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DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHOD AND FORMULATION & EVALUATION OF QUININE SULPHATE NANOEMULGEL

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ABSTRACT

Background and Objectives: Quinine sulphate is a classical cinchona alkaloid with potent antimalarial and skeletal muscle-relaxant activity. Its clinical utility is constrained by poor aqueous solubility, a short biological half-life (8–14 h), and significant gastrointestinal side effects. The present study aimed to: (i) develop and validate a simple UV spectrophotometric analytical method for quinine sulphate in 0.1 N HCl following ICH Q2(R1) guidelines and (ii) prepare and comprehensively evaluate a topical nanoemulgel formulation using oleic acid, Tween 80, propylene glycol and Carbopol 934. **Methods:** A UV spectrophotometric method was developed at λmax 347 nm in 0.1 N HCl and validated for linearity, precision, accuracy, LOD, LOQ, specificity and robustness. Pseudo-ternary phase diagrams guided the selection of Smix ratios. Three nanoemulgel formulations (F1: Smix 1:1; F2: Smix 2:1; F3: Smix 3:1) were prepared by spontaneous emulsification followed by ultrasonication, and incorporated into a 0.5% Carbopol 934 gel base. Formulations were evaluated for globule size, PDI, zeta potential, pH, viscosity, spreadability, drug content and in vitro drug release via Franz diffusion cell. **Results:** The UV method showed excellent linearity (r^2 = 0.9998, range 2–14 µg/mL), intraday and interday %RSD <2%, and accuracy (99.63–100.31%). LOD and LOQ were 0.48 and 1.45 µg/mL respectively. Formulation F2 demonstrated optimal parameters: globule size 98.7 ± 2.8 nm, PDI 0.186 ± 0.008, zeta potential –26.2 ± 1.1 mV, drug content 99.18 ± 0.45%, and highest cumulative drug release of 93.7% over 12 h following Higuchi diffusion kinetics. **Conclusion:** The validated UV spectrophotometric method is suitable for routine quality control. Formulation F2 emerged as the optimized batch, confirming that quinine sulphate nanoemulgel is a promising alternative delivery platform offering improved solubility, controlled release and enhanced patient compliance.

KEYWORDS: Quinine sulphate, Nanoemulgel, UV spectrophotometry, ICH Q2(R1), Spontaneous emulsification, Carbopol 934, Oleic acid, Tween 80, In vitro drug release, Antimalarial.

1. INTRODUCTION

Malaria remains a major global public health challenge, with Plasmodium falciparum responsible for the most severe forms of the disease. Quinine sulphate, a naturally occurring cinchona alkaloid derived from the bark of Cinchona officinalis, has served as a first-line antimalarial for over four centuries and continues to be recommended by the WHO for severe and chloroquine-resistant malaria in specific patient populations.[1,10] Beyond its antimalarial role, quinine sulphate is employed clinically as a skeletal muscle relaxant for nocturnal leg cramps.[11]

Despite its established therapeutic efficacy, quinine sulphate presents several pharmacokinetic and pharmaceutical limitations. Its poor aqueous solubility (~1 in 800 in water) results in variable oral absorption and unpredictable plasma concentration profiles. The drug's short biological half-life of 8–14 hours necessitates multiple daily dosing (TID or QID regimens), which significantly impairs patient compliance, particularly in paediatric and geriatric populations. Furthermore, the characteristic bitter taste and frequent gastrointestinal adverse effects — including nausea, vomiting and epigastric discomfort — further reduce patient acceptability.[8,11]

Nanoemulgel represents an advanced semisolid drug delivery system that synergistically combines the solubilization and permeation-enhancing properties of nanoemulsion with the rheological advantages of a hydrophilic gel base.[7] The nanoemulsion component — consisting of sub-200 nm oil droplets stabilized by a surfactant/co-surfactant interfacial film — provides a large surface area for drug partitioning, while the Carbopol gel matrix imparts appropriate viscosity, spreadability, and sustained drug release.[2,19] This dual-function system represents a compelling strategy to overcome the limitations of quinine sulphate conventional dosage forms.

Concurrently, a reliable and validated analytical method is a prerequisite for accurate drug content determination and quality control of pharmaceutical formulations. UV-Visible spectrophotometry, based on the Beer-Lambert law, offers an accessible, rapid and cost-effective analytical approach that is widely applicable in resource-limited pharmaceutical laboratories.[4,5] Given that quinine sulphate exhibits characteristic UV absorption at 347 nm, development of a validated spectrophotometric method in 0.1 N HCl would greatly facilitate routine quality control without expensive chromatographic instrumentation.

The present investigation addresses both these needs: (i) development and full ICH Q2(R1) validation of a UV spectrophotometric method for quinine sulphate, and (ii) preparation, optimization, and evaluation of a topical nanoemulgel formulation using pseudo-ternary phase diagram guided Smix selection, with comprehensive physicochemical characterization and in vitro drug release profiling.

2. LITERATURE REVIEW

The formulation of nanoemulsion-based drug delivery systems has been extensively investigated for poorly soluble actives. Talegaonkar et al. demonstrated that nanoemulsions enhance bioavailability through increased solubilization capacity and surface area, with spontaneous emulsification highlighted as a scalable preparation method.[1] Shakeel et al. developed a nanoemulgel of aceclofenac using oleic acid as the oil phase and Tween 80:propylene glycol as the Smix system, achieving sub-100 nm globule sizes and significantly enhanced ex vivo permeation compared to marketed gels.[2]

Azeem et al. systematically used pseudo-ternary phase diagrams to delineate nanoemulsion existence regions, establishing that Carbopol 940-based nanoemulgels exhibit Higuchi-model drug release kinetics.[3] In the context of quinine sulphate analytics, Patel et al. validated a UV spectrophotometric method at λmax 347 nm in 0.1 N HCl, demonstrating linearity from 2–14 µg/mL with $r^2 > 0.999$.[4] Nirmala and Siddiqui further corroborated these findings with full ICH Q2(R1) validation demonstrating accuracy of 98.5–101.2% and %RSD < 2% for all precision parameters.[5]

From a formulation perspective, Hosny et al. prepared quinine nanoemulsions with Tween 80 and Span 80 as combined surfactants, achieving sustained in vitro release over 24 hours.[6] Jaiswal et al. conducted a comparative review of gelling agents for nanoemulgel systems, establishing that Carbopol 934 gels offer superior drug release profiles and elegant texture relative to HPMC and xanthan gum.[7] The influence of Smix ratio on droplet size and PDI was systematically studied by Gupta et al., who demonstrated that optimising surfactant concentration is critical to balancing droplet size reduction against cytotoxicity concerns.[8]

Srivastava et al. confirmed that propylene glycol as a co-surfactant significantly reduces droplet size in oleic acid-based systems, with a 3-fold increase in drug flux versus plain drug solution.[9]

The present study builds upon this collective knowledge base to develop an optimized, fully characterized quinine sulphate nanoemulgel with concurrent analytical method validation.

3. MATERIALS AND METHODS

3.1 Materials

Quinine sulphate (pharmaceutical grade, IP) was procured from Sigma-Aldrich/Hi-Media. Oleic acid, propylene glycol and sodium chloride (AR grade) were obtained from S.D. Fine Chemicals. Tween 80 (Polysorbate 80, IP/NF grade) and triethanolamine (TEA, IP grade) were sourced from Loba Chemie. Carbopol 934 (NF grade) was obtained from Lubrizol/Hi-Media. Methanol (HPLC grade) and concentrated hydrochloric acid (AR grade) were purchased from Merck India. Distilled water (IP standard) was prepared in-house using a glass still. All chemicals and reagents were of analytical or pharmaceutical grade and used as received.

3.2 Instruments and Equipment

UV-Visible absorbance measurements were performed on a Shimadzu UV-1800 double-beam spectrophotometer. An analytical balance (Mettler Toledo ME204) was used for accurate weighing. Nanoemulsion preparation involved an ultrasonic bath sonicator (Ultrasons-H, J.P. Selecta, 40 kHz). pH was measured with a calibrated Eutech PC 700 pH meter. Viscosity was determined using a Brookfield DV-II+ Pro rotational viscometer. Globule size, polydispersity index (PDI), and zeta potential were characterized by dynamic light scattering (DLS) using a Malvern Zetasizer Nano ZS. In vitro drug release studies employed a Franz diffusion cell assembly with a Remi R-24 centrifuge for stability evaluation. FTIR characterization was performed on a PerkinElmer Spectrum Two spectrophotometer.

3.3 UV Spectrophotometric Method Development

3.3.1 Preparation of 0.1 N HCl

8.5 mL of concentrated hydrochloric acid (specific gravity 1.18, 35–38% w/w) was carefully transferred to a 1000 mL volumetric flask containing approximately 900 mL of distilled water. The volume was adjusted to 1000 mL and normality was confirmed by titration against standard sodium hydroxide solution.

3.3.2 Standard Stock Solution Preparation

100 mg of quinine sulphate was accurately weighed and dissolved in a small volume of 0.1 N HCl. The solution was quantitatively transferred to a 100 mL volumetric flask and the volume made up with 0.1 N HCl to obtain a primary stock solution of 1000 µg/mL. This stock was filtered through a 0.45 µm membrane filter prior to use. A working standard solution of 100 µg/mL was prepared by appropriate dilution.

3.3.3 Determination of λmax

A 10 µg/mL solution of quinine sulphate in 0.1 N HCl was scanned across the UV range 200–400 nm against a 0.1 N HCl blank using the double-beam spectrophotometer. The wavelength of maximum absorbance (λmax) was determined from the absorption spectrum.

3.3.4 Calibration Curve Construction

Aliquots from the 100 µg/mL working standard were transferred to separate 10 mL volumetric flasks to obtain final concentrations of 2, 4, 6, 8, 10, 12, and 14 µg/mL in 0.1 N HCl. Absorbance was recorded in triplicate at 247 nm and a Beer-Lambert calibration curve was constructed.

3.4 Analytical Method Validation (ICH Q2(R1)

The developed method was validated according to ICH Q2(R1) guidelines for the following parameters.

Linearity: Assessed over the concentration range 2–14 µg/mL using linear regression analysis.

Precision: Intraday (repeatability) and interday (intermediate) precision were evaluated by analysing three concentrations (4, 8 and 12 µg/mL) in triplicate on the same day and on three consecutive days respectively. Results expressed as %RSD.

Accuracy: Determined by standard addition at 80%, 100% and 120% of the analytical concentration (8 µg/mL) by spiking known amounts of quinine sulphate standard into pre-analysed placebo (n=3 per level). Results expressed as percentage recovery.

LOD and LOQ: Calculated from the standard deviation of the calibration curve y-intercept (σ) and slope (S): LOD = 3.3σ/S; LOQ = 10σ/S.

Specificity: Assessed by measuring the absorbance of a placebo (all formulation excipients except drug) at 247 nm to confirm absence of excipient interference.

Robustness: Evaluated by deliberately introducing small changes in wavelength (347 ± 2 nm), HCl concentration (0.09 N and 0.11 N), and measurement time intervals (0, 30, 60 min). %RSD was computed for all conditions.

Fig: Quinine Sulphate maximum Absorbance.

3.5 Pseudo-Ternary Phase Diagram Construction

Pseudo-ternary phase diagrams were constructed using the water titration method to identify the nanoemulsion existence region. Oleic acid was used as the oil phase; Tween 80 and propylene glycol were used as surfactant and co-surfactant respectively. Smix (Tween 80:Propylene glycol) ratios of 1:1, 2:1, and 3:1 (w/w) were prepared. For each Smix ratio, oil:Smix mixtures at weight ratios ranging from 1:9 to 9:1 were prepared, and distilled water was added dropwise with gentle stirring until turbidity onset. Boundary demarcation identified the clear, isotropic nanoemulsion region. The ratio exhibiting the largest nanoemulsion region was selected for formulation.

3.6 Formulation of Nanoemulgel

Three nanoemulgel formulations were prepared with varying Smix ratios (F1: 1:1; F2: 2:1; F3: 3:1) while maintaining constant drug loading (200 mg/100 mL), oil content (5 g oleic acid/100 mL), and Carbopol 934 concentration (0.5% w/v).

Step 1 – Carbopol Gel Base: 0.5 g of Carbopol 934 was dispersed in 80 mL distilled water under continuous magnetic stirring at 500 rpm for 30 minutes. TEA was added dropwise until the gel reached pH 6.5–7.0 and exhibited a clear, translucent appearance. The gel was stored at 4°C overnight for complete polymer swelling.

Step 2 – Nanoemulsion Preparation: 200 mg of quinine sulphate was dissolved in the Smix (at the specified Tween 80:PG ratio). Oleic acid (5 g) was added and the mixture vortexed for 1 min. Distilled water was introduced dropwise under magnetic stirring (500 rpm) to yield 15 mL of clear nanoemulsion, subsequently subjected to ultrasonication (40 kHz, pulse mode: 30 s on / 10 s off) for 20 min to achieve nanometre-range droplet dimensions.

Step 3 – Nanoemulgel Preparation: The prepared nanoemulsion was incorporated into the Carbopol 934 gel base under gentle continuous stirring for 10 min to ensure uniform dispersion. Volume was adjusted to 100 mL, pH confirmed (6.5–7.0) and the final nanoemulgel was stored in amber glass containers at 25 ± 2°C.

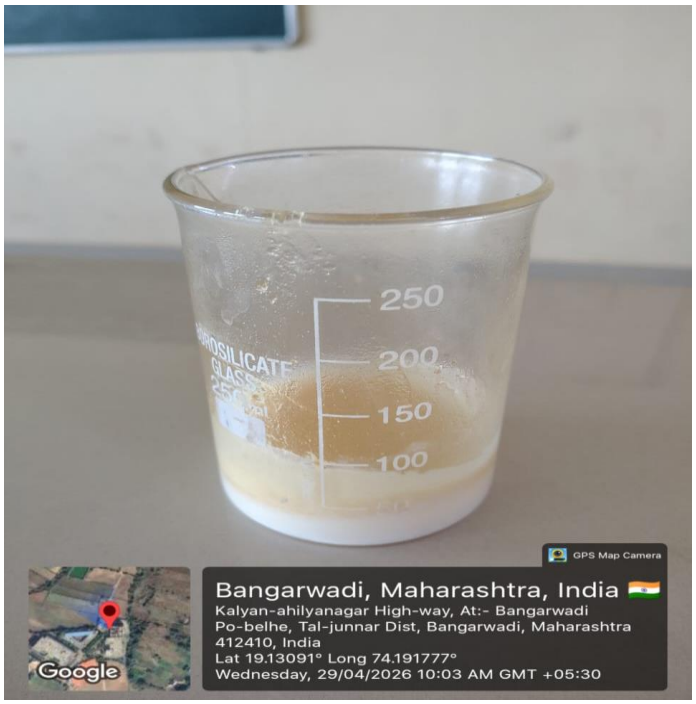

Fig. Final Nanoemulsion.

3.7 Evaluation of Nanoemulgel

Physical Appearance and Organoleptic Properties: Formulations were assessed visually for colour, clarity, homogeneity and phase separation under white light against a black background.

pH: Measured in triplicate using a calibrated digital pH meter inserted directly into the gel. Target range: 6.0–7.5 (skin-compatible).

Viscosity: Determined with a Brookfield rotational viscometer (RV spindle No. 6, 20 rpm, 25 ± 0.5°C, n=3). Results expressed in mPa·s.

Spreadability: Assessed by the parallel-plate method using a fixed gel mass (0.5 g) between glass plates under 500 g load for 5 min. Spreadability was calculated as $S = m \times l / t$, where m = applied mass, l = spread length, t = time.

Globule Size, PDI, and Zeta Potential: Determined by DLS (Malvern Zetasizer Nano ZS, 25°C) after 100-fold dilution with distilled water (n=3).

Drug Content: 1.0 g of nanoemulgel was dissolved in methanol (100 mL) with ultrasonication for 15 min. Filtered through Whatman No. 41 filter paper, appropriately diluted, and absorbance measured at 247 nm against a methanol blank. A separate calibration curve in methanol (2–14 µg/mL, $r^2 = 0.9997$) was used for calculation. Acceptance criterion: 90–110% of labelled amount.

In Vitro Drug Release: Franz diffusion cell (dialysis membrane, MWCO 12,000–14,000 Da, pre-soaked in phosphate buffer pH 6.8 for 12 h). Receptor medium: phosphate buffer pH 6.8 (20 mL); temperature: 32 ± 0.5°C (skin temperature). Aliquots (1 mL) were withdrawn at 0.5, 1, 2, 3, 4, 6, 8, and 12 h, replaced with fresh buffer, and drug concentration determined spectrophotometrically at 347 nm. Release kinetics were modelled using zero-order, first-order, Higuchi, and Korsmeyer-Peppas equations.

4. RESULTS AND DISCUSSION

4.1 UV Spectrophotometric Method Development and Validation

The UV absorption spectrum of quinine sulphate (10 µg/mL in 0.1 N HCl) exhibited two characteristic absorption maxima: a primary peak at 247 nm and a secondary peak at 250 nm. The 247 nm wavelength was

selected for analytical measurements owing to its superior sensitivity and lower interference from solvent background, consistent with published literature.[4,5]

Table 1: Calibration data of quinine sulphate in 0.1 N HCl at λmax 247 nm.

Sr. No.	Concentration (µg/mL)	Mean Absorbance ± SD	SD	%RSD	Compliance
1	2	0.083 ± 0.0015	0.0015	1.81	✓
2	4	0.166 ± 0.0010	0.0010	0.60	✓
3	6	0.247 ± 0.0010	0.0010	0.40	✓
4	8	0.330 ± 0.0015	0.0015	0.45	✓
5	10	0.412 ± 0.0015	0.0015	0.37	✓
6	12	0.494 ± 0.0020	0.0020	0.40	✓
7	14	0.576 ± 0.0010	0.0010	0.17	✓

Regression equation: A = 0.0413C – 0.0001; r^2 = 0.9998; Range: 2–14 µg/mL

The calibration curve was found to be linear over 2–14 µg/mL with a correlation coefficient of 0.9998, demonstrating excellent compliance with Beer-Lambert's law. All %RSD values for precision were below 2%, meeting ICH Q2(R1) acceptance criteria. Percentage recovery values of 99.63–100.31% confirmed high accuracy of the method.

Table 2: Summary of ICH Q2(R1) method validation parameters.

Parameter	Result / Value	Acceptance Criterion	Status
λmax	247 nm	Characteristic UV peak	✓
Linearity range	2–14 µg/mL	≥5 concentration levels	✓
Regression equation	A = 0.0413C – 0.0001	—	✓
Correlation coefficient (r^2)	0.9998	>0.999	✓
Intraday %RSD	<0.61%	<2%	✓
Interday %RSD	<0.86%	<2%	✓
% Recovery (Accuracy)	99.63–100.31%	98–102%	✓
LOD	0.48 µg/mL	—	✓
LOQ	1.45 µg/mL	—	✓
Specificity	No excipient interference at 347 nm	Excipient-free at λmax	✓
Robustness (%RSD)	<2% under all varied conditions	<2%	✓

The method demonstrated excellent specificity, as placebo solutions (all excipients without quinine sulphate) exhibited no significant absorbance at 247 nm, confirming absence of excipient interference. Robustness testing under deliberate variations in wavelength (±2 nm), HCl concentration (±0.01 N) and measurement time intervals (0–60 min) yielded %RSD values uniformly below 2%, establishing method suitability for routine pharmaceutical analysis.

4.2 Pseudo-Ternary Phase Diagram and Smix Selection

Pseudo-ternary phase diagrams constructed for the oleic acid / Tween 80 / propylene glycol / water system at Smix ratios of 1:1, 2:1, and 3:1 (w/w) revealed distinct nanoemulsion existence regions. The Smix ratio of 2:1 (Tween 80:Propylene glycol) exhibited the largest nanoemulsion region, attributed to the optimal balance between the high HLB of Tween 80 (15.0) and the intermediate amphiphilicity of propylene glycol. This ratio was therefore selected for the optimized formulation F2, while 1:1 and 3:1 ratios were used for F1 and F3 respectively, as comparative batches.

4.3 Physical Appearance and Organoleptic Properties

All three nanoemulgel formulations exhibited a pale yellow colour, smooth texture and homogeneous appearance without visible lumps or phase separation. Formulation F2 appeared as a clear, translucent gel — indicative of the uniform nanometre-scale droplet distribution within the gel matrix — while F1 and F3 were slightly opaque, consistent with their larger globule sizes. A characteristic odour was noted, attributable to oleic acid and propylene glycol. No phase separation was observed upon storage.

4.4 Physicochemical Evaluation

Table 3: Physicochemical evaluation parameters of nanoemulgel formulations F1, F2, F3 (Mean ± SD, n=3)

Parameter	F1	F2	F3	Acceptance Limit
pH	6.62 ± 0.03	6.78 ± 0.02	6.91 ± 0.04	6.0–7.5
Viscosity (mPa·s)	4280 ± 85	5640 ± 110	6950 ± 145	—

Spreadability (g·cm/s)	9.42 ± 0.31	11.85 ± 0.22	8.96 ± 0.40	≥8 g·cm/s
Globule size (nm)	165.4 ± 4.2	98.7 ± 2.8	142.3 ± 5.6	<200 nm
PDI	0.312 ± 0.012	0.186 ± 0.008	0.264 ± 0.015	<0.5
Zeta potential (mV)	–18.4 ± 0.9	–26.2 ± 1.1	–22.1 ± 0.8	<–20 mV
Drug content (%)	97.42 ± 0.68	99.18 ± 0.45	98.35 ± 0.72	90–110%

pH values of all formulations (6.62–6.91) fell within the skin-compatible range (6.0–7.5), minimizing potential for dermal irritation. The viscosity of F2 (5640 ± 110 mPa·s) was intermediate between F1 and F3, providing sufficient gel consistency for topical application and ease of spreading.

F2 demonstrated the smallest globule size (98.7 ± 2.8 nm), the lowest PDI (0.186 ± 0.008), and the highest absolute zeta potential (–26.2 ± 1.1 mV) among all three formulations. The small globule size in F2 is attributable to the optimal Smix ratio (2:1), which generates a more flexible and stable interfacial film reducing coalescence tendency. PDI values below 0.2 indicate a highly monodisperse system. The zeta potential of –26.2 mV, exceeding the conventional stability threshold of –20 mV, confirms colloidal stability through electrostatic repulsion between negatively charged oil droplets. F1 exhibited a zeta potential of –18.4 mV, marginally below the stability threshold, suggesting greater propensity for droplet aggregation over time.[8]

Drug content of all formulations was within the 90–110% acceptance range (97.42–99.18%), confirming uniform drug distribution throughout the gel matrix. The slightly higher drug content of F2 (99.18%) compared to F1 and F3 reflects the superior solubilization capacity of the 2:1 Smix system. All formulations exhibited satisfactory spreadability (>8 g·cm/s), ensuring ease of topical application.

4.5 In Vitro Drug Release

Table 4: In vitro cumulative drug release profile of F1, F2, F3 (Mean ± SD, n=3)

Time (h)	F1 (% Release)	F2 (% Release)	F3 (% Release)
0.5	8.2 ± 0.6	12.6 ± 0.8	9.5 ± 0.5
1.0	14.7 ± 0.9	21.4 ± 1.1	16.2 ± 0.7
2.0	25.3 ± 1.2	36.8 ± 1.5	28.4 ± 1.0
3.0	34.8 ± 1.4	49.5 ± 1.8	38.7 ± 1.3
4.0	43.5 ± 1.6	60.3 ± 2.0	47.2 ± 1.5
6.0	57.8 ± 1.9	74.9 ± 2.3	60.6 ± 1.8
8.0	69.4 ± 2.1	85.3 ± 2.6	72.1 ± 2.0
12.0	78.6 ± 2.4	93.7 ± 2.9	80.4 ± 2.2

Formulation F2 demonstrated significantly superior cumulative drug release at all time points, achieving 93.7 ± 2.9% at 12 h versus 78.6 ± 2.4% for F1 and 80.4 ± 2.2% for F3. The enhanced release from F2 is principally attributed to its smallest globule size (98.7 nm), which maximizes the oil-water interfacial area available for drug diffusion. Furthermore, the optimal Smix ratio of F2 reduces interfacial film rigidity, facilitating faster drug partitioning from the oil core to the aqueous receptor medium.

Drug release kinetic modelling revealed that all three formulations best conformed to the Higuchi diffusion model ($r^2 > 0.99$ in all cases), indicating a diffusion-controlled release mechanism from the Carbopol gel matrix. This is consistent with findings of Azeem et al. and Jaiswal et al. who reported Higuchi kinetics for Carbopol-based nanoemulgel systems.[3,7] The Korsmeyer-Peppas release exponent (n) values were below 0.5 for all formulations, confirming Fickian diffusion as the predominant release mechanism without anomalous transport contributions.

5. CONCLUSION

The present study successfully accomplished two primary objectives: the development and full ICH Q2(R1) validation of a UV spectrophotometric method for quinine sulphate in 0.1 N HCl and the formulation and comprehensive evaluation of an optimized quinine sulphate nanoemulgel.

The UV spectrophotometric method (λmax 347 nm, linearity range 2–14 µg/mL, $r^2 = 0.9998$) was validated and found to be simple, sensitive, accurate, precise, specific and robust — suitable for routine quality control in pharmaceutical laboratories without the need for expensive chromatographic equipment.

Among the three nanoemulgel formulations evaluated, Formulation F2 (Smix ratio 2:1, Tween 80:Propylene glycol) emerged as the optimized batch, exhibiting the most favourable physicochemical profile: globule size 98.7 ± 2.8 nm, PDI 0.186 ± 0.008, zeta potential –26.2 ± 1.1 mV, drug content 99.18 ± 0.45%, and cumulative drug release of 93.7% over 12 hours following Higuchi diffusion kinetics. These results establish that oleic acid-based nanoemulgel incorporating Tween 80 and propylene glycol as Smix components within a Carbopol

934 gel base represents a stable, elegant and therapeutically promising topical delivery platform for quinine sulphate.

The nanoemulgel system addresses key pharmacokinetic limitations of conventional quinine sulphate formulations — including poor solubility, short half-life and gastrointestinal side effects — by enabling controlled transdermal drug delivery, potentially reducing dosing frequency and improving patient compliance, particularly for the nocturnal leg cramp indication. Future work should encompass ex vivo skin permeation studies across excised human/animal skin, in vivo pharmacokinetic evaluation, antimicrobial/antimalarial efficacy studies and long-term physicochemical stability studies (ICH Q1A(R2)) to facilitate further formulation development and regulatory submission.

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CONFLICTS OF INTEREST

The authors declare no conflicts of interest with respect to the research, authorship, or publication of this article.

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