

Study to verify the specific cosmetic efficacy of the food supplements
for
MF3 PE Evolution Softgels
MF3 VP Evolution Softgels
MF3 MCE Evolution Softgels

INTRODUCTION

It is the responsibility of the cosmetic industry to provide the consumer with safe products they can trust in, which meet their requirements.

Scientific investigation of the efficacy and tolerance of new cosmetic products leads to reliable and honest marketing arguments, to transparency and to the protection of consumer's health.

OBJECTIVES

The objectives of this home study were to verify the specific cosmetic efficacy of the food supplements called "MF3 PE Evolution Softgels", "MF3 VP Evolution Softgels" and "MF3 MCE Evolution Softgels", by means of the following parameters: skin hydration, skin elasticity, skin surface sebum level, melanin index. A secondary criteria was the opinion of the users about the effectiveness of the supplements by means of a questionnaire adapted to the particular claims of food supplements.

MATERIALS AND METHODS

30 healthy volunteers participated in the study. They were divided into the 3 groups of 10 persons. The standard questionnaire designed by the physician was given to all the participants to detect possible diseases and current concerns before the start of the soft gel study.

Different supplementation was organized as one capsule daily by three groups during 2 months.

Standard, usual skin care products were allowed during the whole period of the study. Skin changes were regularly assessed during this period by non-invasive bioengineering techniques (on day 1 before starting with the treatment, in 1 and 2 months after starting the treatment, one month after stopping the supplementation.

All measurements were conducted by on the cheeks and forearms (skin hydration, elasticity, melanin index), except for sebum level, which was measured on the forehead.

These measurements were evaluated and rated by the aesthetic practitioner before and after the treatment.

Standard photographs were obtained from the treatment area at baseline, at the end of treatment to

evaluate the cosmetical effectiveness of VP EVO Softgels and wound healing capacity of PE EVO Softgels.

The subjective evaluation was done by means of a questionnaire. It was designed by the aesthetic practitioner and was handed over to the study participants after the end of the study.

We also proposed to rate the improvement after the course of soft – gels consumption. The rating was based on a 5-point scale on which improvement was rated as 1- none, 2 - mild, 3 - moderate, 4 - good and 5 - excellent.

TEST PRODUCTS

Content: 30 Softgels

Dosage form: enteric coated soft gel

Packaging: 3 perforated aluminium foil blisters, pouch with resealing able zipper, packed in a premium box Manufacturing sites: Switzerland, USA, Germany Certifications: Halal, GMP, Free Sale Shelf life: 4 years from the date of manufacturing

MCE EVO softgels (test formulation):

Fish hydrolyzed collagen and elastin; Fish nucleic acids; Fish peptide; Soluble fish cartilage extract;

Extracellular Matrix Component;
Collagen, Elastin, Glycosaminoglycans;
Eicosapentaenoic acid (EPA);

Docosahexaenoic acid (DHA);

Natural Astaxanthin;

Ubiquinol.

VP EVO Softgels (test formulation)

Phosphatidylcholine;

Isoflavones (daidzein, glycitein, genistein);

Amino acids and Peptides;

Carotenoids;

Saponins:

Flavonols and flavanones;

Alkamides:

Ginsenosides;

Oligomeric proanthocyanidin;

Cysteine:

Glutamine;

Glycine;

Ubiquinol;



PE EVO Softgels (test formulation):

Extracellular Matrix Component;

Collagen, Elastin, Laminin, glycosaminoglycans,

fibronectin and glycoprotein;

Nucleic Acid (RNA & DNA);

Amino acids and Peptides;

Vitamins and Minerals;

Cytokines and Growth Factors;

Fish hydrolyzed collagen elastin;

Fish nucleic acids;

Fish peptide;

Soluble fish cartilage extract;

Glycosaminoglycans;

Ubiquinol.

BRIEF DESCRIPTION OF THE EQUIPMENTS

The following equipments were used for bioengineering measurements:

Skin hydration

Manufacturer: Callegari S.P.A.; Model: SOFT PLUS CPU; Parma Italy. Callegari S.P.A. evaluates the capacitance of the upper layers of the skin. The value of this parameter is dependent on the hydration of the measured layers.

Skin elasticity

Callegari S.P.A.; Model: SOFT PLUS CPU; Parma Italy. Callegari S.P.A. evaluates the mechanical properties of the skin by applying stress to the skin (vacuum). Negative pressure is created, and the skin is drawn into the aperture of the probe to then relax upon establishment of normal pressure.

Skin surface sebum level

Callegari S.P.A.; Model: SOFT PLUS CPU; Parma Italy. Callegari S.P.A. Measurements are based on grease-spot photometry. A special tape becomes transparent in contact with the sebum on the skin surface. The transparency of the tape is measured by photocell behind a light source sending light through the tape. The light trans-mission is correlated to the sebum level of the measured surface.

Skin melanin index

Callegari S.P.A.; Model: SOFT PLUS CPU; Parma Italy. Callegari S.P.A. Melanin is mainly responsible for the tan and the pigmentations. The measurement is based on absorption principle.

ANATOMICAL LOCATIONS OF THE BIOENGINEERING MEASUREMENTS

Face: Measurements were conducted on the cheeks (area defined at the crossing of a vertical line from the eye corner with a horizontal line from the mouth corner) on both sides of the face.

Forehead: Measurements were conducted on both sides of the forehead.

Forearms: Measurements were conducted in the middle of each forearm between wrist and elbow.

THE SUBJECTIVE EVALUATION				
Questionnaire 1(VP Softgels)	YES	% YES	NO	% NO
Q1 Did you notice the improvement on the skin of your face?	8	80%	2	20%
Q2 Did you notice whitening effect on your skin?	7	70%	3	30%
Q3 Did you notice the improvement on the skin of your body?	9	90%	1	10%
Q4 Does your skin seem to be smoother after the supplementation?	9	90%	1	10%
Q5 Did you experience any side effects after/during consuming of softgels?	0	0%	10	100%
Questionnaire 2 (PE Softgels)	YES	% YES	NO	% NO
Q1 Did you notice the improvement in your general wellness?	9	90%	1	10%
Q2 Did you notice the improvement of your stamina?	9	90%	1	10%
Q3 Did you notice the improvement of musculoskeletal functions(lower back pain, joints pain)?	7	70%	3	30%
Q4 Did you notice the improvement of your quality of sleep?	8	80%	2	20%
Q5 Did you experience any side effects after/during consuming of softgels?	0	0%	10	100%
Questionnaire 3 (MCE Softgels)	YES	% YES	NO	% NO
Q1 Did you notice the improvement in your general wellness?	7	70%	3	30%
Q2 Did you notice the improvement of your stamina?	7	70%	3	30%
Q3 Did you notice the improvement of musculoskeletal functions(lower back pain, joints pain)?	9	90%	1	10%
Q4 Did you notice the improvement of your quality of sleep?	6	60%	4	40%
Q5 Did you experience				

any side effects

of softgels?

after/during consuming

10

100%

0

0



CONCLUSIONS

The objectives of this home study were to verify the specific cosmetic efficacy of the food supplements called "MF3 PE Evolution Softgels", "MF3 VP Evolution Softgels" and "MF3 MCE Evolution Softgels", by means of the following parameters: skin hydration, skin elasticity, skin surface sebum level, melanin index. A secondary criterion was the opinion of the users about the effectiveness of the supplements by means of a questionnaire adapted to the particular claims of food supplements.

30 healthy volunteers participated in the study. They were divided into the 3 groups of 10 persons. The standard questionnaire designed by the physician was given to all the participants to detect possible diseases and current concerns before the start of soft gel study.

Different supplementation was organized as one capsule daily by three groups during 2 months.

Standard, usual skin care products were allowed during the whole period of the study. Skin changes were regularly assessed during this period by non-invasive bioengineering techniques (on day 1 before starting with the treatment, after 1 and 2 months after starting the treatment, one month after stopping the supplementation the same skin.

The following measurements were conducted:

- Skin hydration;
- · Skin elasticity;
- Skin surface sebum level;
- Melanin index.

The measurements were conducted on the forearms, on the cheeks and on the forehead.

Standard photographs were obtained from the treatment area at baseline, at the end of treatment to evaluate the cosmetical effectiveness of VP EVO softgels and wound healing capacity of PE EVO Softgels.

The subjective evaluation was done by means of questionnaire. It was designed by the aesthetic practitioner and was handed over to the study participants after the end of the study.

We also proposed to rate the improvement after the course of soft – gels consumption. Rating was based on a 5-point scale on which improvement was rated as 1-none, 2 - mild, 3 - moderate, 4 - good and 5 - excellent.

After 1 month of treatment and later on until supplementation was stopped, the test products showed a beneficial effect on the skin as measured by an increase in skin hydration (especially VP EVO Softgels). The whitening effect and pigmentation changes were recorded simultaneously due to the decrease of melanin index (Chart 1). An improvement of skin elasticity was also measured, leading to an

improvement of visual skin appearance (Chart 2). The obtained results show that the test product provides a measurable moisturising effect, which isn't usually expected feature for a food supplement (Chart 3).

The once-daily supplementation of VP EVO softgels with the test product also leads to an interesting tendency in sebum decrease after the first month, and a slight increase after the second month. A sebum regulation process could not be evidenced as such, however, but the tendency would need to be confirmed in a further evaluation (Chart 4).

Generally, the parameters, which had been improved during the 2-month treatment period, were only slightly reduced during the third, unsupplemented month. Thus a true, residual effect could be noted, and the corresponding values were reduced during that time to reach about the level of one month of supplementation.

Concerning the subjective evaluation, the test product was rated from "a very good" to "excellent" by 75% of all the volunteers in test groups (Chart 5).

Overall, besides good tolerance, a good efficacy concerning general wellness and beneficial improvement in stamina was attested by the volunteers among both MCE EVO and PE EVO test groups - 70 % and 90 % respectively (Chart 6). These results are in line with the common improvement of the quality of sleep, which is also observed by the participants of two test groups but is more pronounced among the participants of PE test group (PE EVO test group – 80%, MCE EVO test group – 60% - Chart 6).

The consumption of MCE EVO Softgels has shown the significant improvement of musculoskeletal functions among the participants. Main part of MCE group reported about pain relief & increased rate of joint movements, while some of the volunteers noticed the dramatical result in decrease of symptoms associated with manifestations of arthritis (knee joints, elbow joints, finger joints) and lower back pains - 90% of participants in total (Chart 6).

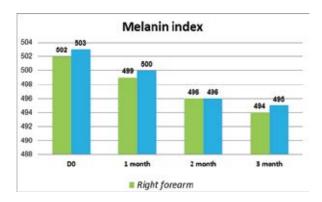


Chart 1. Measurement of Melanin Index





Chart 2. Measurement of Skin Elasticity

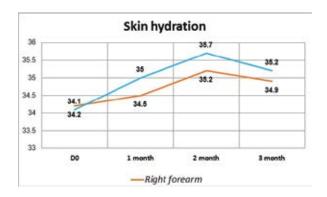


Chart 3. Measurement of Skin Hydration

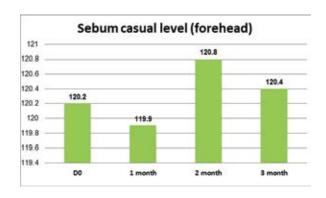


Chart 4. Measurement of skin sebum level

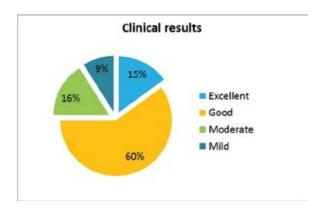


Chart 5. Subjective evaluation of clinical results

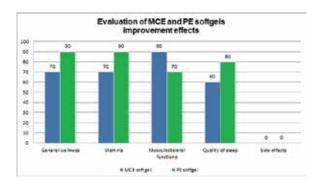


Chart 6. Subjective evaluation of clinical results by the questionnare

VP EVO SOFTGELS (48 years old female before and after the course of consumption)







PE EVO SOFTGELS (wound healing effect, 36 years old male, before the treatment, after 2 weeks of treatment, after one month)

