

AQUACELLE®

For enhanced bioavailability



Pharmako's AquaCelle® is a customisable, self micro-emulsifying delivery system (SMEDS), specifically designed and clinically proven to optimise the bioavailability of lipophilic active ingredients whilst maintaining product stability. Clinically tested to improve bioavailability by up to 600%.

Micelles

Micelles are structures formed naturally in the human GI tract to improve the absorption of lipids and lipophilic substances. The body does this through biliary excretions, such as lipase. Their formation is necessary for the proper absorption of fats and fat soluble nutrients in our diet. Micelles are formed using a combination of compounds with fat soluble (hydrophobic) and water soluble (hydrophilic) properties.

AquaCelle® optimises micelle formation for increased bioavailability.

AquaCelle® is a self micro-emulsifying delivery system (SMEDS), specifically designed to increase the bioavailability of lipophilic active ingredients. It optimises formulations for micelle formation (bioactivity) and product stability. These optimised micelle formations are verified by laser light obscuration analysis and Dynamic Light Scattering (DLS).

Scientifically validated

AquaCelle®'s technology and superior bioavailability is confirmed through laser light obscuration analysis and DLS (including particle size and volume). Pharmacokinetic studies ensure that active nutrients are delivered to the systemic circulation.

Supported by ongoing clinical research.

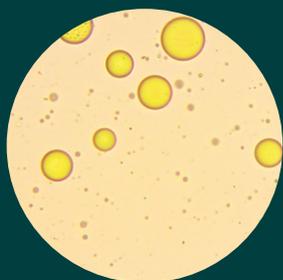
Pharmako conducts regular pharmacokinetic studies to prove enhanced bioavailability of AquaCelle®. Confirmed superior bioavailability is also supported by a calendar of ongoing pharmacokinetic and longer term studies to show clinical significance.

Australian made.

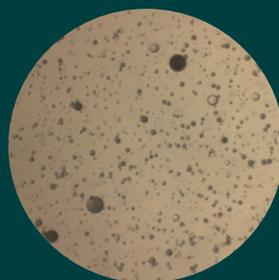
AquaCelle® is made in Australia from pharmacopoeial grade ingredients, under cGMP standards.



AquaCelle® Algal DHA micelles.



AquaCelle® omega-3 micelles.



AquaCelle® lutein micelles.

AquaCelle® formulations can be customised:

- to optimise diverse active ingredient(s) bioavailability.
- for customer requirements.
- for regulatory frameworks.
- for dosage format(s).

AquaCelle®'s technology and superior bioavailability is scientifically validated through:

- laser light obscuration analysis.
- human pharmacokinetic trials.

Pharmako have developed AquaCelle® formulations for use in multiple product sectors and applications including:

- nutraceutical,
- cosmetic,
- pharmaceutical,
- veterinary,
- antibacterial,
- dietary supplements,
- food and beverage.

AquaCelle® is approved and customised for active ingredients such as:

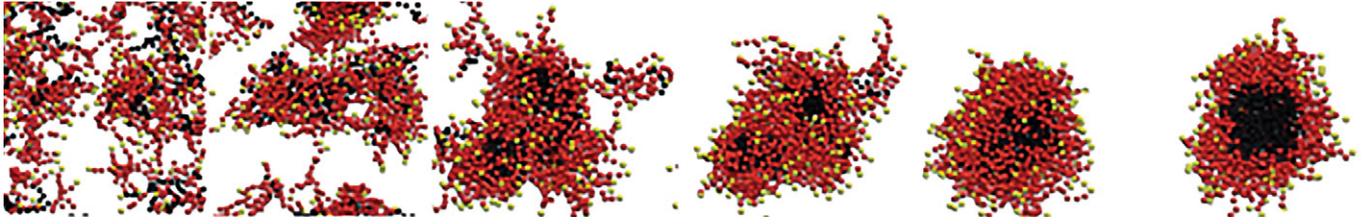
- omega-3s,
- CoQ₁₀
- vitamins A, D, E & K,
- carotenoids,
- botanicals,
- and flavonoids.

Shelf life

24 months when stored at 25°C.

Exclusive use.

AquaCelle® is a patented technology and a registered trade mark owned exclusively by Pharmako Biotechnologies Pty. Ltd.



AquaCelle® in water - Computer generated simulation at the molecular level.

The randomly positioned molecules first aggregate into small clusters, which then come together to form a single micelle, the entire process taking about 8000 picoseconds (800 trillionths of a second).

Scientific studies.

The impact of an innovative drug delivery system (AquaCelle®) on the bioavailability of fish oil, compared to a standard formulation.

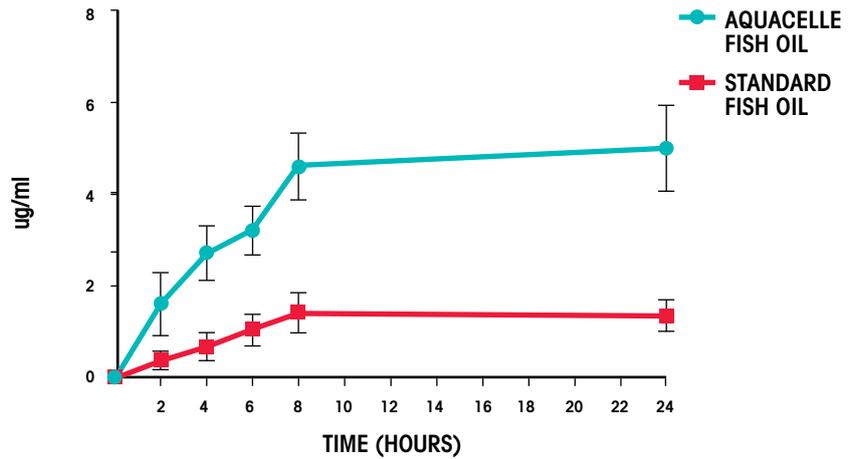
A single dose, randomised, double blinded study was used to evaluate the pharmacokinetics of two different fish oil formulations. Fish oil pharmacokinetics were determined from blood samples taken prior to dosing (t = 0), followed by intervals of 2, 4, 6, 8 and 24 hours post supplementation. 60 healthy male and female volunteers (mean age 23.0 years) were recruited to take part in this study.

After administration of equal doses of 680mg fish oil (272mg EPA and 204mg DHA) as ethyl ester, there was a significant difference in absorption (Cmax and AUC) in the AquaCelle® group compared to the control group. There was no significant difference in baseline plasma concentration or demographic features between groups. There was a significant increase in geometric mean (6.14 times higher; p < 0.05) for total absorption (AUC_{0-24h}) in the EPA + DHA for the AquaCelle® group compared to the standard control group.

The mean Cmax values were significantly higher (P < 0.05) in the AquaCelle® group for EPA, DHA and EPA+DHA as compared to the standard control group. Both groups had a median Tmax of approximately 6-9 hours and there was no significant difference observed between the two treatments.

Based on these results, we can conclude that total absorption (EPA + DHA) in the AquaCelle® group was significantly higher than in the standard group by 6.1 times, with an increase in Cmax of 3.6 times.

EPA

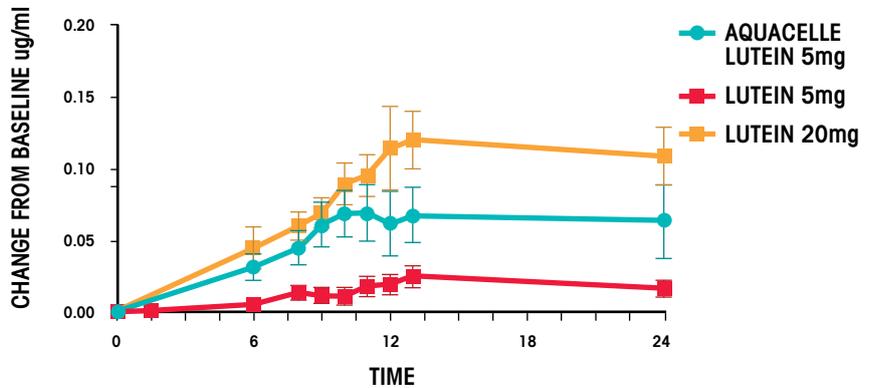


A study to evaluate the absorption of 3 Lutein formulations on increasing plasma Lutein concentration and total availability in healthy participants over a 72 hour period.

Forty-seven subjects were recruited into the study. This study was a single-centre, randomized, double-blind, 72-h bioavailability clinical investigation. Participants were then given one of the three randomized blinded treatments with the provided breakfast. Participants and investigators were blinded to treatment and the blind was not broken during the trial. Standard Lutein 20mg - single dose; Standard Lutein 5mg - single dose; and AquaCelle® Lutein 5mg - single dose. Blood samples were collected at 0, 6, 8, 9, 10, 11, 12, 13, 24, 48 and 72 hours post-dose.

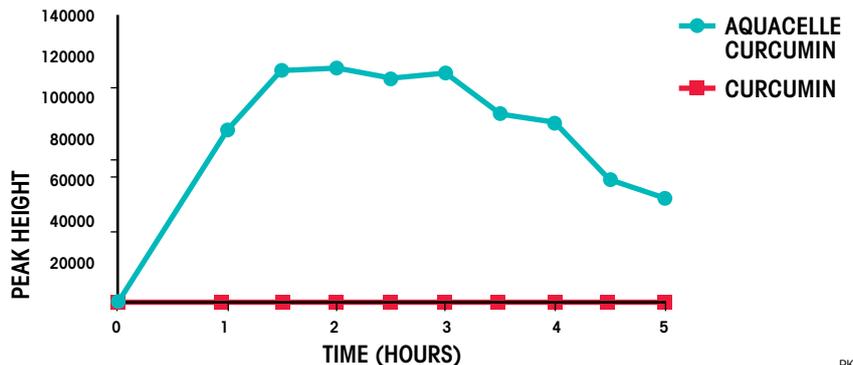
Measurements of MPOD was performed by the same trained operator using the well-established psychophysical method of heterochromatic flicker photometry (HFP) on a portable screening instrument, the Elektron Technology MPS II, using a standard protocol as used in Davey 2016 & Howells 2013.

The mean AUC (0-72hour) results indicate that there is a difference in Lutein absorption (approximately 4 times) between the AquaCelle® 5 mg and the standard 5 mg lutein.



C-Max determination of curcuminoids: standard curcumin v AquaCelle® curcumin. RDC Global. 2016.

A randomised, non-blinded study design was used. Two groups (n1=2, n2=2) of clinically healthy males and females (2 males, 2 females), between the ages of 30 to 50 years, participated in the study. Product A - AquaCelle® Curcumin with 200 mg curcumin extract with 95% curcuminoids per capsule. 2 capsules were consumed. Product B - Control with 200 mg curcumin extract with 95% curcuminoids per capsule. 2 capsules were consumed. After supplementation with the curcumin, only the AquaCelle® group experienced any increase in plasma levels. The increase was steady and continued for 3 hours. The plasma concentration of AquaCelle® Curcumin remained well above Product B over the duration of the study. The bioavailability of AquaCelle® Curcumin to Product B (Δ in AUC(0-24h)) is yet to be determined but it appears to be quite significant.



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