# Public assessment summary report

| | |
|---|---|
| **Name of the Finished Pharmaceutical Product** | M-QUINE(Quinine sulphate) 300 mg tablets |
| **Manufacturer of the Product** | Medopharm , India No.34-B, Industrial area, Malur-563 160 , kolar district , karnataka , India |
| **Active Pharmaceutical Ingredient(s) (API)** | Quinine sulphate |

## 1. Introduction

M-QUINE is indicated for the treatment of falciparum malaria. Treatment and prevention of nocturnal leg cramps in adults and the elderly, when cramps cause regular disruption of sleep.

Quinine is a highly active blood schizonticide and suppresses the asexual cycle of development of malaria parasites in the erythrocytes

The application for registration of M-QUINE(Quinine sulphate) 300 mg tablets was submitted on 24/07/2022. The product underwent full assessment procedure . M-QUINE(Quinine sulphate) 300 mg tablets was registered on 13-01-2023.

## 2. Assessment of quality

### Active pharmaceutical Ingredient (API)

Quinine Sulfate is described in the USP. It is the sulfate of an alkaloid obtained from the bark of species of Cinchona.

Quinine sulphate is a white to off white crystalline powder. Slightly soluble in water, in alcohol, and in chloroform; and in ether freely soluble in alcohol at 80°C and in a mixture of volumes of chloroform and 1 volume of dehydrated alcohol: sparingly soluble in water at 100°C

The API specifications include tests for description, solubility, identification (TLC, colour test, flourecence test, reaction for sulphate test), PH, sulphated ash, heavy metals, loss on drying, specific optical rotation, assay (potontiometrically), residual solvents, and particle size distribution

Stability testing was conducted according to the requirements of international guidelines (WHO and ICH). The proposed re-test period is justified based on the stability results when the API is stored in the original packing material

**Finished pharmaceutical product (FPP)**

*Pharmaceutical development and manufacture:*

M-Quine tablets are yellow coloured, circular, slightly bi-convex film coated tablet. Quinine Sulfate Tablets USP 300 mg (F/C) (M-QUINE)is available as 10 x 10's and 100x10's PVC Blister pack and 1000's bulk pack(HDPE).

The development of the final composition of M-QUINE (Quinine Sulfate) F/C Tablets USP 300 mg has been described and the compatibility of the API with the excipients demonstrated. The manufacturing process entails a conventional wet granulation followed by drying, lubrication, compression and packaging. Appropriate in-process controls have been set to ensure batch-to-batch reproducibility. Validation data presented on three production batches and batch analysis data demonstrate the consistency of the process and the quality of the product. The pharmacopoeial based specifications and analytical methods with validation are considered adequate for controlling the quality of this finished pharmaceutical product at release and during shelf life.

The dissolution profiles of M-QUINE (Quinine Sulfate) F/C Tablets USP 300 mg and the Reference Product Quinimax tablets USP 500 mg in all three BCS media were demonstrated to be similar, and this was also the basis of the biowaiver allowed for M-QUINE (Quinine Sulfate) F/C Tablets USP 300 mg.

*Specifications:*

The finished product specifications include tests for description, average weight, diameter, thickness, disintegration time, identification of the APIs (HPLC and TLC), uniformity of dosage units, assay (HPLC), dissolution (HPLC detection), organic impurities and microbial limits. The test procedures have been adequately validated.

*Other ingredients:*

Other ingredients used in the tablet formulation include lactose monohydrate, maize starch, talc, gelatin, sodium lauryl sulphate,sodium propyl paraben, microcrystalline cellulose (ph 101), colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, titanium dioxide, tartrazine lake, PEG 400 n ,isopropyl alcohol and methylene chloride.

*Stability testing:*

Stability studies have been conducted at 30°C/75%RH as long-term storage condition and for six months at 40°C/75%RH as accelerated condition in the packaging proposed for marketing of the product. The product proved to be quite stable at both storage conditions. Based on the available stability data the proposed shelf life and storage conditions as stated in the SmPC are acceptable.

## 3. Assessment of bioequivalence or Clinical trial

M-Quine (Quinine sulphate) 300 mg tablets meet the criteria for a bio waiver in accordance with the *EFDA's Guidance on waiver of in vivo bioequivalence requirements. Second Edition July, 2021.*

## 4. Conclusion

Based on assessment of data on quality, safety and efficacy the assessors considered that the benefit–risk profile of M-QUINE(Quinine sulphate) 300 mg tablets manufactured at Medopharm , India No.34-B, Industrial area, Malur-563 160 , kolar district , Karnataka , India was acceptable for the following indication: ' the treatment of falciparum malaria '.

## 5. Post-approval updates

| List of approved Variation | Approval dates |
|---|---|
| **Nil** | **nil** |

## 6. Renewal date

**NA**

## 7. Label

# ETHIOPIA

PROOF FOR APPROVAL - 08th Jan., 2021

26.67


6 — 85 — 7 — 4 — 7 — 85 — 6

BLISTER SIZE : 200mm


**MEDOPHARM** | *Editorial:* | *Version:* | *D-2*

*Brand Name:* **M-QUINE** | *Client:* **ETHIOPIA** | *Date:* **08-01-2021**

*Item Code:*

*Software:*

*Language:*

*Packing:*

*Colors:* **BLACK**

*Generic Name:* **QUININE SULFATE TABLETS USP 300 MG**

*Specification:* **0.025 MM THICKNESS**

*Remarks:* **Pharma Code : 3594**

*Type of Material:* **BLISTER**

**PBP3074**

**CDR 2019**

**ENG/FRE**

*Size:* **200 mm**

**10's**

**Software Specification**

Item Code KTK/

- ☐ Pharma Code Value
- ☐ Specification
- ☐ No. of Language Text
- ☐ Color / Pantone Specification

Comments

Sign & Date

artwork (Fonts/ Designs /Specification /Size) Please inform to Artwork Department for further action. Do not make any change to the artwork without written instruction from "Artwork Department"

| Artwork Dept. | Regulatory Affairs | Corporate QA | Quality Control | Production | Quality Assurance |
|---|---|---|---|---|---|
| ☐ Item Code/Artwork Code<br>☐ Pharmacopeial Status<br>☐ Pharma Code Value<br>☐ Specification<br>☐ Storage Condition<br>☐ Product License<br>☐ Different Language Text<br>☐ Product Registration No.<br>☐ Proof Reading<br>☐ Color / Pantone Specification<br>☐ Text Match with Other PM Components | ☐ Product and Specification<br>☐ Pharmacopeial Status<br>☐ Storage Condition<br>☐ Product License<br>☐ Client Requirement<br>☐ Different Language Text<br>☐ Product Registration No.<br>☐ Company Details<br>☐ Text Match with Other PM Components | ☐ Pharmacopeial Status<br>☐ Storage Condition<br>☐ Product License<br>☐ Different Language Text<br>☐ Product Registration No.<br>☐ Company Details<br>☐ Item Code<br>☐ Text Match with Other PM Components | ☐ Product and Specification<br>☐ Pharmacopeial Status<br>☐ Pharma Code Value<br>☐ Storage Condition<br>☐ Product License<br>☐ Color / Pantone Number<br>☐ Product Registration No.<br>☐ Text Match with Other PM Components | ☐ Dimensions<br>☐ Change Parts<br>☐ Over Printing Area<br>☐ Other Printing / Sticker fixing Space<br>☐ Operation Feasibility<br>☐ Machine Suitability<br>☐ HDPE Container Volume | ☐ Product and Specification<br>☐ Pharmacopeial Status<br>☐ Pharma Code Value<br>☐ Storage Condition<br>☐ Product License<br>☐ Product Registration No.<br>☐ Item Code / Artwork Code<br>☐ Text Match with Other PM Components |
| Comments | Comments | Comments | Comments | Comments | Comments |
| Sign & Date | Sign & Date | Sign & Date | Sign & Date | Sign & Date | Sign & Date |

**QUININE SULFATE TABLETS USP 300MG (F/C)**

**M-QUINE**

**Secondary packaging:**


**MEDOPHARM, INDIA**