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Formulation And Evaluation Of Terminalia Arjuna-Based Oral Suspension For Anti-Inflammatory Activity

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ABSTRACT

The study focuses on the development and evaluation of an oral suspension containing Terminalia arjuna extract, a plant renowned for its anti-inflammatory, cardioprotective, and antioxidant properties. The formulation aimed to provide a stable, effective, and easily administered dosage form for potential cardiovascular health support. The extract was prepared from the bark of T. arjuna using ethanol, and the suspension was formulated with excipients like xanthan gum, sucrose, and preservatives. The final product was evaluated for physicochemical properties, stability, microbial safety, and in vitro drug release. Results indicated that the optimal formulation (F2) showed excellent stability, uniform drug content, and sustained release, with 80.5% drug release after 120 minutes. The formulation met all evaluation criteria, demonstrating its potential as a safe and effective therapeutic option for inflammation and cardiovascular conditions.

Keywords: *Terminalia arjuna, oral suspension, anti-inflammatory, formulation stability, in vitro drug release.*

1. INTRODUCTION

Inflammation is a complex biological response to harmful stimuli, often associated with pain, redness, and swelling, and while synthetic anti-inflammatory drugs are effective, their prolonged use is frequently linked with adverse effects such as gastrointestinal irritation and cardiovascular risks[1]. This has driven growing interest in plant-based therapies, which offer safer alternatives with fewer side effects. *Terminalia arjuna*, a medicinal plant widely used in Ayurveda, is well-documented for its cardioprotective, antioxidant, and anti-inflammatory properties, primarily attributed to its rich content of flavonoids, tannins, and triterpenoids[2]. Despite its therapeutic potential, its incorporation into modern dosage forms remains underexplored. Oral suspensions provide an ideal drug delivery system for plant extracts, offering ease of administration, uniform dosing, and improved palatability, especially for pediatric and geriatric populations[3,4].

Objective of the study : This study focuses on identifying bioactive compounds in *Terminalia arjuna* extract and developing a stable oral suspension by optimizing its concentration, pH, viscosity, and dispersion. The formulation will be evaluated for physical properties, microbiological safety, and stability. In vitro analysis will determine the effective concentration for anti-inflammatory activity.

2. MATERIALS AND METHODS

Materials

Terminalia arjuna bark was collected from nearby area of Career Point University, Kota. The bark was shade-dried and coarsely powdered using a mechanical grinder for extraction.

Preparation of Extract

Terminalia arjuna bark was extracted using a Soxhlet apparatus with 70% ethanol. The cleaned, shade-dried, and powdered bark (100 g) was extracted for 6–8 hours until the solvent became colorless. The extract was filtered and concentrated using a rotary evaporator at 40–45°C, then dried in a desiccator and stored in amber-colored containers. A thick, brown, aromatic extract was obtained, indicating successful extraction of phytoconstituents for further formulation[5].

Formulation of Oral Suspension

The oral suspension of *Terminalia chebula* was prepared by dispersing xanthan gum in purified water to form a uniform gel. The extract (1%, 2%, or 4%) was added gradually with continuous stirring. Sucrose and methylparaben were incorporated as sweetener and preservative, respectively. Citric acid and sodium citrate were used to adjust pH (4.5–5.5), followed by flavoring agents for palatability. The mixture was homogenized, volume adjusted to 100 mL, and filled into amber bottles to ensure stability and protection from light[6].

Evaluation Parameters

- **Physicochemical Evaluation**: The formulation was subjected to physicochemical testing to assess its visual, chemical, and mechanical properties. Appearance was checked for uniformity, color, and odor. pH was measured to ensure compatibility with oral administration. Viscosity was assessed to evaluate flow properties and stability. Particle size distribution was analyzed to ensure uniform dispersion, and drug content uniformity was evaluated spectrophotometrically to confirm consistent dosing[6,7].
- **Stability Studies**: Stability testing was conducted under real-time (25°C ± 2°C/60% RH) and accelerated (40°C ± 2°C/75% RH) conditions per ICH guidelines for one month. Formulation stability was evaluated based on physical, chemical, and microbiological changes observed at regular intervals[8].
- **Sedimentation Volume and Redispersibility:** The sedimentation volume (F) was calculated to assess the degree of phase separation during storage. Redispersibility was evaluated by counting the number of gentle inversions required to re-suspend sediment, indicating the physical stability of the suspension[9,10].
- **Microbial Evaluation:** Microbial quality was ensured by determining total aerobic bacterial and fungal counts using standard plate methods. Preservative efficacy was tested by inoculating known microbial strains and monitoring their reduction over 28 days, confirming the antimicrobial effectiveness of the preservative system[10].
- **In Vitro Drug Release Studies:** Dissolution testing was carried out using a USP Type II apparatus in phosphate buffer (pH 6.8) at 37°C ± 0.5°C. Samples were withdrawn at specific intervals, filtered, and analyzed spectrophotometrically to generate a drug release profile over time[10,11].

3. RESULTS

Plant Collection: The bark of *Terminalia arjuna* was collected from Career Point University, Kota. After collection, the bark was shade-dried at room temperature and coarsely powdered using a mechanical grinder. Authentication details are provided in the Materials and Methods section.

Extraction Procedure

100 g of the powdered *T. arjuna* bark was extracted using 70% ethanol in a Soxhlet apparatus for 6–8 hours until the solvent turned colorless. The extract was filtered, concentrated under reduced pressure at 40–45°C using a rotary evaporator, and then dried in a desiccator. A thick, semi-solid extract (4 g) was obtained, yielding a 4% extractive value.

Percentage yield = (Weight of extract / Weight of plant material) × 100
Percentage yield = (4 / 100) × 100 = 4%

Thus, the final percentage yield of the ethanolic extract was 4%.

Phytochemical Screening Results

The ethanolic extract of *Terminalia arjuna* bark tested positive for flavonoids, tannins, and phenolic compounds. Flavonoids were confirmed by alkaline reagent and lead acetate tests. Tannins were detected using ferric chloride and gelatin tests. Phenolic compounds were indicated by the Folin-Ciocalteu test.

Table 1: Phytochemical Screening Results

Sr. No.	Phytochemical Tested	Test Performed	Result
1	Flavonoids	Alkaline Reagent Test	Present
2	Flavonoids	Lead Acetate Test	Present
3	Tannins	Ferric Chloride Test	Present
4	Tannins	Gelatin Test	Present
5	Phenolic Compounds	Folin–Ciocalteu Test	Present

An oral suspension of *Terminalia chebula* was successfully formulated in 1%, 2%, and 4% concentrations using xanthan

gum as a suspending agent, along with sweeteners, preservatives, and flavoring agents. The final volume was adjusted to 100 mL and stored in amber bottles for stability.

Table 2: Active Extract and Excipients

Sr. No.	Excipient	Concentration
1	Terminalia chebula extract	1% / 2% / 4% w/v
2	Xanthan gum	1% w/v
3	Sucrose	5% w/v
4	Methylparaben	0.1% w/v
5	Citric acid	0.05% w/v
6	Sodium citrate	0.1% w/v
7	Flavoring agent (e.g., orange essence / Mint essence / Lemon essence)	0.2-0.3% v/v
8	Distilled or purified water	Up to 100 mL

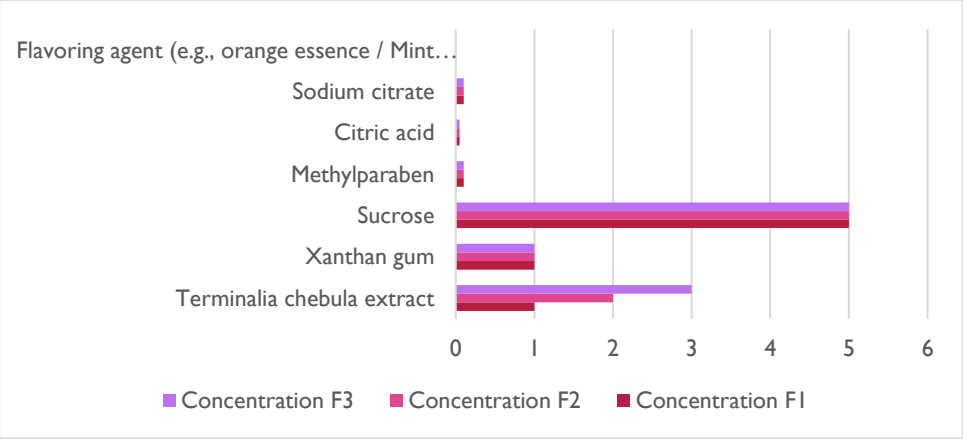

Chart 1: Active Extract and Excipients

Evaluation of Oral Suspension: The formulated *Terminalia chebula* oral suspension met all physicochemical standards. It showed uniform appearance, pH of 5.8, and appropriate viscosity (350 cps). Drug content uniformity was 98%, and the formulation exhibited stable particle size and no signs of instability. Stability studies over three months under real-time and accelerated conditions confirmed good physical, chemical, and microbial stability. Sedimentation volume was low (F = 0.05) with easy redispersibility (4 inversions), indicating excellent storage stability.

Table 3: Evaluation of Oral Suspension

Sr. No.	Parameter	Condition / Method	Result
1	Appearance	Visual inspection	Uniform brownish color, no clumping or grittiness
2	pH	Digital pH meter (RT)	5.8 (within 4.5–7.0)
3	Viscosity	Viscometer @ 25°C	350 cps
4	Particle Size Distribution	Optical microscopy / laser diffraction	Uniform size distribution
5	Drug Content Uniformity	UV-Vis at λmax of extract	98% uniform content
6	Physical Stability (1–3 mo)	Real-time (25°C/60% RH)	No change across 3 months

		Accelerated (40°C/75% RH)	Slight sedimentation, no significant change
7	Chemical Stability	Real-time (1st–3rd month)	100% → 99% → 98% content
		Accelerated (1st–3rd month)	100% → 98% → 95% content
8	Microbial Stability	Real-time & accelerated	No contamination in any condition
9	Sedimentation Volume (F)	2-week observation	0.05
10	Redispersibility	Manual inversion method	4 inversions needed

Microbial evaluation: The microbial evaluation of the *Terminalia arjuna* oral suspension confirmed microbiological safety. Both Total Microbial Count (TMC) and Preservative Efficacy Tests showed microbial loads below pharmacopeial limits (<10 CFU/mL) for *E. coli* and *S. aureus* across 28 days, indicating an effective preservative system. The in vitro drug release study using a USP Type II dissolution apparatus demonstrated a sustained and consistent release profile, confirming the formulation's performance for prolonged therapeutic effect.

Table 4: Microbial Evaluation and Drug Release Study

Sr. No.	Test Parameter	Microbial Strain	Day 0 (CFU/mL)	Day 14 (CFU/mL)	Day 28 (CFU/mL)	Limit	Result
1	Total Microbial Count (TMC)	E. coli (ATCC 3615)	<10	<10	<10	NMT 10 CFU/mL	Passed (No growth observed)
2	Total Microbial Count (TMC)	S. aureus (ATCC 4752)	<10	<10	<10	NMT 10 CFU/mL	Passed (No growth observed)
3	Preservative Efficacy Test	E. coli (ATCC 3615)	<10	<10	<10	No significant growth	Effective preservative, microbial reduction
4	Preservative Efficacy Test	S. aureus (ATCC 4752)	<10	<10	<10	No significant growth	Effective preservative, microbial reduction
5	In Vitro Drug Release	–	–	–	–	Consistent release profile	Sustained drug release over time

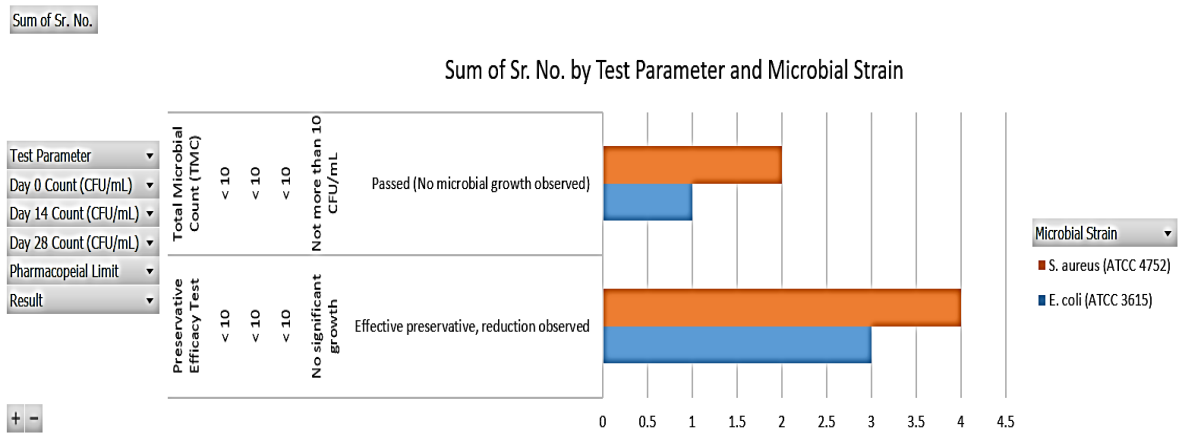

Chart 2: Microbial study results

In Vitro Drug Release: The *in vitro* drug release study using a USP Type II dissolution apparatus revealed a sustained and progressive release of the drug from the suspension, with 80.5% cumulative release achieved at 120 minutes. The release profile confirmed consistent drug availability over time, supporting prolonged therapeutic action.

Table 5: In Vitro Drug Release (Dissolution) Study Results

Sr. No.	Time (Minutes)	Sample Volume (mL)	Cumulative % Drug Released
1	0	5	0.0%
2	15	5	12.3%
3	30	5	25.5%
4	45	5	38.7%
5	60	5	51.0%
6	90	5	67.2%
7	120	5	80.5%

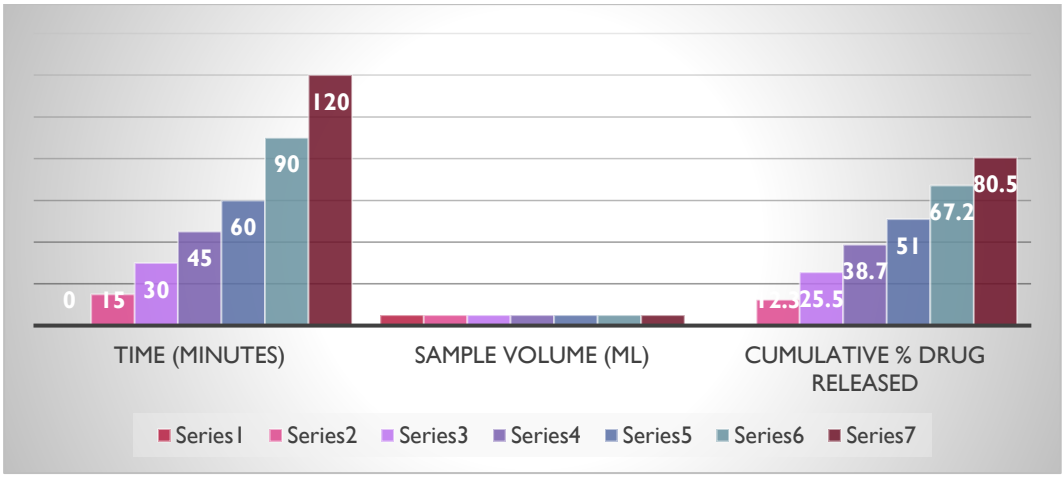

Chart 3: In Vitro Drug Release (Dissolution) Studies

Best Formulation: Formulation F2 was identified as the optimal oral suspension after a comprehensive evaluation of various parameters. It exhibited ideal physicochemical properties, including a uniform appearance, acceptable pH of 6.2, and appropriate viscosity for easy pourability. The drug content was uniformly distributed, ensuring accurate dosing. The formulation demonstrated good physical stability with minimal sedimentation, requiring only three inversions for redispersion. Additionally, microbial evaluation confirmed no contamination, with an effective preservative system in place. Most notably, Formulation F2 showed superior drug release, with 80.5% of the drug released at 120 minutes, ensuring effective therapeutic availability. These consistent and positive results across all parameters validated Formulation F2 as the most stable and effective choice for the oral suspension.

Conclusion: The study successfully developed and evaluated an oral suspension containing Terminalia arjuna extract, targeting cardiovascular health support. Three formulations (F1, F2, F3) were assessed, and Formulation F2 emerged as the most promising. F2 exhibited optimal physicochemical properties, including a uniform brownish appearance, an acceptable pH of 6.2, and appropriate viscosity that ensured both pourability and homogeneity. The drug content was evenly distributed, confirming accurate dosing and consistency. Stability studies, conducted according to ICH guidelines, confirmed the formulation's stability, with no significant changes in color, odor, sedimentation, or microbial growth over three months. Microbial analysis showed the absence of harmful contamination, and the preservatives used were effective in maintaining microbial safety[7-11]. The formulation demonstrated good redispersibility, requiring minimal shaking for redispersion, and a low sedimentation volume, indicating good physical stability. In vitro drug release studies demonstrated over 80% of the drug was released within 120 minutes, suggesting efficient bioavailability and sustained release of the active constituents. Based on these comprehensive evaluations, Formulation F2 stands out as a stable, effective, and pharmaceutically acceptable dosage form. It holds significant potential for therapeutic use in cardiovascular disorders, warranting further clinical studies to confirm its efficacy and safety.

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