Evaluation in human of the whitening effect of Yellow Cream

Instrumental evaluation

Checking in human of its acceptability after application under normal conditions of use subjective assessment of its cosmetic qualities and efficacy

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Aim and principle of the study

This study intended:

To assess the whitening effect of a cosmetic product under strictly controlled conditions, to check the acceptability and to assess the cosmetic qualities and efficacy of a cosmetic product after application under the normal conditions of use.
To meet the requirements of the Directive 93/35/EEC of 14/6/93 - Art 7 bis - concerning the justification of the effect claimed in the advertising media.

The whitening effect of the product was assessed:

Objectively and quantitatively: Whitening effect by measurements of melanin index before and after treatment.
Subjectively: By questioning the volunteers at the end of the treatment.

The acceptability was:

Checked every day by the volunteers themselves at home.
Controlled after visual examination of the experimental area, by a Dermatologist or the responsible technician, and after questioning of the volunteers.

The cosmetic qualities:

Were assessed, at the end of the study, using a target questionnaire.

Type of the study

This monocentric study was performed in open.
12 volunteers were included in the study.
No volunteer discontinued and no exclusion was decided by the Investigator.
The specific inclusion criteria were the following ones:

sex female, age 35-70 years, phototype (Fitzpatrick) I to IV, exhibiting at least one senescence or actinic spot or cloasma on the face >=5mm, non tanned, regular or occasional users of care products.

Methodology

Experimental conditions of use of the test product

Experimental areas: Whole face insisting on dark spots (avoiding eye outline).

Product directions for use: Application of the product as it is by the volunteer himself, by gentle digital massage until its complete penetration.
Applications at home Freguency/duration: From D0 to D28, Application once a day (night) during 28 consecutive days +/- 2 days (4 weeks).

Efficacy assessment
Instrumental assessment of the whitening effect

The whitening effect was assessed by comparing the skin colour of the dark spot chosen, before and after treatment (D0 and D28).
The experimental area was the spot selected on face, by the responsible technician, This spot (>= 5 mm) was perfectly documented in the investigator's brochure as the measurements before and after the treatment have to be performed exactly on the same spot.
The measurements were performed with a Mexarneter® MX 16 (Courage & Khazaka) which has a measuring probe with a diameter of measuring surface of 5mm.
The melanin and hemoglobin (erythema) are mainly responsible for the skin's colour. The special probe emits light of two wavelengths defined (red and near infrared) for which the melanin absorbs and the absorption of the hemoglobin pigment is minimal, avoiding therefore the interference of the vascular state of the skin in the evaluation of the melanin content. The amount of light absorbed by the skin is calculated from the amount of light emitted by the

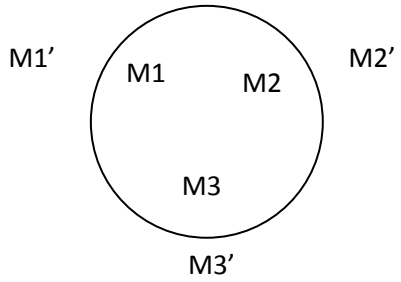
device and the amount of light reflected by the skin, obtaining then the melanin index (parameter M):

$$M = (\ 500/Log\ 5\ ).\ \{\ Log\ (Infrared - Reflection\ /\ Red - Reflection) + Log\ 5\ \}$$

The melanin content is expressed in arbitrary units in the range 0-1000 (melanin index). The higher the values the more melanin are detected.

At each experimental time, the triplicate measurements of melanin index were performed on the spot, i.e. Ml, M2, M3 and on the non pigmented skin around the spot i.e. Ml', M2', M3' according to the following scheme*.
The interpretation of the results was based on the results of the statistical analysis of data: comparison of the values obtained on D0 and D28 using a Student's "t" test for paired series.

* *The measurements of the melanin index were performed on D0 and D28.*



Results

A-Efficacy assessment
Instrumental assessment of the whitening effect on day 0 and day 28.

Volunteer reference	D0			D28			% variation ΔM (D28-D0)
1	491	499	8	486	489	3	-63%
2	491	520	29	496	510	14	-51%
3	500	510	11	499	504	6	-47%
4	486	523	37	488	525	37	1%
5	475	498	22	482	496	14	-39%
6	477	520	42	477	514	38	-11%
7	480	512	32	480	508	28	-12%
8	491	519	27	499	520	20	-26%
9	473	499	26	473	490	17	-36%
10	504	516	13	504	513	10	-24%
11	493	538	45	488	526	38	-15%
12	471	485	14	470	476	6	-60%
Mean	486,1	511,5	25,4	486,9	506,0	19,1	-32%
Standard deviation	10,5	14,2	12,3	10,9	15,5	13,1	21%

The statistical analysis (Student's "t" test for paired series) enabled to compare the variations of the melanin index obtained before and after the treatment.

Melanin index (M)

	D0			D28			% variation
Mean	486,1	511,5	25,4	486,9	506,0	19,1	-32%
Standard deviation	10,5	14,2	12,3	10,9	15,5	13,1	-21%

The results of this analysis are gathered below:

T value	P value	Significance
5,78168	0,000122534	S

S= significant NS= non significant

B- Cosmetic efficacy

Items (12 exploitable results)	N° satisfied volunteers	% satisfied volunteers
Makes the hyperpigmented spots lighter	9	75%
Avoids the appearance of new hyperpigmented spots	12	100%
Skin softer and smoother	10	84%

Conclusion

According to the experimental conditions adopted and taking into account the grading scale established by the investigator centre, the product Yellow Cream has a whitening effect reducing in 32% the melanin index of the hyperpigmented spots in the first month.

Bibliography

Piérard G.E., EEMCO guidance for the assessment of skin colour. Jour Europ Acad of Dermatology and Venerology, 1998, *10, 1-11*

Chardon A., Crétois 1., *Hourseau*

C *Skin colour typology and sun tanning pathways. International Journal of Cosmetic science, 1991, 13,191-208*

Ok-Sub Lee, Eun-Joung KIm: Skin /ightning, Cosmetics & Toiletries 1995, 110, pp. 51-56

ZuidhoJJH. W, Van Rijsbergen JM:

Whitening efficacy of frequently used whitening ingredients, Cosmetics & Toiletries 2001, 116, pp. 53-59

Jackson E.M & Robillard N.F, The controlled use test in a cosmetic product safety substantation program, J.Toxicol.Cut. Ocular. Toxicol., 1982,20, pp. 11 7-132

Frances Pascher M.D., Adverse reactions to eye area cosmetics and their management, JSoc.Cosmet. Chem., 1982, 33, *pp. 249-258*

Keswick B.H., Ertel K.D., Visscher

MO., Comparison of exaggerated and normal use techniques for assessing the mildness of personal cleansers, J.Soc. Cosm. Chem., 1992,43, *pp.* 187-193.

Biological screening of100 plant extracts for cosmetic use: inhibitory activities oftyrosinase and dopa autooxidation. 1nl. Journal ofCosmetic Science, 1997, 19, *pp.291-298*

Melanins and melanogenesis, Cosmetics and Toiletries, 1996, 11 l, *pp.59-62*

Kojic acid, a cosmetic skin whitening agent, is a slow-binding inhibitor ofcatecholase activity oftyrosinase, J Pharm Pharmacol, 1994, 46, pp. 982-985

Melanogenesis inhibitor from Morus Alba, Cosmetics and Toiletries, 1997,112.