index	5 - 15%	8.86%	7.88%	8.74%
4.	Hausner Ratio	1.0 - 1.1	1.09	1.08	1.09
5.	Angle of Repose	< 25	21.20º	22.50º	20.15º

Evaluation of Polyherbal Capsules (Gas Relief Pro)

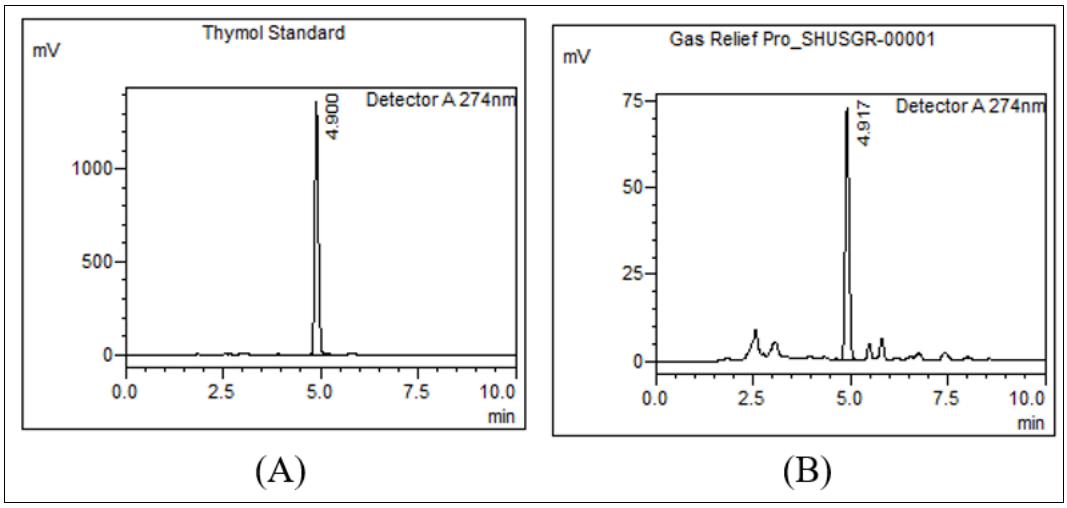
The polyherbal capsules of Gas Relief Pro were evaluated for their organoleptic characters, average weight, weight variation, disintegration time, and moisture content. The results are presented in Table 3.

Table 3: Evaluation of polyherbal Gas Relief Pro Capsules

S. No.	Evaluation Parameters	Specification	Observations		
			SHUSGR-00001	SHUSGR-00002	SHUSGR-00003
1.	Color	Brown Color	Brown Color	Brown Color	Brown Color
2.	Size	Double zero	Double zero	Double zero	Double zero
3.	Taste of filled powder	Bitters	Bitters	Bitters	Bitters
4.	Odour	Characteristic	Characteristic	Characteristic	Characteristic
5.	Average weight (mg)	579.5 - 640.5mg	632 mg	588.5 mg	635 mg
6.	Weight Variation	Avg wt. ±5%	600.4-663.6 mg	559.07-617.92 mg	603.2-666.7 mg
7.	Average Fill Weight	Avg wt. -130mg	502 mg	458.5 mg	505 mg
8.	Moisture content	NMT- 6%w/w	5.18%w/w	5.16%w/w	5.21%w/w
9.	Disintegration Time	NMT- 30 min	5 min	5 min	5 min
10.	Drug Content Thymol Content	NLT- 25 mg	28.82 mg	28.34 mg	29.64 mg

Thymol content in Gas Relief Capsules by HPLC

The assay of Thymol Content in 3 batches of Gas Relief Pro Capsules was 5.74%w/w, 6.18%w/w & 5.87%w/w. The chromatogram of the Thymol Standard and Gas Relief Pro Capsule samples is given in Fig. 1.



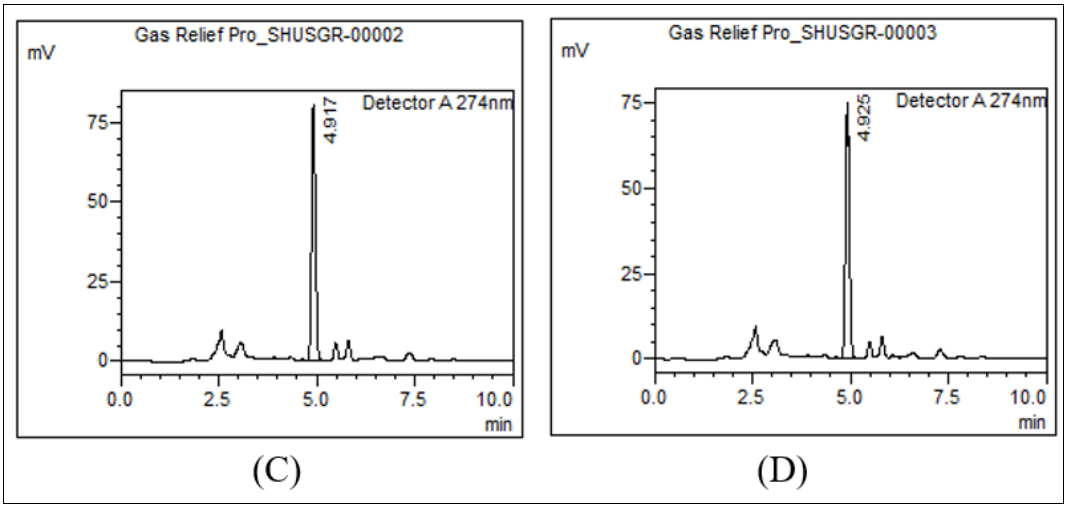


Fig 2: HPLC Chromatogram of (A) Thymol Standard, (B) Gas Relief Pro Capsule SHUSGR-00001, (C) Gas Relief Pro Capsule SHUSGR-00002 & (D) Gas Relief Pro Capsule SHUSGR-00003

Discussion

The capsule demonstrated excellent flow and uniformity, ensuring reproducible manufacturing. Moisture content (<6%) enhances stability. A disintegration time of 5 minutes suggests a rapid onset of therapeutic action. Thymol, a bioactive monoterpene with carminative and antimicrobial effects, was used as a marker compound. Standardization ensured batch-to-batch consistency (>25 mg/capsule). Validation confirmed the accuracy, precision, and robustness of the HPLC. Compared to previous polyherbal formulations, this study uniquely demonstrates validated thymol quantification and standardized capsule quality, supporting its use as a reproducible herbal therapeutic.

Conclusion

The polyherbal capsule (*Gas Relief Pro*) exhibited excellent physicochemical properties, reproducible thymol content, and validated analytical standardization. These results support its potential as a safe, stable, and effective herbal formulation for gastrointestinal discomfort.

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