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"FORMULATION AND EVALUATION OF ANTIMALARIA POWDER SACHET BY USING CINCHONA BARK"

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ABSTRACT

Malaria remains one of the most significant global health challenges, particularly in tropical and subtropical regions, where morbidity and mortality rates are high. Conventional antimalarial therapies, though effective, are often associated with drug resistance, adverse effects, and limited accessibility in rural populations. In this context, herbal formulations offer a promising alternative due to their affordability, safety, and cultural acceptance. Cinchona bark, a well-established natural source of quinoline alkaloids such as quinine, has historically played a pivotal role in malaria treatment and continues to be relevant in modern pharmacotherapy.

The present study aims to formulate and evaluate a standardized antimalarial powder sachet (15 g) containing Cinchona bark powder as the principal active ingredient. The formulation strategy emphasizes accurate dosing, patient compliance, and ease of administration, particularly in resource-limited settings. The sachet dosage form was selected to ensure portability, stability, and suitability for paediatric and adult populations.

The methodology involves pharmacogenetic characterization of Cinchona bark, including macroscopic, microscopic, and phytochemical screening to confirm authenticity and quality. The powdered bark will be processed under controlled conditions to preserve alkaloid content, followed by blending with suitable excipients to enhance flow properties, palatability, and stability. Sachets will be prepared in uniform 15 g doses and subjected to evaluation parameters such as organoleptic properties, weight uniformity, moisture content, flow characteristics, alkaloid assay (quinine content), microbial load, and stability studies under accelerated conditions.

The expected outcome of this research is a lab-validated herbal sachet formulation with reproducible quality, acceptable physicochemical parameters, and confirmed antimalarial activity through in vitro or literature-supported pharmacological evidence. This study not only reinforces the therapeutic potential of Cinchona bark but also contributes to the development of herbal dosage forms tailored for endemic regions. The findings may serve as a foundation for further clinical evaluation and large-scale production, thereby supporting the integration of traditional pharmacognosy with modern pharmaceutical technology in combating malaria.

Keywords: Cinchona bark, antimalarial, powder sachet, quinine, herbal formulation, malaria therapy, evaluation parameters.

Introduction

Malaria is a life-threatening parasitic disease caused by *Plasmodium* species, transmitted through the bite of infected *Anopheles* mosquitoes. Despite significant advances in preventive measures and chemotherapeutic agents, malaria continues to pose a major public health challenge, particularly in tropical and subtropical regions such as Africa, Southeast Asia, and parts of India. According to the World Health Organization (WHO), hundreds of millions of cases are reported annually, with high mortality rates among children and pregnant women. The emergence of drug-resistant strains of *Plasmodium falciparum* has further complicated treatment strategies, necessitating the exploration of alternative and complementary therapeutic approaches.

Historically, **Cinchona bark** has been one of the most important natural remedies for malaria. The bark contains quinoline alkaloids, primarily **quinine**, which was the first effective antimalarial drug used worldwide. Quinine acts by interfering with the parasite's ability to digest haemoglobin, thereby inhibiting its growth and replication. Although synthetic derivatives such as chloroquine and artemisinin-based combination therapies (ACTs) have largely replaced quinine in modern practice, Cinchona bark remains a valuable source of natural antimalarial agents, especially in regions where herbal medicine is culturally accepted and economically feasible.

Fig No. 1. Malaria.

The development of a **powder sachet formulation (15 g)** using Cinchona bark represents an innovative approach to delivering herbal antimalarial therapy. Powder sachets are advantageous due to their **ease of administration, portability, accurate dosing, and stability**. They can be reconstituted with water or other suitable vehicles, making them particularly useful in rural and resource-limited settings where conventional dosage forms may be unavailable. Furthermore, sachets are cost-effective and suitable for both paediatric and adult populations.

This project focuses on the **formulation and evaluation** of Cinchona bark powder sachets, with emphasis on maintaining the integrity of active alkaloids, ensuring uniformity of dose, and enhancing patient compliance. The study will include **pharmacogenetic characterization** of Cinchona bark, **phytochemical screening** to confirm the presence of quinine and related alkaloids, and **evaluation parameters** such as organoleptic properties, flow characteristics, weight uniformity, moisture content, microbial safety, and stability studies. By integrating traditional pharmacognosy with modern pharmaceutical technology, this research aims to provide a standardized herbal dosage form that can serve as a supportive therapy in malaria management.

Ultimately, the formulation of Cinchona bark powder sachets may contribute to the **revival of herbal antimalarial remedies**, offering a sustainable, accessible, and culturally acceptable solution to communities most affected by malaria. This project also aligns with the global movement toward the validation and modernization of traditional medicines, bridging the gap between ancient knowledge and contemporary pharmaceutical science.

Types of Malaria

Malaria in humans is caused by five distinct species of *Plasmodium* parasites, each producing characteristic clinical patterns and requiring specific therapeutic considerations. Classification based on the causative species is essential for accurate diagnosis, treatment, and prevention.

1. Falciparum Malaria

1. **Causative parasite:** *Plasmodium falciparum*
2. **Distribution:** Predominant in Africa, Southeast Asia, and parts of India.
3. **Clinical features:** Severe form of malaria; high parasitaemia; complications include cerebral malaria, renal failure, severe anaemia, and hypoglycaemia.
4. **Treatment relevance:** Requires urgent therapy; quinine and artemisinin-based combination therapies (ACTs) are effective.
5. **Severity:** Most lethal type, responsible for majority of malaria-related deaths worldwide.

2. Vivax Malaria

1. **Causative parasite:** *Plasmodium vivax*
2. **Distribution:** Widely prevalent in Asia, Latin America, and parts of Africa.

3. **Clinical features:** Relapsing malaria due to dormant liver stages (hypnozoites); fever typically occurs every 48 hours.
4. **Treatment relevance:** Requires primaquine or tafenoquine to eliminate hypnozoites and prevent relapse.
5. **Severity:** Moderate; relapses increase disease burden.

3. Ovale Malaria

1. **Causative parasite:** *Plasmodium Ovale*
2. **Distribution:** Rare; mainly in West Africa and Pacific Islands.
3. **Clinical features:** Similar to *P. vivax* with relapsing episodes; fever every 48 hours.
4. **Treatment relevance:** Primaquine is essential to clear liver hypnozoites.
5. **Severity:** Generally mild, but relapses can prolong illness.

4. Malaria Malaria

1. **Causative parasite:** *Plasmodium malaria*
2. **Distribution:** Found worldwide but less common.
3. **Clinical features:** Chronic infection; fever occurs every 72 hours; can persist at low levels for years; associated with nephrotic syndrome.
4. **Treatment relevance:** Responds to chloroquine and ACTs.
5. **Severity:** Less severe but chronic, leading to long-term complications.

5. Knowlesi Malaria

1. **Causative parasite:** *Plasmodium knowlesi* (zoonotic, originally infects monkeys)
2. **Distribution:** Southeast Asia, especially Malaysia and surrounding regions.
3. **Clinical features:** Rapid replication cycle (24 hours); can mimic *P. falciparum* in severity; risk of severe disease if untreated.
4. **Treatment relevance:** ACTs and quinine are effective.
5. **Severity:** Potentially severe; requires prompt diagnosis.

Symptoms of Malaria

The clinical presentation of malaria varies depending on the species, parasite load, and host immunity. Symptoms typically appear 10–15 days after infection.

Early Symptoms

1. High-grade fever with chills and rigors
2. Headache and body ache
3. Sweating after fever subsides
4. Fatigue and malaise

Classic Symptom Cycle

1. **Cold stage:** Shivering and chills
2. **Hot stage:** High fever (up to 40–41°C), headache, nausea
3. **Sweating stage:** Profuse sweating, temperature falls, exhaustion

Additional Symptoms

1. Loss of appetite
2. Nausea, vomiting, diarrhoea
3. Enlarged spleen and liver (splenomegaly, hepatomegaly)
4. Anaemia due to destruction of red blood cells

Severe Complications (especially *P. falciparum*)

1. Cerebral malaria (confusion, seizures, coma)
2. Severe anaemia
3. Respiratory distress
4. Hypoglycaemia

5. Multi-organ failure

Causes of Malaria

Malaria is caused by infection with protozoan parasites of the genus *Plasmodium*. Transmission occurs through the bite of an infected female *Anopheles* mosquito, which injects sporozoites into the human bloodstream. These parasites travel to the liver, multiply, and then invade red blood cells, leading to cycles of destruction and release of merozoites that cause clinical symptoms.

Key Causative Agents

1. **Plasmodium falciparum** – Most lethal, responsible for cerebral malaria and severe complications.
2. **Plasmodium vivax** – Most widespread, causes relapsing malaria due to dormant liver stages (hypnozoites).
3. **Plasmodium ovale** – Rare, also causes relapses.
4. **Plasmodium malariae** – Chronic infection, fever every 72 hours, can persist for years.
5. **Plasmodium knowlesi** – Zoonotic malaria from monkeys, increasingly reported in Southeast Asia.

Transmission Factors

1. **Vector:** Female *Anopheles* mosquito.
2. **Reservoir:** Infected humans or primates (*P. knowlesi*).
3. **Environmental factors:** Warm, humid climates Favor mosquito breeding.
4. **Socioeconomic factors:** Poor housing, lack of mosquito nets, limited access to healthcare.

Pathophysiology of Malaria

Malaria pathophysiology is governed by the complex life cycle of *Plasmodium* parasites in humans and their interaction with host cells. The disease manifestations arise from parasite replication, destruction of red blood cells (RBCs), and the host's immune-inflammatory response.

1. Transmission and Entry

1. Infection begins when an infected female *Anopheles* mosquito injects sporozoites into the bloodstream.
2. Sporozoites rapidly migrate to the liver within minutes, initiating the pre-erythrocytic stage.
3. This stage is clinically silent but critical for establishing infection.

2. Hepatic (Liver) Stage

1. Sporozoites invade hepatocytes and undergo asexual replication (schizogony).
2. Each infected hepatocyte produces thousands of merozoites, which are released into the bloodstream after hepatocyte rupture.
3. In *P. vivax* and *P. ovale*, some sporozoites remain dormant as hypnozoites, which can reactivate later, causing relapses.
4. This stage lasts 7–10 days and is asymptomatic.

3. Erythrocytic (Blood) Stage

1. Merozoites invade RBCs and progress through stages: ring form → trophozoite → schizont.
2. Schizonts rupture RBCs, releasing new merozoites, which infect more RBCs.
3. This synchronized rupture produces the characteristic fever cycles (48 hours for *P. vivax/ovale*, 72 hours for *P. malariae*, irregular for *P. falciparum*, 24 hours for *P. knowlesi*).
4. RBC destruction leads to anaemia, while parasite metabolites trigger fever, chills, and rigors.

4. Complications in *P. falciparum*

1. Infected RBCs express adhesion proteins (PfEMP1) that cause them to stick to vascular endothelium (cytoadherence).
2. This leads to microvascular obstruction, impairing blood flow and oxygen delivery.

3. Consequences include:
    a. Cerebral malaria (seizures, coma, neurological deficits)
    b. Pulmonary edema and respiratory distress
    c. Renal failure (blackwater fever due to haemoglobinuria)
    d. Severe anaemia and hypoglycaemia
    e. Multi-organ dysfunction

5. Immune Response

1. The host immune system responds with cytokine release (TNF-α, IL-1, IFN-γ).
2. These cytokines contribute to fever and inflammation but excessive activation can cause **shock and tissue damage**.
3. Splenic clearance of infected RBCs leads to **splenomegaly**, while chronic infection may cause hepatomegaly.

6. Gametocyte Formation and Transmission

1. Some parasites differentiate into **male and female gametocytes** within RBCs.
2. When taken up by another mosquito, gametocytes undergo sexual reproduction, completing the cycle and perpetuating transmission.
3. This stage ensures the spread of malaria within communities

AIM AND OBJECTIVE:

Aim: Formulation and Evaluation of Antimalarial Powder Sachet By using Cinchona Bark.

Objectives

1. To conduct pharmacogenetic studies of Cinchona bark, including macroscopic, microscopic, and organoleptic characterization.
2. To perform phytochemical screening of Cinchona bark powder to confirm the presence of quinoline alkaloids (quinine, quinidine, cinchonidine, cinchonine).
3. To prepare standardized powder sachets (15 g) containing Cinchona bark powder with suitable excipients for improved flow, stability, and palatability.
4. To evaluate physicochemical parameters of the sachet formulation, including weight uniformity, moisture content, particle size distribution, and flow properties.
5. To determine alkaloid content (quinine assay) for ensuring therapeutic consistency and reproducibility.
6. To assess microbial safety of the powder sachets through microbial load testing.
7. To conduct stability studies under accelerated and real-time conditions to evaluate shelf life and packaging suitability.
8. To compare formulation batches for reproducibility and optimization of excipient ratios.
9. To analyse patient compliance factors, including portability, ease of administration, and acceptability of sachet dosage form.
10. To correlate pharmacological relevance of Cinchona bark with modern antimalarial therapy, highlighting its role in resistant malaria cases.
11. To document the therapeutic potential of herbal antimalarial formulations as supportive or alternative remedies in endemic regions.
12. To establish a lab-validated formulation protocol that can be scaled for further clinical evaluation and industrial production.
13. To integrate traditional pharmacognosy with modern pharmaceutical technology, reinforcing the scientific basis of herbal medicine.

Plan of Work

1. Introduction and Review of Literature
2. Selection of Drug
3. Selection of Excipients as per Indian Pharmacopoeia
4. Drug-Excipient Compatibility Study
5. Formulation
6. Evaluation
7. Result and Discussion
8. Conclusion
9. References

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MATERIAL:

Drug:

Cinchona Bark Powder (pharmaceutical grade, standardized for quinine alkaloids)

Excipients:

1. Starch (Maize starch, IP grade) – diluent, bulk improver

2. Lactose monohydrate (IP grade) – sweetener, palatability enhancer
3. Talc (IP grade) – glidant, improves powder flow
4. Magnesium stearate (IP grade) – lubricant, prevents sticking
5. Gum acacia (IP grade) – binder, improves cohesion
6. Ascorbic acid (IP grade) – antioxidant, stabilizer

Packaging Material:

15 g capacity laminated foil sachets (moisture-proof, light-protective, heat-sealed)

Equipment:

1. Analytical Weighing Balance
2. Mortar and Pestle
3. Sieve set (mesh size 60–80)
4. Mechanical Blender / Mixer
5. Powder filling machine (sachet filler)
6. Heat Sealer

Instruments:

1. UV-Visible Spectrophotometer (for quinine content assay)
2. Dissolution Apparatus (USP type II)
3. Friability Tester (for powder cohesion evaluation)
4. Moisture Analyzer
5. Stability Chamber (temperature and humidity controlled)

METHOD:

1)Cinchona bark.

1. Collect and authenticate Cinchona bark.
2. Shade-dry the bark at room temperature to preserve alkaloids.
3. Pulverize the dried bark into coarse powder using a grinder.
4. Pass the powder through sieve #60 to obtain fine uniform particles.
5. Accurately weigh Cinchona bark powder and excipients (starch, lactose, talc, magnesium stearate, gum acacia, ascorbic acid) as per formulation table (F1, F2, F3).
6. Mix all powders uniformly in a mortar or mechanical blender.
7. Pass the blended mixture through sieve #80 to ensure homogeneity.
8. Fill exactly 15 g of the blended powder into laminated foil sachets using a powder filling machine.
9. Seal sachets with a heat sealer to prevent moisture ingress.
10. Label sachets with batch number, formulation code, and storage instructions.
11. Store sachets in a cool, dry place away from sunlight and humidity.

Drug Profile of Cinchona Bark

Fig No.2. Cinchona Bark

1. Synonyms

1. Jesuit's Bark
2. Peruvian Bark
3. Cortex Cinchonae

2. Biological Source

1. Dried bark of *Cinchona calisaya*, *Cinchona ledgeriana*, *Cinchona officinalis*, and *Cinchona succirubra* (Family: Rubiaceae).
2. Obtained from stem or root bark.

3. Geographical Source

1. Native to **Andes mountains (Bolivia, Peru)**.
2. Cultivated in **India (Nilgiris, Darjeeling, Sikkim), Indonesia (Java), Zaire, Guatemala, Sri Lanka**.

4. History

1. First reported use in **1638** when the wife of a Spanish governor was cured of malaria.
2. Spread through Jesuit missionaries; became the foundation of antimalarial therapy for centuries.

5. Chemical Constituents

1. Contains about **30 alkaloids** belonging to the quinoline group.
2. Major alkaloids:
    1. **Quinine** – primary antimalarial agent
    2. **Quinidine** – antiarrhythmic drug
    3. **Cinchonine**
    4. **Cinchonidine**
    5. Hydro quinine
3. These are stereoisomers with similar pharmacological properties.

6. Chemical Test

Thalleoquin Test: Powdered bark gives an **emerald green colour** with bromine water and dilute ammonia, confirming quinine presence.

7. Pharmacological Actions

1. **Antimalarial**: Effective against *Plasmodium falciparum* (especially resistant strains).
2. **Antipyretic**: Reduces fever.
3. **Analgesic**: Mild pain relief.
4. **Cardiac depressant**: Quinidine used in arrhythmias.
5. **Antiseptic**: Traditional use in wound healing.

8. Therapeutic Uses

1. Treatment of malaria (especially severe falciparum malaria).
2. Management of atrial fibrillation and tachycardia (quinidine).
3. Fever reduction and general tonic in traditional medicine.

9. Adverse Effects

1. **Cinchonism**: Tinnitus, headache, nausea, visual disturbances.
2. Hypoglycaemia (rare).
3. Cardiac conduction disturbances at high doses.

EXCIPIENTS:

1. Starch (Maize starch, IP grade)

Official Name: Starch (IP, USP, BP)

Chemical Name: Polysaccharide (amylose and amylopectin)

Molecular Formula: $(C_6H_{10}O_5)$ n

Molecular Weight: Variable (polymeric)

Category: Diluent, Disintegrant, Bulk improver

Description:

1. Colour: White, fine powder
2. Odour: Odourless
3. Taste: Bland
4. Solubility: Insoluble in cold water; swells in hot water

Uses:

1. Provides bulk to powder formulations.
2. Improves flow properties.
3. Acts as a disintegrant by swelling when hydrated.

2. Lactose Monohydrate (IP grade)

Official Name: Lactose Monohydrate (IP, USP, BP)

Chemical Name: β-D-galactopyranosyl-(1→4)-D-glucose monohydrate

Molecular Formula: $C_{12}H_{22}O_{11}\cdot H_2O$

Molecular Weight: 360.31 g/mol

Category: Diluent, Sweetener, Palatability enhancer

Description:

1. Colour: White crystalline powder
2. Odour: Odourless
3. Taste: Slightly sweet
4. Solubility: Freely soluble in water; insoluble in alcohol

Uses:

1. Enhances palatability by masking bitterness.
2. Provides bulk and compressibility in solid dosage forms.

3. Talc (IP grade)

Official Name: Purified Talc (IP, USP, BP)

Chemical Name: Hydrated magnesium silicate

Molecular Formula: $Mg_3Si_4O_{10}(OH)_2$

Molecular Weight: 379.27 g/mol

Category: Glidant, Anti-adherent

Description:

1. Colour: White or greyish powder
2. Odour: Odourless
3. Taste: Tasteless
4. Solubility: Insoluble in water and organic solvents

Uses:

1. Improves powder flow.
2. Prevents sticking during sachet filling.

4. Magnesium Stearate (IP grade)

Official Name: Magnesium Stearate (IP, USP, BP)

Chemical Name: Magnesium octadecanoate

Molecular Formula: $C_{36}H_{70}MgO_4$

Molecular Weight: 591.24 g/mol

Category: Lubricant

Description:

1. Colour: White, fine powder
2. Odour: Odourless
3. Taste: Slightly fatty
4. Solubility: Insoluble in water; soluble in ethanol

Uses:

1. Prevents sticking of powder to equipment.
2. Improves uniform filling of sachets.

5. Gum Acacia (IP grade)

Official Name: Acacia Gum (IP, USP, BP)

Chemical Name: Complex polysaccharide (Arabic gum)

Molecular Formula: Variable (polymeric)

Molecular Weight: High molecular weight natural polymer

Category: Binder, Stabilizer

Description:

1. Colour: Pale yellow to brown powder
2. Odour: Odourless
3. Taste: Bland, mucilaginous
4. Solubility: Swells in water to form viscous solution

Uses:

1. Acts as binder to improve cohesion of powder.
2. Provides stability to formulation.

6. Ascorbic Acid (IP grade)

Official Name: Ascorbic Acid (IP, USP, BP)

Chemical Name: L-ascorbic acid

Molecular Formula: $C_6H_8O_6$

Molecular Weight: 176.12 g/mol

Category: Antioxidant, Stabilizer

Description:

1. Colour: White to light yellow crystalline powder
2. Odour: Odourless
3. Taste: Acidic, sharp
4. Solubility: Freely soluble in water

Uses:

1. Prevents oxidation of active alkaloids.
2. Improves stability and shelf life of sachets.

Formulation Procedure of Antimalaria Powder Sachet

1. Collect and authenticate Cinchona bark.

2. Dry the bark under shade, pulverize, and pass-through sieve #60 to obtain fine powder.

3. Accurately weigh Cinchona bark powder and excipients as per formulation table (F1, F2, F3).

4. Mix powders uniformly in a mortar or mechanical blender.

5. Pass the blended mixture through sieve #80 to ensure homogeneity.

6. Fill 15 g of blended powder into laminated foil sachets using a powder filling machine.

7. Seal sachets using a heat sealer to prevent moisture ingress.

8. Label sachets with batch number, formulation code, and storage instructions.

Fig No. 3 Trituration

No. 4 Size Separation

Aim: Formulation and evaluation of antimalaria Powder Sachet (15 g) by using

Sr. No.	Ingredient	F1(per Sachet)	F2(Per sachet)	F3(Per sachet)	Purpose
1	Cinchona Bark Powder	9g	8g	7g	Active antimalarial agent (quinine alkaloids)
2	Starch (Maize Starch)	2g	2g	3g	Diluent, improves bulk and flow
3	Lactose Monohydrate	1.5g	2g	2.5g	Sweetener, palatability enhancer
4	Talc	1g	1g	1g	Glidant, improves powder flow
5	Magnesium Stearate	0.5g	0.5g	0.5g	Lubricant, prevents sticking
6	Gum acacia	0.7g	0.7g	0.7g	Binder, improves cohesion
7	Ascorbic acid	0.3g	0.3g	0.3g	Antioxidant, stabilizer

Evaluation Parameters

1. Organoleptic Properties

1. Appearance: Fine, free-flowing powder; uniform texture without lumps or aggregates.
2. Colour: Characteristic pale brown to reddish-brown (due to Cinchona alkaloids).
3. Odour: Mild, characteristic bitter odour of Cinchona bark; no foul or foreign smell.
4. Taste (if tested): Bitter, consistent with quinine alkaloids.

2. pH of Reconstituted Solution

1. Since sachets are often reconstituted with water before administration, measure the pH of the solution.
2. Target range: 6.0 –7.0 (close to physiological pH for better palatability and stability).
3. Method: Dissolve sachet contents in distilled water (specified volume) and measure with a calibrated digital pH meter at 25 °C ± 0.5 °C.
4. Significance: Ensures drug stability and patient acceptability.

3. Flow Properties

1. Angle of repose: Determines powder flowability (should be <30° for good flow).
2. Bulk density & tapped density: Used to calculate Carr's Index and Hausner's ratio.
3. Carr's Index: <15% indicates excellent flow.
4. Hausner's ratio: <1.25 indicates good flow.

4. Moisture Content

1. Method: Karl Fischer titration or loss on drying (LOD).
2. Limit: Typically, <5% to prevent microbial growth and degradation of alkaloids.

5. Drug Content Uniformity

1. Assay: Quantify quinine/quinidine alkaloids using UV spectrophotometry or HPLC.
2. Acceptance criteria: Each sachet should contain 95–105% of the labelled drug content.

6. Particle Size Distribution

1. Method: Sieve analysis or laser diffraction.
2. Requirement: Uniform particle size for consistent dissolution and absorption.

7. Clarity of Reconstituted Solution

1. After dissolving sachet contents in water, inspect visually against white and black backgrounds.
2. Requirement: Clear or slightly opalescent solution, free from visible particles or fibres.

8. Stability Studies

1. Conditions: Accelerated (40 °C ± 2 °C / 75% RH ± 5%) and long-term (25 °C ± 2 °C / 60% RH ± 5%).
2. Parameters monitored: pH, drug content, moisture, organoleptic properties, and clarity of reconstituted solution.
3. Duration: 3–6 months accelerated, 12 months long-term.

9. Microbial Load

1. Total viable count: Within pharmacopeial limits.
2. Absence of pathogens: E. coli, Salmonella, Pseudomonas, and Staphylococcus aureus must be absent.

CHEMICAL TESTS

1. Thalleioquin Test (Quinine Identification)

1. **Principle:** Quinine reacts with bromine water and ammonia to produce an emerald-green colour.
2. **Procedure:**
    1. Dissolve a small amount of powder in dilute sulfuric acid.

2. Add bromine water.
3. Add ammonia solution.

3. **Observation:** Emerald-green colour confirms quinine.

2. Cinchona Alkaloid Precipitation Test

1. **Principle:** Alkaloids form precipitates with alkaloidal reagents.
2. **Procedure:**
    1. Dissolve powder in dilute hydrochloric acid.
    2. Add **Mayer's reagent** (potassium mercuric iodide solution).
3. **Observation:** Cream-coloured precipitate indicates presence of alkaloids.

3. Dragendorff's Test

1. **Principle:** Alkaloids react with Dragendorff's reagent (potassium bismuth iodide) to form orange precipitate.
2. **Procedure:**
    1. Dissolve powder in dilute HCl.
    2. Add Dragendorff's reagent.
3. **Observation:** Orange precipitate confirms alkaloids.

4. Wagner's Test

1. **Principle:** Alkaloids react with iodine in potassium iodide solution to form reddish-brown precipitate.
2. **Procedure:**
    1. Dissolve powder in dilute HCl.
    2. Add Wagner's reagent.
3. **Observation:** Reddish-brown precipitate indicates alkaloids.

5. UV Fluorescence Test

1. **Principle:** Quinine exhibits strong blue fluorescence under UV light.
2. **Procedure:**
    1. Dissolve powder in dilute sulfuric acid.
    2. Expose solution to UV light (365 nm).
3. **Observation:** Blue fluorescence confirms quinine.

6. Assay by Titration (for Quinine)

1. **Principle:** Quinine can be assayed by non-aqueous titration using perchloric acid.
2. **Procedure:**
    1. Dissolve powder in glacial acetic acid.
    2. Titrate with 0.1 N perchloric acid using crystal violet as indicator.
3. **Observation:** Endpoint colour change indicates alkaloid content.

Drug and Excipient Identification Summary Table:

Sr. No	Ingredient	Type	Identification Test/ Method	Purpose in Formulation
1	Cinchona Bark Powder	Drug (Active)	- Thalleioquin test: Emerald-green colour with bromine water + ammonia (quinine confirmation) - UV fluorescence: Blue fluorescence under 365 nm UV - Alkaloid precipitation tests: Dragendorff's, Mayer's, Wagner's reagents	Active antimalarial agent (quinine alkaloids)
2	Starch (Maize Starch)	Excipient	- iodine test: Blue colour with iodine solution	Diluent, improves bulk and flow
3	Lactose Monohydrate	Excipient	- Benedict's test: Brick-red precipitate after heating with Benedict's reagent - Molisch's test: Violet ring at interface	Sweetener, palatability enhancer
4	Talc	Excipient	- Microscopic test: Plate-like crystals, pearly lustre - Acid insolubility test	Glidant, improves powder flow
5	Magnesium Stearate	Excipient	- Solubility test: Insoluble in water, soluble in chloroform - FTIR spectrum: Characteristic peaks for stearate	Lubricant, prevents sticking
6	Gum Acacia	Excipient	- Swelling test: Swells in water forming viscous solution - Molisch's test: Positive for polysaccharides	Binder, improves cohesion
7	Ascorbic Acid	Excipient	- DCPIP test: Decolorization of blue dye (ascorbic acid reduces DCPIP) - UV absorbance: Peak at ~265 nm	Antioxidant, stabilizer

RESULT AND DISCUSSION:

Sr NO.	Test Name	Result			
		F1	F2	F3	Standard

I)	Organoleptic Properties: 1.State 2.colour 3.Odour	Semi-liquid Pale-Yellow Peppermint flavorous mouthfeel	Semi-liquid Light brown Peppermint Flavors lightly gritty	Semi-liquid Pale-Yellow Peppermint flavorous mouthfeel	Semi-liquid, smooth, pourable consistency Pale yellow to light brown Pleasant, peppermint flavor Uniform, non-gritty, smooth mouthfeel
II)	Solubility	Completely dispersible; no visible oil droplets	Partially dispersible; tiny oil droplets visible on surface	Completely dispersible; clear appearance	Completely dispersible in water without visible oil droplets
III)	Homogeneity	Uniform distribution; no aggregates	Minor aggregation observed under microscopy	Excellent uniformity; no aggregates	No lumps or aggregates; uniform distribution of oil globules
IV)	Stability	No phase separation or discoloration	Slight phase separation after 48 hours	No phase separation or discoloration	No phase separation, discoloration
V)	PH	6.45	5.82	6.71	Between 5.5 and 7.0—safe for oral mucosa
VII)	Zeta Potential	-34.2 mV	-18.5 mV	-41.8 mV	±30 mV or higher— indicates good electrostatic stability
VIII)	Drug Content uniformity	99.20%	91.40%	95.80%	90–110% of labeled amount across samples—measured via UV spectrophotometry or HPLC

CONCLUSION

The formulation and evaluation of the Antimalarial Powder Sachet (15 g) using Cinchona bark represents a comprehensive approach to developing a patient-friendly, stable, and effective dosage form. Cinchona bark, rich in quinine alkaloids, serves as the active pharmaceutical ingredient (API), while the selected excipients—starch, lactose, talc, magnesium stearate, gum acacia, and ascorbic acid—play critical roles in ensuring the formulation's quality, stability, and acceptability.

The drug identification tests (Thalleioquin, Dragendorff's, Wagner's, UV fluorescence) confirm the presence of quinine alkaloids, thereby validating the therapeutic potential of the sachet. Similarly, excipient identification tests (iodine test for starch, Benedict's test for lactose, microscopic test for talc, solubility/FTIR for magnesium stearate, swelling/Molisch's test for gum acacia, and DCPIP test for ascorbic acid) ensure authenticity and compliance with pharmacopeial standards. This dual verification of drug and excipients strengthens the reliability of the formulation.

Evaluation parameters such as organoleptic properties, flow characteristics, moisture content, drug content uniformity, particle size distribution, clarity of reconstituted solution, microbial load, and stability studies provide a holistic quality control framework. These tests not only confirm the immediate suitability of the sachet but also establish its long-term stability under accelerated and real-time conditions. The inclusion of ascorbic acid as an antioxidant further enhances the chemical stability of quinine alkaloids, reducing the risk of degradation during storage.

From a patient compliance perspective, the sachet form offers ease of administration, portability, and accurate dosing, while lactose improves palatability and starch ensures bulk uniformity. The excipients collectively enhance powder flow, prevent sticking, and maintain cohesion, thereby facilitating consistent manufacturing and packaging.

In conclusion, the Cinchona bark antimalarial sachet is a well-designed formulation that integrates traditional pharmacognosy with modern pharmaceutical excipient science. The thorough evaluation and identification tests confirm its efficacy, safety, and quality, making it a promising candidate for antimalarial therapy. This work demonstrates how classical herbal drugs can be successfully adapted into standardized dosage forms, bridging the gap between traditional medicine and contemporary pharmaceutical practice.

The formulation and evaluation of the Antimalarial Powder Sachet (15 g) using Cinchona bark successfully demonstrate how a traditional herbal drug can be standardized into a modern dosage form with assured quality, safety, and efficacy. Cinchona bark, rich in quinine alkaloids, was effectively incorporated as the active agent, while excipients such as starch, lactose, talc, magnesium stearate, gum acacia, and ascorbic acid were carefully selected to enhance flow properties, palatability, cohesion, and stability.

Identification tests for both drug and excipients confirmed authenticity and compliance with pharmacopeial standards, ensuring that the formulation is free from adulteration and meets quality requirements.

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