

The Preclinical Drug Development Platform

Pheroid® Phytofare® Technology

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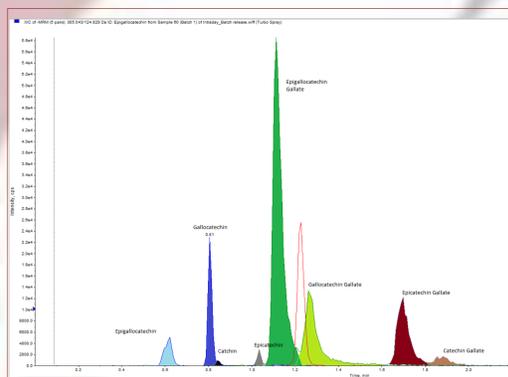
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Background

Pheroid® penetrates skin increasing delivery of active ingredients (AI) 2.5 to 3.5 times. Pheroid® vesicles / microsponges transverse most biological barriers, including skin. Cellular uptake actively facilitated by the fatty acid membrane binding protein. Formulated with α and β -hydroxy acids, fruit extract, salicylic acid, collagens, hydrolyzed elastin, vitamin C, anti-oxidants, suitable preservatives, Phytol V7, Konakian amp and essential oils. Pheroid® facilitated penetration through stratum corneum to epidermal skin layer shown in clinical trials.

Phytofare® is a trademarked extraction process of flavonoids/polyphenols from a variety of organic sources, in this case *Camellia sinensis*, and converts these molecules into a highly bioavailable form.



LC-MS-MS: Phytofare(R) green tea extract >90% catechins, Galliccatechin (3.3%) Epigallocatechin (16.4%), Catechin (1.5%), Epicatechin (6.5), Galliccatechin Gallate (4.6%), Epigallocatechin Gallate (50.2%), Catechin Gallate (0.5%) and Epicatechin Gallate (7.6%).

Aim

Case study to compare skin moisture content, elasticity and surface parameters of Phytofare® green tea extract entrapped in Pheroid® (Formulation A) and reference formulation (Formulation B).

Methods

Formulation A: Phytofare® green tea extract was added to aqueous phase portion. After combination of oil phase (vitamin F ethyl ester, Kolliphor® and α -tocopherol) and aqueous phase (H_2O-N_2O) at 70 °C, solution homogenised at 1500 rpm until at acceptable temperature. The extract solution was added during further homogenization to micro-emulsion. This formulation was then combined with a basic carrier formulation which also served as the reference formulation B.

The Pheroid® pre-formulation was characterized by confocal laser scanning microscopy (CLSM) and particle size distribution determined by Malvern mater sizer.

Each formulation was prepared 10 days prior to T0 days of the clinical trial.

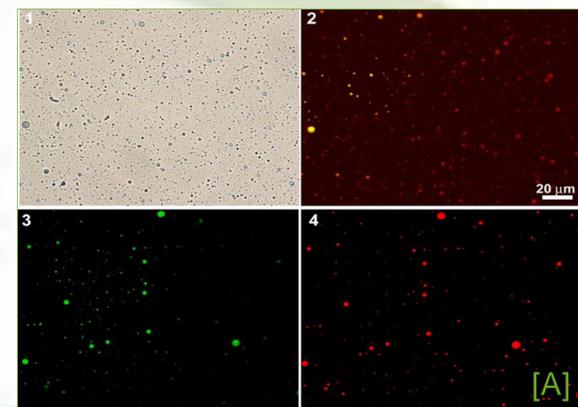
The formulations were distributed in 1000 μ L syringes, without needles, to allow accurate administration.

Study design

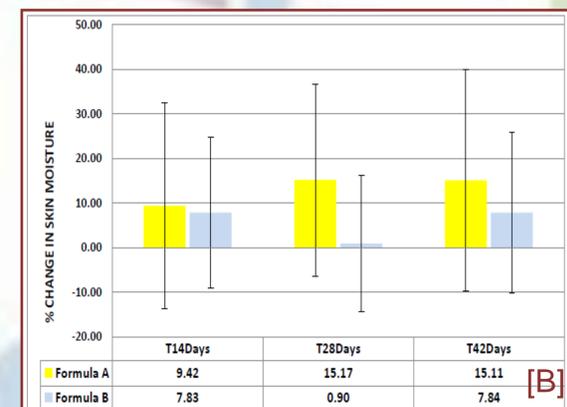
- Crossover study - 35 female Caucasian volunteers.
- Measurement time points at 0,14, 28 and 42 days post application.
- Recording area 2 x 6 =12cm², non-dominant inner forearm.
- Recorded Corneometer® (skin moisture content), Cutometer® (skin elasticity) and Visioscan® VC 98 camera (skin surface parameters) .
- Following T0 days, Formulation A applied at 2mg/cm², twice daily.
- Washout period 2 months.

Results

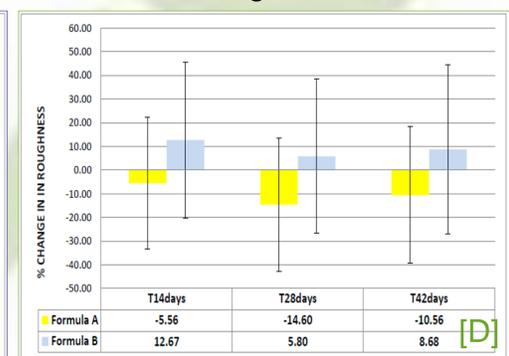
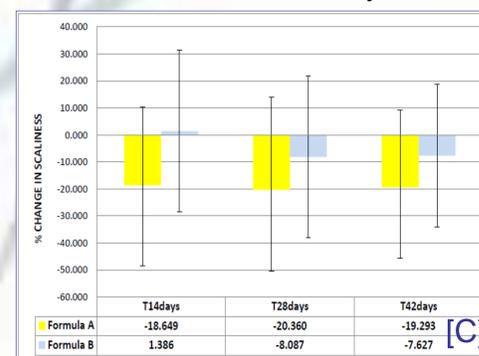
[A] Tungsten light, CLSM images pre-lotion Pheroid® formulation. Vesicles of varying sizes, containing significant AI observed. Average size 1.135 μ m, concentration ~7781.23 x 10⁸ per ml. Red fluorescence indicate Pheroid structures, green auto-fluorescence AI.



[B] Both Pheroid® Phytofare® (A) and reference formulation B hydrated skin at all time intervals. Formulation A was superior to Formulation B and maintained effect up to 42 days.



Pheroid® Phytofare® (Ph²) reduced, while Formulation B enhanced skin roughness [C]. Formulation A also reduced skin scaliness [D] with maximum effect at 28 days maintained effect through out.



The elasticity parameter, R2, was calculated from the deformation graph. Formulation A (Ph²) showed a trend towards enhancing skin elasticity increasing from 14 to 42 days post application. The reference formulation had no significant effect.

Conclusions

- No adverse effects were reported or observed.
- The Phytofare® Pheroid® (Ph²) formulation significantly improved skin hydration and skin surface parameters.
- The Ph² formulation has superior anti-aging properties to the reference formulation.
- The Phytofare® Pheroid® formulation is a good candidate for further exploitation as a moisturiser and anti-aging skin care product.

References and Acknowledgements

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