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ASSESSMENT OF PHARMACEUTICAL QUALITY PARAMETERS OF QUININE SULPHATE CAPSULE FOR THE TREATMENT OF MALARIA

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1. ABSTRACT

Malaria is a major vector-borne parasitic disease caused by *Plasmodium* species and transmitted through infected *Anopheles* mosquitoes. Among the human pathogenic species, *Plasmodium falciparum* is the most severe and responsible for the majority of malaria-related deaths. The disease is characterized by symptoms such as fever, chills, headache, fatigue, jaundice, and severe complications including cerebral malaria. The malaria parasite undergoes a complex life cycle involving hepatic and erythrocytic stages in humans and sexual reproduction in mosquitoes. Antimalarial agents play a vital role in treatment and prevention, with quinine sulphate being an important drug especially in resistant malaria cases. Quinine acts by inhibiting the conversion of toxic heme into non-toxic hemozoin inside the parasite, leading to parasite death.`

This document also describes the formulation and evaluation of quinine sulphate capsules. Preformulation studies including physicochemical characterization, compatibility studies, and optical analysis are essential for developing a stable and effective dosage form. Hard gelatin capsules are prepared using suitable excipients such as diluents, lubricants, disintegrants, and glidants to ensure proper drug release and stability. Various evaluation tests including weight variation, disintegration, dissolution, content uniformity, and stability studies are performed to ensure quality and therapeutic effectiveness. Proper packaging, labeling, and storage conditions are also important to maintain capsule stability and patient safety.

2. KEYWORDS

- Malaria

- Quinine Sulphate
- Antimalarial Agents
- Capsule Formulation
- Preformulation Studies
- Evaluation of Capsule.

3. INTRODUCTION

- It is an endemic vector-borne parasitic disease caused by protozoan parasites of the genus *Plasmodium* in tropical and subtropical regions worldwide. *Plasmodium* consists of over 200 species, infecting mammals, birds, and reptiles, and malaria parasites generally tend to be host-specific. *Plasmodium falciparum, Plasmodium vivax, Plasmodium malariae, Plasmodium ovale*, and *Plasmodium knowlesi* are the five known species of the genus *Plasmodium* that causes malaria in humans.
- Among them, *P. falciparum* is the most pathogenic species that accounts for 60–70% deaths. Malaria parasite completes its life cycle in two different hosts; invertebrate—*Anopheles* mosquitoes, and vertebrate—humans. [1]

SYMPTOMS

The most common early symptoms of malaria are fever, headache and chills.

Symptoms usually start within 10–15 days of getting bitten by an infected mosquito.Symptoms may be mild for some people, especially for those who have had a malaria infection before. Because some malaria symptoms are not specific, getting tested early is important.

Some types of malaria can cause severe illness and death. Infants, children under 5 years, pregnant women, travellers and people with HIV or AIDS are at higher risk. Severe symptoms include:

1) Extreme tiredness and fatigue
2) Impaired consciousness
3) Multiple convulsions
4) Difficulty breathing
5) Dark or bloody urine
6) Jaundice (yellowing of the eyes and skin)
7) Abnormal bleeding.[2]

ETIOLOGY

Protozoan parasites of the genus Plasmodium originate from photosynthetic protozoa named Dinoflagellates. About 200 different species of protozoa have been identified so far and among them, at least 13 species are known to be pathogenic to humans. Five of the parasites namely P. falciparum, P. vivax, P. malariae, P. ovale (P. ovale curtisi and P. ovale wallikeri), and P. knowlesi are well-known etiologies of malaria in humans.

In Africa, the most prevalent and pathogenic species is P. falciparum. However, malaria infection from most malaria-endemic regions of Africa shows the presence of multiple sympatric species and co-infection within an individual human host or mosquito vector. P. malariae is the species most commonly found in sympatry with P. falciparum in malaria-endemic regions of Africa.

In each endemic area, malaria is transmitted by a specific set of Anopheles species. So far, more than 400 different species of Anopheles mosquitoes have been identified. But only 30 of them are known to transmit malaria. All vectors of malaria undergo the bite between dusk and dawn.

Stability is observed in the distribution pattern of the mosquito species in malaria-endemic regions of the African continent. The complete disappearance of a given vector species from a region is unusual and when the non-indigenous vector is introduced to the area, it is a serious public health concern since it is known to result in devastating epidemics. Indigenous vectors are hard to eradicate with known vector eradication activities.[3]

LIFE CYCLE OF MALARIA

The life cycle of the malaria parasite is a complex process involving an Anopheles mosquito and a vertebrate host. The first stage of the infection is the entrance of the sporozoites in mosquito saliva into the skin and bloodstream of the human host and then, it invades hepatocytes to undergo asexual replication. During this phase (hepatic or pre-erythrocytic phase) the rupture of infected hepatocytes results in the release of thousands of merozoites. In the case of P. vivax and P. ovale infections, some form dormant hypnozoites which remain within hepatocytes for periods of several months, and even as long as 4 years, before developing and multiplying to initiate a new episode of erythrocytic infection.

The erythrocytic infection involves the interaction of the merozoites with the red blood cells (RBC). The merozoites head orients and adjoin with the erythrocytes membrane by deforming the surface host cell. Then, through parasite-induced reorganization of the erythrocyte cytoskeleton, the parasite enters the erythrocyte to undergo the second asexual

reproduction. While younger erythrocytes are targeted favorably by P. vivax and P. ovale, erythrocytes of any age are invaded by P. falciparum and P. knowlesi. In contrast, P. malariae prefers senescent erythrocytes. After invading RBC, merozoites reproduce into trophozoites and then into schizonts which erupt from the erythrocytes to release merozoites and reinvade new RBCs and continue the asexual replication cycle.

The sexual reproduction cycle of malaria starts when a portion of trophozoites matures to male and female sexual progeny or gametocytes. The transmission of the malaria parasite from the mammalian host to the mosquito is mediated by these gametocytes. During the bite of an anopheles mosquito, the matured gametocytes will be taken to the midgut of the mosquito. Inside the midgut, gametocytes get converted into fertile gametes and the next stage involves the conversion of zygotes into ookinetes which are motile and invasive. The ookinetes in turn get converted into oocysts in the midgut basal lamina. The oocyst then matures releasing sporozoites, which migrate to the salivary gland of the mosquito. The parasite is transmitted to another mammalian host through an infected mosquito bite.

PATHOPHYSIOLOGY OF MALARIA

Malaria pathophysiology differs between uncomplicated and severe disease. In uncomplicated malaria, fever results from the rupture of infected red blood cells and the release of merozoites, which stimulate macrophages to produce pro-inflammatory cytokines, especially TNF-α. The fever pattern varies by species: Plasmodium vivax and Plasmodium ovale cause tertian fever (every 48 hours), Plasmodium malariae causes quartan fever (every 72 hours), while Plasmodium falciparum typically produces an irregular fever pattern.

Severe malaria is mainly due to cytoadherence, where infected red blood cells bind to vascular endothelium. In P. falciparum, the virulence factor PfEMP1 forms surface “knobs” that mediate adhesion to endothelial receptors, leading to sequestration of infected cells in deep microvasculature. This process contributes to complications such as cerebral malaria. In addition, rosetting (binding of infected to uninfected red blood cells) impairs microcirculation and causes tissue hypoxia. Parasite toxins such as glycosylphosphatidylinositol (GPI) further stimulate excessive cytokine production, resulting in high fever, endothelial activation, nitric oxide release, tissue damage, and suppression of bone marrow function.[4]

ANTI-MALARIAL AGENTS

Antimalarial medications are a type of antiparasitic chemical agent, often naturally derived, that can be used to treat or prevent malaria.Effective anti-malarial drug treatment reduces

malaria transmission. This alone can reduce the incidence and prevalence of malaria, although the effects are greater in areas of low transmission where a greater proportion of the infectious reservoir is symptomatic and receives anti-malarial treatment.[5]

CLASSIFICATION

a.CinchonaAlkaloids:

e.g.Quinine,quinidine

b.4-Aminoquinolines:

e.g.Chloroquine,amodiaquine.piperaquine

c.8-Aminoquinolines:

e.g.Primaquine,Pamaquine

d.Quinoline-Methanol:

e.g.Mefloquine

e.Naphthaquinone:

e.g.Atovaqoune

f.Pyrimidines:

e.g.Pyrimithamine,Trimethoprim

g.Sulphones:

e.g.Dapsone,Sulfamethopyrazine

h.Biguanides:

e.g.Proguanil,Chloroproguanil

i.SesquiterpineLactone:

e.g.Artemisinin,Artemether

k.Antibiotics:

e.g. Tetracycline, doxycycline, clindamycin [6]

QUININE SULPHATE CAPSULE

Quinine sulphate is an established antimalarial drug widely used for the treatment of uncomplicated and complicated malaria cases. Due to its bitter taste, poor patient compliance, and variable gastrointestinal irritation, capsule formulation offers a suitable oral dosage form for improved acceptability and therapeutic effectiveness. quinine sulphate play an important role in its management, particularly in cases where resistance to other antimalarial agents has emerged.[7]

MECHANISM OF ACTION

Quinine acts by interfering with the parasite's ability to digest hemoglobin inside red blood cells. The malaria parasite feeds on hemoglobin and releases a toxic substance called free heme. Normally, the parasite converts this toxic heme into a harmless crystalline form called hemozoin. Quinine blocks this conversion, causing accumulation of toxic heme, which damages the parasites cell membrane and finally leads to its death. Thus, quinine works by starving and poisoning the malaria parasite within infected red blood cells.[8]

4. MATERIALS AND METHODS

PREFORMULATION STUDIES

It is defined as an investigation of physical & chemical properties of drug substance alone and when combined with excipient. Pre formulation involves the application of biopharmaceutical principles to the physicochemical parameters of drug substance are characterised with the goal of designing optimum drug delivery system.[9]

CLASSIFICATION OF PRE-FORMULATION STUDIES OF QUININE SULPHATE

1. PHYSICOCHEMICAL PROPERTIES:

i) Organoleptic Properties

ii) Solubility

iii) pka

iv) pH

v) Partition coefficient

vi) Melting point

2. COMPATIBILITY STUDIES:

i) Fourier Transmission Infra-Red Spectroscopy(FTIR)

3. OPTICAL PROPERTIES:

i) UV-VIS Spectroscopy (λ-Max)

PHYSIOCHEMICAL PROPERTIES

Molecular Formula: C40H50N4O8S

Molecular Weight: 746.9 g/mol

Organoleptic Properties [10]

PROPERTIES	DESCRIPTION
Appearance	Bulky, white, amorphous powder or crystalline alkaloid
Odour	Odourless
Taste	Very Bitter taste
Physical nature	Crystalline Powder

Solubility:

Solubility, the phenomenon of dissolution of solute in solvent to give a homogenous system, is one of the important parameters to achieve desired concentration of drug in systemic circulation for desired pharmacological response.[11]

Procedure: Solubility data of primaquine were generated by performing solubility studies of the API using the standard shake-flask method in water and compendial buffers of pH 1.0, 1.2, 4.5, 6.8, and 7.5 at 37°C. The experimental studies were carried out according to the Biopharmaceutical Classification System (BCS) guidelines for the determination of API solubility. Around 30mg of primaquine phosphate was added to 3mL of the buffer medium.[12]

pka:

The acid dissociation constant (pKa) is an index of the extent of ionization of a drug at different pH values, and is therefore, an important parameter that reflects optimization.

pH:

pH (potential of hydrogen) is a logarithmic scale from 0 to 14 measuring the acidity or alkalinity of an aqueous solution. A pH of 7 is neutral (e.g., pure water), less than 7 is acidic (higher H^+ concentration), and greater than 7 is alkaline/basic.

Partition Coefficient:

When a material is placed in an environment consisting of organic and aqueous phase, it gets distributed into two phases. The relative quantities that get distributed are expressed in the form of ratio known as partition co-efficient.

$$\text{Partition coefficient } (P) = \frac{\text{Concentration of drug in organic phase}}{\text{Concentration of drug in aqueous phase}}$$

Procedure: The partition coefficient of chloroquine between n-octanol & water was determined by slight modification of "Shake Flask Method", at room temperature. Excess amount of API was added in 10ml mixture of n-Octanol and water (1:1). The system was prepared in triplicate and was shaken gently in the separating funnel for 24 hours for achieving equilibrium. Then the two phases were separated and the concentration of API in both phases was determined by UV spectroscopy and partition coefficient was calculated using the equation.[13]

Melting Point:

The melting point is the specific temperature at which a solid converts into a liquid at a given pressure, where both solid and liquid phases exist in equilibrium.

Procedure: The melting point of the drug was determined by using capillary method. Organic compound was filled in the capillary (10-15mm long and 1mm inside diameter) tube sealed at one end up to a height of approximate two mm from closed end and capillary was introduced into digital melting point apparatus. The temperature at which the drug melts was noted down as the melting point of the drug. The average of three values was considered as the melting point of drug.[14]

OPTICAL PROPERTIES

λ-Max:

The analytical technique measures the amount of monochromatic light absorbed by colorless substances in the near UV (200–400 nm) range. The processes required to ascertain the "identity, strength, quality, and purity" of such chemicals are included in the pharmaceutical analysis. It also covers the examination of raw materials and intermediates used in the pharmaceutical production process. [15]

Procedue: To prepare a spectrophotometer sample, it is essential to begin with a suitable specimen that is homogeneous and free from contaminants. Next, prepare the appropriate medium, dissolve and filter to remove any particulates. Additionally, prepare a standard solution to construct a calibration curve. Preparation before measurement: Confirm that the spectrophotometer is in normal working condition for calibration to ensure measurement accuracy. Measure the sample according to the established steps and record the measurement values. Finally, Analyze the measurement results and calculate the sample concentration. [16]

COMPATIBILITY STUDIES

Drug-excipient compatibility study is a very much important stage of formulation development of drug products in combination with excipients. It's a significant phase of the pre-formulation study. Drug product not only contains active pharmaceutical ingredient (API) but it's a combination of different forms of excipients. it's important to study the physical and chemical interaction between API and excipient.[17]

Fourier Transmission Infra-Red Spectroscopy(FTIR)

Fourier Transform Infrared Spectroscopy Infra – Red spectroscopy is used to estimate the interaction between cyclodextrin and the guest molecules in the solid state 15,16 . FTIR spectra were obtained using JASCO FT 761 photometer at SIC-SFRC. The sample of pure drug quinine sulphate, hydroxy chloroquine sulphate, α-CD and solid inclusion complexes were previously grounded and thoroughly mixed with KBr. The KBr disks were prepared by compressing the powder blend. The FTIR spectra were executed at a resolution of 1cm-1 (from 4000-400 cm-1). [18]

FORMULATION OF CAPSULES

Capsules are defined as unit solid dosage form of medicaments available as small containers (shells) made up of gelatin enclosing accurately measured drug substances

ADVANTAGES

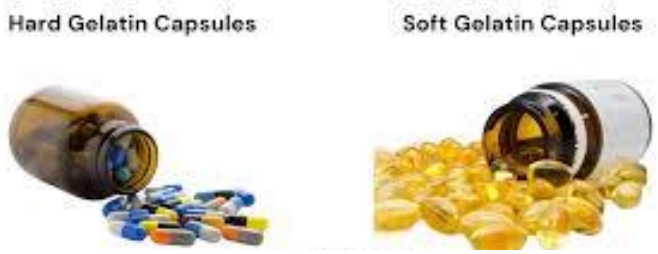
- It is easier to vary the dose.
- Less adjuncts are necessary than for tablets
- Capsule manufacturing requires fewer steps than tablet manufacturing.
- Easy to swallow hence improves patient compliance
- Simple separation of two incompatible products

DISADVATAGES

- Capsules are not suitable for liquids that dissolve gelatin, such as aqueous or hydro alcoholic solution
- The concentrated solution which require previous dilution are unsuitable for capsule because if administered as such lead to irritation into stomach.
- Not useful for efflorescent or deliquescent material. Efflorescent cause capsule soften & Deliquescent may dry the capsule shell to brittleness.

TYPES OF CAPSULES

1. Hard Gelatin capsule
2. Soft gelatin capsule



FORMULATION OF HARD GELATIN CAPSULES

Empty hard gelatin capsules are manufactured using the dip-coating method.

Preparation of the gelatin solution

↓

Dip coating the prepared gelatin solution on the metal pins

↓

Dip coated pins are rotated

↓

Gelatin coated pins drying stage

↓

This stage involves drying and trimming

↓

Trimmed capsule shells are joined

↓

The printing process takes place at this stage

FORMULATION OF SOFT GELATIN CAPSULES

Formulation of soft gelatin capsules are by following methods:

1. Plate process
2. Rotary die process
3. Reciprocating die process
4. Accogel process
5. Seamless gelatin capsules

METHOD OF PREPARATION OF QUININE SULPHATE CAPSULE

Formulation chart

ingredients	strength	function
Quinine sulfate	324mg	Active ingredient
Corn Starch	20-100mg	Binder and disintegrant
Talc	1-5mg	Glidant/lubricant
Ferrosoferric oxide	0.1-2mg	Coloring agent
gelatin	5-10mg	Binder
Magnesium stearate	2-5mg	Lubricant
Potassium hydroxide	0.1-1mg	pH adjuster
Propylene glycol	1-5mg	Solvent and plasticizer
Shellac	5-15mg	Polishing/sealing agent
Sodium lauryl sulfate	1-3mg	Surfactant

EQUIPMENT

1. Manual capsule filling machines

2. Semi-automatic capsule filling machines

3. Automatic capsule filling machines

Ingredients

1. Active Ingredient Quinine sulphate (200 mg)
2. Diluents / Fillers Lactose monohydrate microcrystalline cellulose (MCC)
3. Disintegrant Starch / Crospovidone / Sodium starch glycolate
4. Lubricant Magnesium stearate / Talc
5. Glidant: Colloidal silicon dioxide (optional)

PROCEDURE

1. WEIGHING OF INGREDIENTS:

The process begins with accurately weighing quinine sulphate and all selected excipients using a calibrated balance. Precise weighing is essential because any variation in the quantity of the active drug can lead to underdosing or overdosing, while incorrect amounts of excipients may affect flow property, capsule fill weight, and disintegration behavior. This step ensures that the final product contains the correct therapeutic dose.

2. SIEVING OF DRUG AND EXCIPIENTS:

The drug and excipients are individually passed through a suitable mesh sieve (commonly 40# or 60#). Sieving removes physical lumps, creates a uniform particle size, and improves surface area contact among particles. Uniform particle size distribution promotes proper mixing and prevents segregation during handling or filling. It also enhances the smooth flow of powder inside the capsule filling apparatus.

3. INITIAL MIXING (GEOMETRIC DILUTION TECHNIQUE);

Since the quantity of drug is relatively small compared to the total blend, a geometric dilution method is used. The drug is first mixed with a small portion of the diluent, and then progressively larger amounts of diluent are added in stages. This method ensures homogeneous distribution of quinine sulphate throughout the blend, ensuring every capsule contains an equal amount of drug.

4. INCORPORATION OF DISINTEGRANT:

After uniform mixing of drug and diluent, the disintegrant (such as starch, crospovidone, or sodium starch glycolate) is added and blended thoroughly. The disintegrant helps the capsule contents break apart quickly after ingestion, allowing rapid release of quinine sulphate in the gastrointestinal tract. The proper dispersion of disintegrant ensures faster onset of therapeutic action.

5. ADDITION OF GLIDANT:

A glidant like colloidal silicon dioxide is added to improve the flow characteristics of the powder blend. This is especially useful when the powder has poor natural flow due to small particle size or electrostatic behavior. The presence of glidant minimizes friction between particles, helping the powder move smoothly through filling equipment without clogging or uneven filling.

6. LUBRICATION OF THE BLEND:

Lubricants such as magnesium stearate or talc are added at the final stage of mixing. Lubricants prevent adhesion of powder to machine surfaces and reduce internal friction during filling. However, overmixing with lubricants must be avoided, as excessive coating of particles can delay disintegration and slow dissolution of the drug. Therefore, short and gentle mixing is preferred.

7. FILLING OF CAPSULE SHELLS:

The empty hard gelatin capsules are separated into body and cap. The prepared blend is then filled into the capsule body manually using a capsule filling tray, or by a semi-automatic/automatic capsule filling machine on a larger scale. Each capsule is filled to the required volume to deliver 200 mg of quinine sulphate along with the required excipients. Consistent filling prevents weight variation.

8. CLOSING AND LOCKING OF CAPSULES:

After filling, the capsule body is closed with its cap securely. Proper locking is important to ensure that the powder blend remains sealed inside, preventing leakage during handling, storage, or transportation. A well locked capsule maintains product integrity until administration.

9. CLEANING AND POLISHING:

The filled capsules are then cleaned or polished to remove any loose powder adhering to the surface. This step enhances the appearance of the finished capsules and reduces the risk of contamination. It also ensures that the dosage form looks professional and is easy to handle during packaging.

10. PACKAGING AND STORAGE:

The final capsules are stored in airtight, moisture-resistant containers to protect them from environmental factors like humidity, heat, and light. Quinine sulphate can degrade in the presence of moisture or strong light, so protective packaging helps maintain stability and increases shelf life. Capsules should be kept in a cool, dry place until use.

EVALUATION OF CAPSULES

1) Appearance

Check capsule colour, shape, surface finish, and for any visible damage or leakage. Purpose: First line quality check to ensure patient acceptability and detect obvious manufacturing faults.

2) Disintegration test:

Disintegration of hard and soft gelatin capsules is evaluated to ensure that the drug substance is fully available for dissolution and absorption from the gastrointestinal tract. The compendial disintegration test for hard and soft gelatin capsules follows the same procedure and uses the same apparatus described in the article "Quality Control Tests for Tablets"

The capsules are placed in the basket-rack assembly, which is repeatedly lowered 30 times per minute into a thermostatically controlled bath of fluid at 37 +2°C and observed over the time described in the individual monograph.

3) Content uniformity test:

This test is performed only when the content is specified in the individual monographs and when capsules fail weight variation test. If the weight of capsules is completely filled no need of this test. Unless otherwise stated in the monograph for an individual capsule, the amount of drug substance, determined by assay, is within the range of 85.0% to 115.0% of the label claim for nine (9) of ten (10) dosage units assayed, with no unit outside the range of 75.0% to 125.0% of the labelled drug content. Additional tests are prescribed when two or three dosage units are outside of the desired range but within the stated extremes.

4) Weight variation test:

 20 capsules are selected or taken at randomly and weighed individually, take average and compare each capsule weight with average.

Then test passes if none of the individual weights are less than 90% and more than 110% of average.

If test requirements are not met we have to remove the powder, net content of powder can be weighed individually. They have to be averaged.

Test requirements are met if not more than 2 of the individual's difference is not greater than10 of average. In any case difference should not be more than or equal to 25% .

If more than 2 and less than 6 net weights determined, they deviates 10% Then we go for additional 40 capsules.

The average of 60 capsules is determined by weighing capsules individually and comparedwith average

Test requirements are met if the difference does not exceed more than of the 60 Capsule

Deviation should not be more than 25% in any case

Then particular batch passes weight variation test

To weigh capsules we use Rotoweigh and Varicap 1200

5) Dissolution test:

Dissolution test for capsules Drug absorption and physiological availability depend on the drug substance being in the dissolved state at the site of drug absorption. The rate and extent of dissolution of the drug from the capsule dosage form is tested by a dissolution test. This test provides means of quality control in ensuring that, different hatches of the drug product have similar drug release characteristics and also, a given batch has similar dissolution as the batch of capsules that was shown initially to be clinically effective

6) Moisture permeation test:

The USP requires determination of the moisture permeation characteristics of single-unit and unit dose containers to assure their suitability for packaging capsules. The degree and rate of moisture penetration is determined by packaging the dosage unit together with a colour revealing desiccant pellet, exposing the packaged unit to known relative humidity over a specified time, observing the desiccant pellet for colour change (indicating absorption of moisture) and comparing the pre-test and post-test weight of the packaged unit

STABILITY STUDIES:

The ability of particular formulations in a particular container to remain within its physical, chemical, therapeutic, and toxicological specifications has been defined as stability of the drug. The objective of stability testing is to demonstrate how a drug substance or drug product's quality changes over time in response to a variety of environmental factors, such as temperature, humidity, and so on. The accelerated condition (40 2°C / 75 5% RH) and the long-term condition (25 2°C / 60 5% World Journal of Pharmaceutical and Life Science RH) were the storage conditions used for stability studies. The capsules were induction sealed with adsorbent cotton 26-29 in HDPE containers with a count of 30.[20]

Table: Test conditions for accelerated physical stability tests for capsule dosage forms Test conditions.

Accelerated physical stability	**Observation**
80 % RH at room temperature in an open container	Capsules are observed periodically for 2 weeks; both gross and subtle effects of the storage conditions are noted and recorded. The control capsule should not be affected
40°C in an open container	
40°C in a closed container (glass bottle with tight screw cap)	Except at the 80% RH station.

PACKAGING, LABELLING & STORAGE

Types of Capsule Packaging

Capsule packaging refers to how pharmaceutical capsules (hard-shell or soft gel) are enclosed for distribution and use. It includes primary packaging and secondary packaging.

Primary packaging

Blister Packaging for Capsules

Blister pack***s*** consist of pre-formed plastic cavities ("blisters") that hold individual capsules, sealed with a backing (foil or plastic). This primary packaging offers unit-dose protection. Blisters provide excellent barrier properties: they can be made with materials like PVC/PVDC or foil (Alu-PVC, Alu-Alu) to block moisture, oxygen and light.

Bottle (Bottle/Capsule Jar) Packaging

Bottles are the classic multi-dose container. Capsules are filled into bottles (plastic or glass) which are then capped. This format is well known for vitamins, supplements, and many prescription pills.

Sachets & Stick Packs (Single-dose Pouches)

Sachets are usually flat or pillow-shaped packets sealed on 3 or 4 sides. They are often used for single-dose powders (e.g. effervescent granules) or very small capsules (some pharmacies dispense capsules in sachets for pediatric dosing). Modern form-fill-seal machines can fill sachets with exact small volumes.

Stick Packs are long, narrow sachets (often sealed along one long seam plus an end seam). They are popular for powdered supplements (e.g. instant drink mixes) and can be used for capsule powders. Stick packs generally use less material than sachets and machine throughput is higher (30–50% faster). They are ideal for free-flowing powders due to the slender opening.

Strip Packaging

Strip packs (also called foil strips or "dose bands") are another form of unit-dose primary pack. A strip is typically a narrow web of material (often aluminum or multi-layer laminate) folded over and sealed, with perforations between doses. Unlike blisters, strip packs don't form deep cavities – instead, the capsule is sandwiched between two layers of film. Strip packs are widely used in Asia and for products where high moisture protection is needed but blisters are too bulky.

Secondary Packaging

After choosing a primary pack, capsules are usually placed into secondary packaging like carton boxes or shrink-wrapped cases. Cartons provide extra protection during shipping, allow additional labelling (drug info, branding, tamper-evident seals), and help organize multi-pack products. Key considerations for secondary packaging:

- Cartons & Inserts**:** Medical cartons must include product inserts (Leaflets with dosage instructions, batch number, expiry, manufacturer info, etc.). These are often paper leaflets inserted into the box.
- Tamper Seals: Secondary packaging commonly has tamper-evident seals (e.g. security tapes, shrink bands) to show if the box has been opened.

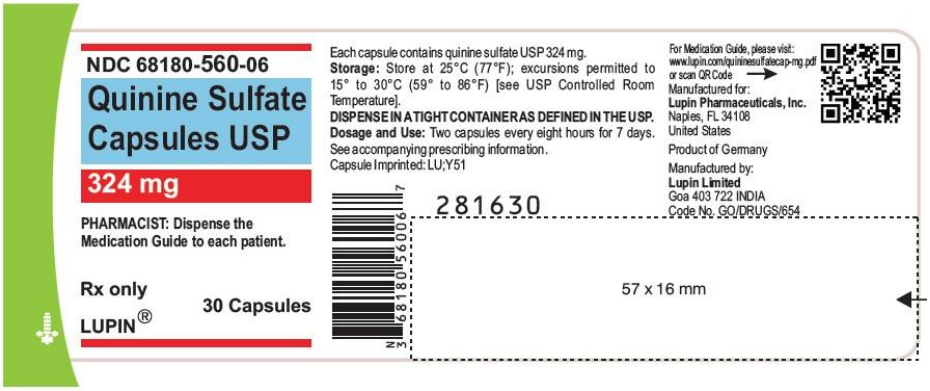
Labelling

Label refers to a display of written, printed, or graphic matter on the immediate container of any

Article.

General labelling requirements

- The name of preparation
- Strength and dosage form
- Quantity
- Instruction for the use
- Precautions and warning
- Registration number
- Batch number
- Manufacturing and expiry date
- Price
- The name and address of pharmaceutical industry



Storage

Quinine sulphate capsules are Stored at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

[See USP Controlled Room Temperature]

Dispense in a tight container as defined in the USP.

- Keep the capsules in a tightly closed container.
- Do not refrigerate or freeze.

5. RESULTS AND DISCUSSION

Result:

The formulated quinine sulphate capsules were evaluated for appearance, weight variation, disintegration time, content uniformity, dissolution, and stability. The capsules showed uniform colour, smooth surfaces, and no defects. Weight variation complied with pharmacopeial limits, indicating consistent filling. Disintegration occurred within 8–12 minutes, well below the official limit. Drug content ranged from 97–102%, confirming uniform distribution. About 90–95% of the drug was released within 45 minutes, showing satisfactory dissolution. Stability studies revealed no significant physical or chemical changes during storage.

DISCUSSION:

The study successfully developed quinine sulphate capsules with acceptable pharmaceutical properties meeting official standards. Uniform weight, rapid disintegration, consistent drug content, and efficient dissolution indicated good formulation quality. Excipients improved flow, lubrication, and disintegration. Stability studies confirmed the suitability of the formulation and packaging. Overall, the capsules demonstrated good quality, stability, and drug release, supporting their use for oral antimalarial therapy.

6.CONCLUSION

Malaria remains a major global health challenge, particularly in tropical and subtropical regions, due to its high morbidity and mortality. This module highlighted the causative organisms, transmission, pathophysiology, clinical manifestations, and therapeutic management of malaria, with special emphasis on quinine sulphate as an important antimalarial agent. The study also explained the mechanism of action of quinine and its significance in treating resistant malaria infections.

Preformulation studies demonstrated the importance of evaluating physicochemical, optical, and compatibility properties to ensure the development of a stable and effective dosage form. The formulation of quinine sulphate capsules using suitable excipients and proper manufacturing techniques was discussed in detail, emphasizing the importance of uniformity, stability, patient compliance, and therapeutic efficacy. In addition, evaluation tests such as weight variation, disintegration, dissolution, and stability studies confirmed the quality and reliability of the capsule formulation.

Overall, the formulation and evaluation of quinine sulphate capsules provide an effective oral dosage form for antimalarial therapy. Proper formulation development, quality control, packaging, and storage conditions are essential to maintain drug stability, safety, and effectiveness, thereby improving patient outcomes in malaria treatment.

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8. REFERENCE

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