

COMPARATIVE BIOAVAILABILITY OF CURCUMINOIDS FROM CURCUMINQA™ A NOVEL ENERGIZED FORMULATION VERSUS STANDARD CURCUMA EXTRACT IN HEALTHY VOLUNTEERS: A RANDOMIZED, OPEN-LABEL, TWO-WAY CROSSOVER STUDY

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ABSTRACT

Objective: Curcumin, the active polyphenolic compound from *Curcuma longa*, exhibits promising anti-inflammatory, antioxidant, and therapeutic properties but suffers from poor oral bioavailability due to low solubility and rapid metabolism. Novel formulations aim to enhance their absorption. This present study compared the bioavailability of CurcuminQA™ from Greenspace Herbs versus a standard curcuma extract (standardized to 95% curcuminoids) in healthy volunteers. **Methods:** This randomized, open-label, two-way crossover study enrolled 65 healthy adults (aged 18-45 years). The participants were given a single oral dose of 500 mg CurcuminQA™ and or curcuma extract (standardized to 95% curcuminoids). The study is 1:1 crossover design with a 14-day washout period. In order to mimic real-life scenario, dosing was scheduled without fasting. Collection of plasma samples was done over a period of 24 hours for pharmacokinetic analysis of total curcuminoids with LC-MS. **Results:** Sixty participants completed the study (5 dropouts due to withdrawal). CurcuminQA™ showed significantly higher bioavailability C_{max} ~454 ng/ml, $AUC_{0-\infty}$ ~1233 ng·h/ml and T_{max} was reduced for CurcuminQA™ (~1 hour vs. ~2 hours); $t_{1/2}$ was similar (~4 hours). There were no reports of adverse events apart from mild gastrointestinal discomfort which was comparable between the treatment groups. **Conclusion:** CurcuminQA™ showed more than 20-fold increased bioavailability in comparison to standard curcuma extract, proving its potential for clinical use in conditions requiring increased curcumin dose. By assessing absorption in non-fasting conditions, our study mimics real-life scenario ensuring relevant and practical results.

KEYWORDS: Bioavailability, Curcuminoids, *Curcuma longa* L., CurcuminQA™, Energized Active Supplement Ingredients, Pharmacokinetics.

INTRODUCTION

Curcuma longa L. is a known spice widely used in alternative medicine for managing many conditions, such as digestive disorders, skin infections, joint dysfunction, respiratory disorders, etc. A yellow pigment, curcuminoids abundantly existing in the rhizomes of *Curcuma longa*, has various pharmacological properties like anti-oxidant, anti-inflammatory, anti-microbial, and anticancer activity. Major components of curcuminoids include curcumin, demethoxycurcumin, and

bisdemethoxycurcumin, with curcumin being up to 77% of the total curcuminoid content.^[1,2]

Curcumin, the principal curcuminoid in turmeric (*Curcuma longa* L.), is extensively studied for its therapeutic potential in inflammation, oxidative stress, metabolic disorders, and cancer prevention. However, its clinical translation is limited by poor aqueous solubility, rapid hepatic metabolism via glucuronidation and sulfation, and intestinal efflux by P-glycoprotein, resulting in plasma concentrations typically below 100

ng/mL after standard oral dosing.^[2,3] The low bioavailability of curcumin has prompted the development of formulations that lead to higher levels of curcumin and/or its metabolites in the body, using strategies that reduce its metabolism or increase its uptake and stability by incorporating curcumin into nanoformulations, micelles, liposomes, nanoparticles, and emulsions.^[4-7]

One of the latest and novel approaches adopted by Greenspace Herbs delivers clinically validated Energized Active Supplement Ingredients (EASI)TM by leveraging AI, Quantum Chemistry, and Ayurveda. CurcuminQATM is an energized, highly bioavailable ingredient developed to address curcumin's bioavailability issues. Quantum Ayurveda at Greenspace Herbs infuses select Ayurvedic ingredients with a controlled energy load, then locks that energy in a metastable form so it stays "primed" until it meets the body. The energized natural curcumin is designed for enhanced absorption, utilizing knowledge of traditional ayurvedic concepts and modern quantum chemistry to enhance bioavailability.^[8-10] Our study intended to confirm the above findings via a comparative pharmacokinetic evaluation between CurcuminTM and standard curcuma extract in healthy volunteers, establishing a real-world evidence for formulation efficacy.

MATERIALS AND METHODS

Study Design

Eligible participants were healthy adults (aged 18-45 years, BMI 18.5-30 kg/m²) with no history of gastrointestinal, hepatic, or renal disorders. Exclusion criteria included curcumin supplementation within 30 days, smoking, or pregnancy. Randomization (1:1) to arrange standard curcuma extract (standardized 95% curcuminoid) first or CurcuminQATM first was performed using computer-assisted blocks via REDCap software.

Each participant received a single oral dose of 500 mg equivalent CurcuminQATM energized capsules or 500 mg standard curcumin extract (standardized 95% curcuminoid) capsules without fasting to simulate real-life conditions. A 14-day washout period minimized carryover effects, based on curcumin's short half-life (~4-6 h).

Participants

A total of seventy-two subjects were screened, and sixty-five were enrolled in the study. Post withdrawal, sixty subjects completed both treatment periods. Participants were admitted to the clinical facility 11 hours prior to dose administration. Subjects received either 500 mg CurcuminQATM or standard curcuma extract (standardized 95% curcuminoid).

A single dose of CurcuminQATM 500mg was administered to each subject, with samples collected at predefined time points for analysis. Following a 14-day

washout period, a single dose of standard curcuma extract 500 mg was given to all sixty-five participants, followed by sampling at different time points.

Interventions

CurcuminQATM contained 500 mg curcuminoids in a proprietary energized formulation leveraging Quantum Ayurveda, AI, and quantum chemistry to infuse and lock energy in a metastable form for enhanced absorption. Standard curcuma extract was a reference 95% total curcuminoids extract. Both were administered as size 00 vegetarian capsules with 240 mL of water.

Assessments

Blood samples (5 mL) were collected pre-dose and at 0.25, 0.5, 1, 1.5, 2, 3, 4, 6, 8, 12, and 24 hours post-dose into EDTA tubes. Plasma was separated by centrifugation (3000 rpm, 10 min, 4°C) and stored at -80°C. Total curcuminoids (free + conjugated) were quantified by validated LC-MS/MS (lower limit of quantification: 1 ng/mL; linearity: 1-5000 ng/mL; intra-/inter-day precision <5%). Non-compartmental analysis (Phoenix WinNonlin v8.0) derived PK parameters: C_{max} and T_{max} (observed), AUC_{0-t} (linear trapezoidal), AUC_{0-∞} and t_{1/2}.

Safety

Safety was monitored through adverse event reporting, vital signs, and laboratory assessments at baseline and follow-up.

Statistical Analysis

Data were summarized descriptively (mean ± SD for arithmetic; geometric mean for log-transformed). Pharmacokinetic analysis used a linear mixed-effects model with fixed effects for period, sequence, treatment, and random subject effects. Geometric mean ratios (GMRs) and 90% CIs for test/reference were computed on a log scale; ANOVA assessed period/sequence effects. T_{max} differences were used with the Wilcoxon signed-rank (non-normal). Safety data were analyzed descriptively. Significance: p<0.05. Analyses performed in SAS v9.4.

RESULTS

Participant Disposition and Baseline Characteristics

Of 72 screened, 65 were randomized and dosed (Sequence 1: n=33; Sequence 2: n=32). Five discontinued (3 withdrew consent, 2 lost to follow-up); 60 completed both periods (male: 32, female: 28; mean age 28.5 ± 7.2 years; BMI 24.1 ± 3.4 kg/m²). No baseline imbalances (p>0.05).

Pharmacokinetic Results

Mean plasma concentration-time profiles showed rapid absorption for CurcuminQATM, with over 20-fold higher exposure (Figure 1). Arithmetic means (SD): C_{max} ~20 ng/mL, CurcuminQATM ~454 ng/mL; AUC_{0-t} ~57 ng·h/mL, CurcuminQATM ~1233 ng·h/mL; AUC_{0-∞} similar trend (Table 1-2).

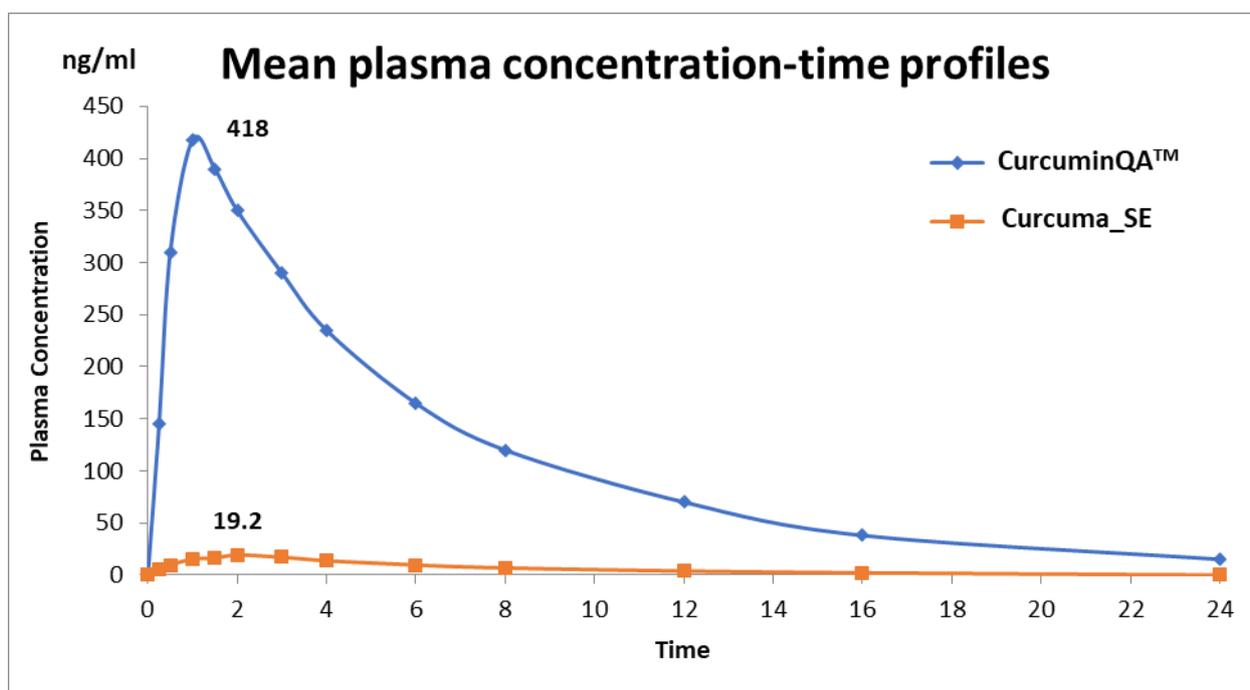


Fig. 1: Geometric means: C_{max} STD-CU 19.17 ng/mL, CurcuminQA™ 418.54 ng/mL (GMR 2183%, 90% CI 1978-2409); AUC_{0-t} STD-CU 54.54 ng·h/mL, CurcuminQA™ 1121.84 ng·h/mL (GMR 2057%, 90% CI 1855-2282); $AUC_{0-\infty}$ GMR 2061% (90% CI 1858-2285). No significant period ($p=0.72$) or sequence ($p=0.41$) effects. T_{max} : STD-CU ~2 hours, CurcuminQA™ ~1 hour ($p<0.0001$). $t_{1/2}$: ~4 hours.

Table 1: Mean (\pm SE) plasma concentrations (ng/mL) of total curcuminoids (n=60); BLQ = Below limit of quantification (<0.5 ng/mL)

Time (h)	CurcuminQA™ (ng/mL) Mean \pm SE	Standard Curcuma extract (ng/mL)-Mean \pm SE
0	BLQ	BLQ
0.25	145 \pm 18	4.8 \pm 0.9
0.5	310 \pm 28	9.6 \pm 1.3
1	418 \pm 36	15.4 \pm 1.8
1.5	390 \pm 33	16.4 \pm 1.9
2	350 \pm 30	19.2 \pm 2.1
3	290 \pm 26	17.1 \pm 1.9
4	235 \pm 22	13.8 \pm 1.6
6	165 \pm 18	9.6 \pm 1.2
8	120 \pm 15	6.8 \pm 1.0
12	70 \pm 11	3.9 \pm 0.7
16	38 \pm 8	2.1 \pm 0.5
24	15 \pm 5	BLQ

Table 2: Pharmacokinetic parameters for total curcuminoids (Mean \pm SE; n=60)

What was measured	CurcuminQA™	Standard Curcumin 95%	What it means
Peak level in blood (C_{max})	~454 ng/ml	~20 ng/ml	CurcuminQA™ reached 22 times higher levels in the blood
Total amount absorbed (AUC)	~1233 ng·h/ml	~57 ng·h/ml	CurcuminQA™ delivered over 20 times more curcumin overall
Time to peak (T_{max})	~1 hour	~2 hours	CurcuminQA™ was absorbed about twice as fast

DISCUSSION

Clinical utility of standard curcuma extract (95% curcuminoids) is largely limited by poor aqueous solubility, rapid metabolism, and low bioavailability. It achieves very little systemic exposure after oral administration, with low plasma levels due to extensive

first-pass metabolism in the liver and intestines, primarily via glucuronidation and sulfation.^[2,3] Published studies reveal that standard curcumin's oral bioavailability is typically very low, attributed to its hydrophobic nature and instability in physiological pH, leading to quick degradation into inactive metabolites.^[11]

Pharmacokinetic studies report a relatively lower plasma concentration even after doses of 2-8 g, with an elimination half-life under 2 hours. These limitations necessitate high doses, risking gastrointestinal side effects without therapeutic efficacy.^[12] Numerous formulation approaches have been developed to overcome these limitations, including liposomal encapsulation for improved stability and absorption. Other methods encompass micelle formulations to boost solubility, nanotechnology, such as nanoparticles for targeted delivery, phospholipid complexes, and adjuvants like piperine to inhibit metabolism. These strategies have shown enhanced bio-accessibility in preclinical and clinical studies.^[13-16]

Curcuma energized by quantum technique is branded as CurcuminQA™, an innovative and first of its kind curcuma ingredient enhanced through quantum energy processes to overcome these limitations, indicating sustained plasma concentration and superior absorption compared to the standard curcuma extract (standardized 95% curcuminoids). Our study confirms the enhanced bioavailability of CurcuminQA™, with more than 20-fold increase in C_{max} and AUC in comparison to standard curcuma extract (Standardized 95% curcuminoid). aligning with mechanism enhancing solubility and absorption by Quantum Ayurveda-infused energy exposure.

Rapid T_{max} in this study suggests quicker dissolution, in agreement with previous cross over trials reporting 3-24-times enhancement for formulated curcumin. Studying absorption without fasting our study mimics the actual life consumer habits, making sure that results are appropriate and practical. The T_{max} for CurcuminQA™ is about half the time of standard curcuma extract, showing quicker onset of action.

The limitation of current study includes open-label design, which has potential to introduce bias, also the focus on healthy volunteers only limits its potential in patient population. Future studies should be aimed at exploring long term safety and efficacy in disease conditions.

CONCLUSION

The present study clearly demonstrates that CurcuminQA™ provides substantially superior oral bioavailability compared with a standard curcuma extract (95% curcuminoids) when administered under non-fasting and real-life conditions. CurcuminQA™ achieved 20-fold higher systemic exposure, as reflected by significantly greater C_{max} and AUC values, along with faster T_{max} , while exhibiting a similar elimination half-life and a comparable safety profile. Both the tested formulations were well tolerated as there were no reports of adverse events. The overall finding of the current study establishes that CurcuminQA™ successfully overcomes the limitations of standard curcuma extract with regards to poor absorption and quick metabolism.

This supports its potential utility in clinical and nutraceutical applications where enhanced and reliable curcumin exposure is required.

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CONFLICT OF INTEREST

The authors declare there are no conflicts of interest.

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