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Bangkok, November 24, 2022

Study Draft Report# DA22A403 (version 0.1)
Related to quote# DA22A403

EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT

Nerrish 7White Melasma cream

Study coordination:
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QUALITY CONTROL IN PROGRESS

Document 1/1 including 34 pages

SUMMARY OF THE STUDY REPORT# DA22A403

EVALUATION OF THE EFFICACY OF A COSMETIC PRODUCT

Claim

- Whitening effect
- Depigmentation effect

Objectives

To evaluate:

- whitening effect by measurement skin color using Spectrophotometer® CM700-d on normal area on face;
- depigmentation effect by measurement skin color using Spectrophotometer® CM700-d on pigmentation spot on face;
- realization of photos using Visia® CAS for illustration (front/left/right views);
- subjectively its cosmetic acceptability and future use by analysis of the subjects' answers to a subjective evaluation questionnaire.

Methodology

- Open, intra-individual study; each subject is his/her own control;
- Before / After.

Kinetics

Evaluation Method	Studied Zone	D0	D28 (±1)
Information of the subject about study conditions and collection of his/her informed consent		●	
Verification of inclusion and non-inclusion criteria		●	
Measurement skin color using Spectrophotometer® CM700-d	Pigmentation spot and Normal area	●	●
Realization of photos using Visia® for illustration (Front/Left/Right views)	Face	●	●
Supply of products + daily monitoring sheet		● (d)	● (c)
Subject self-evaluation using a questionnaire			●

Dates

Product reception	Study start	Study end	1st results by e-mail
October 11, 2022	October 20, 2022	November 17, 2022	Report: December 15, 2022

Product

Reference	Form	Application zone
Nerrish 7White Melasma cream	Opaque beige cream	Face

Study Population

Specific inclusion criteria

- **Sex:** females;
- **Age:** from 18 to 60 years;
- **Phototype:** I to IV;
- **Type:** Asian;
- Subject having pigmentation spot (i.e., dark spot, freckles, melasma) on face.

Number of subjects analyzed	Average age
22	43±2 years (between 24 and 60)

Conclusion

Under the conditions of this study conducted under dermatological control, we observed that:

Product "Nerrish 7White Melasma cream"

DEPIGMENTATION EFFECT

Under study condition after 28 days of use the product induce a depigmentation effect characterized by:

- a significant increase in L* parameter of +2% on average on D28, this effect was observed on 95% of the subjects (p<0.001).
- a significant decrease in b* parameter of -3% on average on D28, this effect was observed on 91% of the subjects (p<0.001).
- a significant increase in ITA° parameter of +15% on average on D28, this effect was observed on 86% of the subjects (p<0.001).

WHITENING EFFECT

Under study condition after 28 days of use the product induce a whitening effect characterized by:

- a significant increase in L* parameter of +1% on average on D28, this effect was observed on 95% of the subjects (p<0.001).
- a significant decrease in b* parameter of -2% on average on D28, this effect was observed on 64% of the subjects (p<0.001).
- a significant increase in ITA° parameter of +5% on average on D28, this effect was observed on 82% of the subjects (p<0.001).

SUBJECTIVE QUESTIONNAIRES

Subjects appreciated for its properties of the product after 28 days of use:

- 100% appreciated for the global appreciation of this product is pleasant and the product is easy to spread.
- 96% appreciated for the scent of product is pleasant.
- 95% appreciated for the product is quickly absorbed and the product does not make the skin greasy and sticky.

Subjects appreciated for its efficacy of the product after 28 days of use:

- 100% appreciated for the appearance of pigmentation spots look fade, the skin is more even tone, the skin feels restored, the product is suitable for your skin type, and the product does not cause skin irritation.
- 96% appreciated for the skin is less dullness.
- 95% appreciated for the size of pigmentation spots look smaller (In size), the number of pigmentation spots is reduced, the skin is brighter, lighter and looks healthy glow, and the skin is more moisturized.

95% of the subjects at the end of this study the subject would like to buy this product (regardless of the price) and 100% of subjects recommend this product to a friend.

	Name and job title	Date	Signature
Project Manager	**Pimrumpa VICHITNARK**	**November 24, 2022**	

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1. QUALITY CONTROL STATEMENT

DERMSCAN ASIA is certified ISO: 9001-2015.

The person responsible for the final quality control certifies that the study above was conducted as closely as possible to Good Clinical Practice (GCP-ICH), in compliance with the study protocol and DERMSCAN standard operating procedures and that the study report reflects raw data.

QUALITY CONTROL ASSESSOR	
Last name	**SANGTET**
First name	**Pramrudee**
Date	November 24, 2022
Signature	

2. STUDY PROCESS

The study is carried out on a cosmetic product whose safety has been assured by the Sponsor.
Its aim is to further confirm, under normal and reasonably foreseeable use conditions, the capacity of products to maintain human body in good condition.

+ See ethical requirements and regulatory standards in **Appendix 8.**

This study will be conducted under the following conditions:

2.1. POPULATION

2.1.1. Selection

INCLUSION CRITERIA
Specific
• **Sex**: female; • **Age**: between 18 and 60 years; • **Phototype**: I to IV; • **Type**: Asian; • Subject having pigmentation spot (i.e., dark spot, freckles, melasma) on face.
General
• Healthy subject; • Subject having given his/her free informed, written consent; • Subject willing to adhere to the protocol and study procedures.

EXCLUSION CRITERIA
• For women: pregnant or nursing woman or woman planning to get pregnant during the study; • Cutaneous pathology on the study zone (eczema, etc); • Subject has history of allergy to cosmetic products; • Use of topical or systemic treatment during the previous weeks liable to interfere with the assessment of the efficacy of the study product; • Subject went through dermatologist treatments or procedures within 2-month period before the study start; • Subject having undergone a surgery under general anesthesia within the previous month; • Excessive exposure to sunlight or UV-rays within the previous month; • Subject enrolled in another clinical trial during the study period; • Subject considered by the investigator to be likely not compliant to the protocol.

2.1.2. Study requirements and constraints

DURING THE STUDY, THE SUBJECTS		
HAVE TO	**MUST NOT**	**ARE ALLOWED TO USE*** (except on visiting days)
• comply with dates and hours of evaluation visits; • follow the conditions of use of the study product at home; • complete the daily-log and bring it back with study product at the end of the study; • avoid excessive UV exposure (including artificial UV).	• apply any product to test areas the days of the visits* to the lab; • apply any other similar product to test areas; • modify their usual make-up, hygiene or use new products; • allow the use of the study product by another person than herself.	• usual cleansing products; • usual face and eyes make-up removers; • usual sunscreen product; • for women, light face make-up (powder and blusher), eyes and lips make-up, with usual products.

2.1.3. Compliance assessment

The compliance is controlled by checking the daily log.

+ See **Appendix 7.2.**

In case of minor protocol deviation, the technician or the investigator repeats the instructions and reminds the subject to follow protocol requirements / study procedures. In case of persistent or major protocol violations, the subject is declared non-compliant and withdrawn from the study because of non-compliance.

2.1.4. Protocol non-adherence

A protocol deviation can be defined as any non-adherence to the final protocol, including:

- wrong inclusion (inclusion criteria or non-inclusion criteria not fulfilled);
- start of a prohibited concomitant treatment;
- non-adherence of the subjects to the study schedule (missed or postponed visit);
- missing data for one or several evaluation criteria;
- low compliance of the subject to the study product(s) application;
- premature study end or untraceable subject;
- no respect of the constraints envisaged by the protocol.

Deviations to the protocol should be classified as:

- **Minor** if they don't impact the rights, safety or well-being of the subjects. They do not increase the risk or do not diminish the benefit for the subject and/or do not have a significant effect on the integrity of the data collected,
- **Major (or protocol violations**) if they affect the rights, safety or well-being of participants. They increase the risk or diminish the benefit for the subject and/or have a significant effect on the integrity of the data in the study.

- **No protocol non-adherence was observed during the study.**

2.1.5. Concomitant treatments

- **None of the subjects took new concomitant medications.**

2.1.6. Follow-up

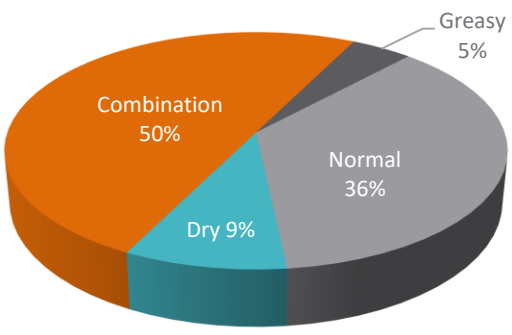
	NUMBER OF SUBJECTS				
	INCLUDED	COMPLETING THE STUDY	ANALYZED	NOT COMPLETING THE STUDY	NOT-ANALYZED
Spectrophotometer® CM700-d	22	22	22	/	/
Visia® CAS (Photographs)					
Subjective evaluation					

+ See observations detailed in **Appendix 7.1**.

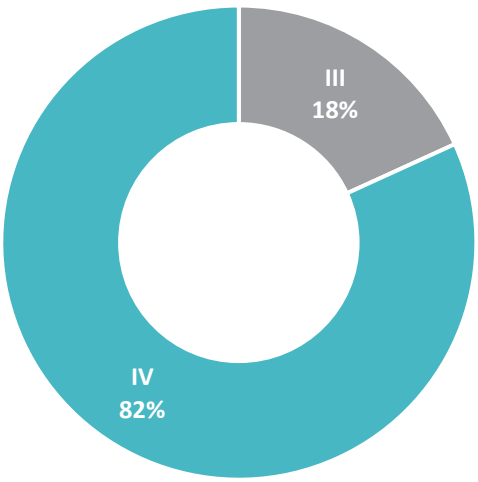
2.1.7. Demographic data

ANALYZED SUBJECTS	SEX	SKIN TYPE	PHOTO-TYPE	AGE (IN YEARS)			EVENT OR MEDICAL TREATMENTS	COMMENTS AND DETAILED DATA
				Mean ± SEM	Min.	Max.		
22	Female	Normal: 8 Dry: 2 Combination: 11 Greasy: 1	III: 4 IV: 18	43±2	24	60	/	See **Appendix 7.1**

TYPE OF SKIN



PHOTOTYPE



2.2. INVESTIGATIONAL PRODUCT

2.2.1. Description

Reference	Batch#	Form	Packaging	Confidentiality procedure	Storage temperature
Nerrish 7White Melasma cream	RD 01/270922	Opaque beige cream	60 samples of 22 grams.	Encoded	Room temperature (Thailand climate)

2.2.2. Application

Zone	Frequency	Mode
Face	At home. Twice a day in the morning and night as a facial cream.	• After facial cleansing, apply product on whole face; • Gently massage until the product absorbed into the skin; • Avoiding eye area; • In case of contact with eyes, rinse them immediately and thoroughly.

2.2.3. Labelling

Example of labelling of each product by Dermscan and translation:

หมายเลขการวิจัย #	DERMSCAN Study #
หมายเลขอาสาสมัคร.:..... เบอร์โทรติดต่อกรณีฉุกเฉิน: ..... ชื่อผลิตภัณฑ์..... วิธีใช้: ..... เก็บรักษาที่อุณหภูมิห้อง กรุณาเก็บให้พ้นมือเด็ก สำหรับใช้ในการวิจัย ภายใต้การดูแลอย่างใกล้ชิดของแพทย์ผู้เชี่ยวชาญเท่านั้น	Subject#: ..... Emergency telephone number:..... Dermscan ref.: ..... Conservation: ..... Keep out of reach and sight of children. To be used only under strict medical supervision for clinical trial.

2.2.4. Storage

Until the beginning of the study, products are kept at room temperature in a dedicated air-conditioned room, which is locked and access controlled.

2.2.5. Attribution to the subjects

➔ *Product*

All the subjects receive the same product reference.

➔ *Application zone*

All the subjects apply the product to the same zone.

2.2.6. Handing-out

The products are delivered to the subjects by the technician with an explanation of the application conditions.

2.2.7. Future

As far as possible, one sample of the study product is kept by the laboratory for a period of six months after its receipt.

- **By default, the products (used and not used) are destroyed at the end of the study according to the current internal Dermscan procedures.**

2.3. STUDY STAGES

ON D0

Subjects:
- come to the laboratory without having applied any product to the study area since the previous evening (except the morning wash);
- are informed about the trial objectives, the procedures and the risks of the study;
- sign two copies of the Consent Form.

Technician:
- verifies inclusion and non-inclusion criteria;
- realizes acquisitions of face (front/ left/ right views) using Visia® (for illustration);
- define of two zones on face: one zone with spot (size ≥ 3mm) and one zone without spots on the face;
- measures of skin color with Spectrophotometer® CM700-d on the two zones defined previously;
- explains to the subjects the products application conditions and frequency.
- gives to the subjects:
  - the **product** to be used on the whole face twice a day for 28 days, in replacement of their usual facial cream while respecting instructions in 2.1.2. and 2.2.2,
  - the **daily log** to write down their possible unpleasant sensations or medications,

  + See A**ppendix 7.2.**

ON D28 (last application being done the previous day)

Subjects:

- return to the laboratory with no product applied on the face in the morning (except the morning wash);
- bring back their daily log and study product;
- fill in the subjective evaluation questionnaire;
  + See **Appendix 7.4**.

Technician:

- realizes acquisitions of face (front/ left/ right views) using Visia® (for illustration);
- measures of skin color with Spectrophotometer® CM700-d on the two zones defined previously;

2.4. DATA ANALYSIS

The following data are analyzed:

	Parameters	Units	Variations DX/D0 Kinetics	Statistical analysis	Expected results
Spectrophotometer® CM700-d	L*	A.U.	D28-D0	≤0.05	↗
	b*	A.U.			↘
	ITA°	°			↗
Visia® (Photographs)	/	/	D0/D28	illustration	
Subjective evaluation	Questionnaire	%	D28	Majority of positive answers	

Individual data are presented in raw value tables. These tables also show the descriptive statistics: means, medians, minima, maxima, standard errors of the means (SEM) and confidence intervals of 95% (95% CI).

Variation tables present raw variations, percentage variations, descriptive statistics and the results of the statistical analysis (p).

2.4.1. Calculation formulas

Data obtained for each parameter, at each measurement time and on each zone are presented in raw value tables. These tables also show the descriptive statistics: means, medians, minima, maxima, standard errors of the means (SEM), confidence intervals of 95% (CI 95%) of these values as well as the variations (Δ) and percentage variations (Δ%).

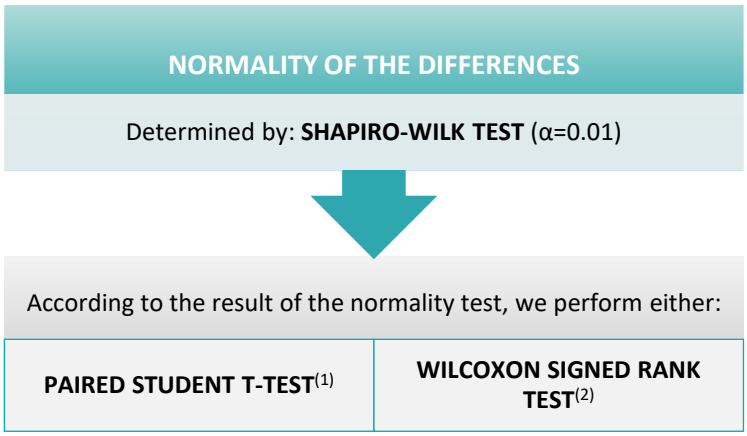
The variations (Δ) and in percentage on the mean (Δ%) are calculated according to the following formulas:

$$\Delta = (TZ_{ti} - TZ_{t0})$$

$$\Delta\% = \frac{(TZti - TZt0)}{TZ_{t0}} \times 100$$

with: TZ: value obtained on the zone treated by the tested product
t0: before product application
ti: at each measurement time after product application

2.4.2. Statistical method



Analysis conditions	p-value	H0	Conclusion
Type I error (α) = 5% in bilateral mod	**p ≤ 0.05**	Rejected	Statistically significant difference
Null hypothesis (H0) = no difference between means(1) or medians(2)	**p > 0.05**	Not rejected	No statistically significant difference

2.4.3. Statistical software

The software used are EXCEL.

2.5. AUDIT AND TRIAL MONITORING VISIT

An audit and/or trial monitoring visit may be carried out at the Sponsor's request or by the appropriate regulatory authority. The aim of the monitoring visit is to verify that the study is conducted according to the determined protocol and current regulations.

- **No monitoring visit occurred for this study.**

3. PRINCIPLES AND RESULTS

3.1. UNDESIRABLE EFFECTS / ADVERSE EVENTS

No Serious Adverse Event was reported during the study.

No Undesirable Effect was observed during the study.

3.2. SPECTROPHOTOMETER® CM700D

3.2.1. Principle

Skin colorimetric measurement is done with a MINOLTA CM700-d Spectrophotometer®, equipped with a 3 mm diameter head.

The Spectrophotometer®® converts colors perceived by man to a digital code composed of three parameters:

L*: for clarity (from dark to light),
a*: for the green-to-red spectrum,
b*: for the blue-to-yellow spectrum.

a* and b* are chrominance parameters and L* is a luminance parameter.

It is therefore possible to express in the slightest details the differences between two cutaneous zones that appear to be the same color. After a calibration phase, measurements are done directly on the skin using a pulsed Xenon light source and a dual beam system designed to measure the light transmitted and to correct any slight deviation.

This instrument is commonly used in cosmetics and medicine to measure skin color.

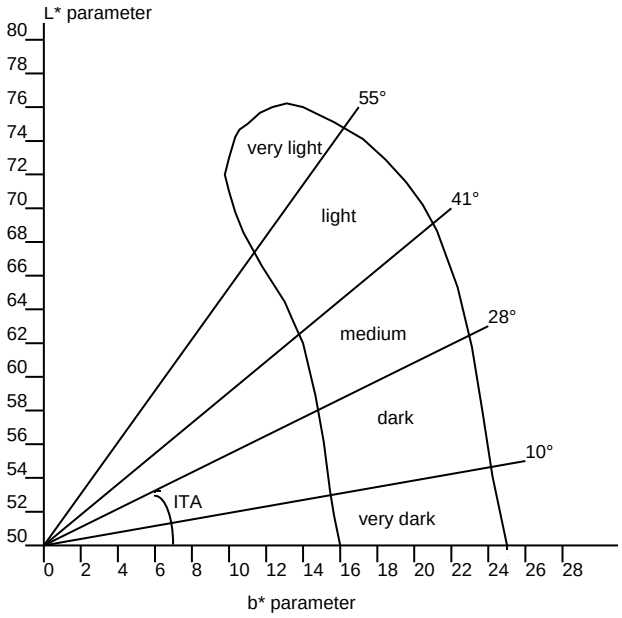
The parameters L* (luminance) and b* (cutaneous melanin yellow color) are studied during a whitening product study.

Both parameters are exploited through the calculation of the Individual Typological Angle, which defines the skin pigmentation degree of a subject according to the following formula:

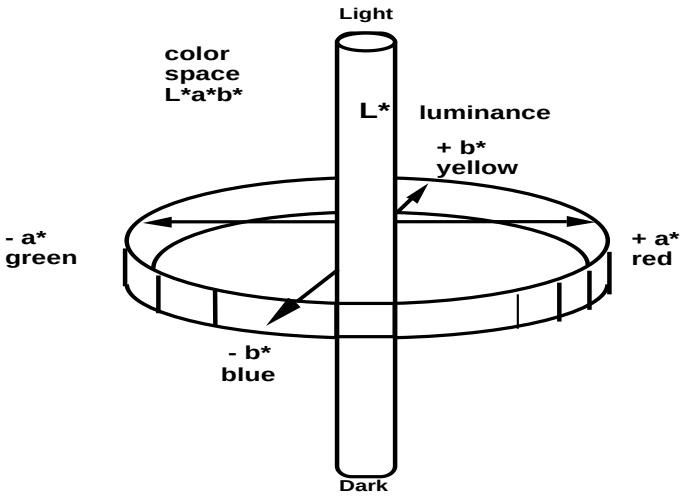
$$ITA° = [\text{Arc tan}((L^*-50)/b^*)] \times 180 / \pi$$

The higher the ITA° is, the lighter the skin is.

Representation of Individual Typological Angles
Different categories of skin pigmentation are defined by dividing the projection of the L* and b* parameters in areas limited by the categories of the angles

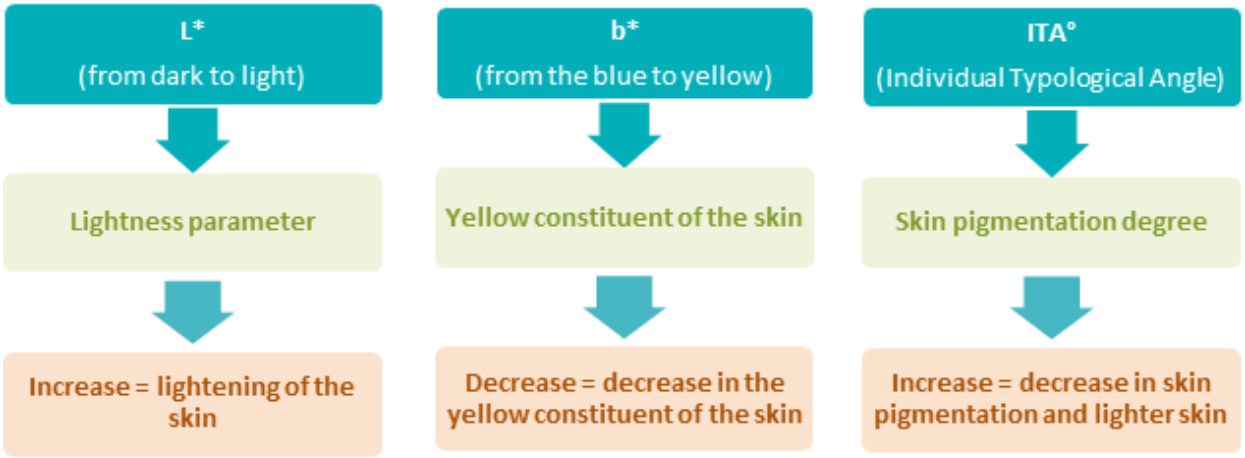


Representation of Minolta® measurement principle



Color is a sensation, a sensory impression transmitted by the eye. In order to perceive color, one needs light, an object and eyes. The combination of these three elements produces a stimulus that the brain transforms into a color sensation. This is what can pose problems when visually evaluating colors.

The studied parameters are:



3.2.2. Summary of the results

A synthesis of the results obtained is presented below

Variation of the colorimetric parameters on the pigmentation skin in comparison with the initial state

				Statistical analysis		
Parameters	Kinetic	Δ (mean ± SEM)	Δ% on the average	p	Significance	% of subjects with the expected effect
L* parameter	Δ D28	+0.87 ± 0.09	+2%	**<0.001**	**Yes**	95%
b* parameter	Δ D28	-0.50 ± 0.11	-3%	**<0.001**	**Yes**	91%
ITA° parameter	Δ D28	+2.84 ± 0.34	+15%	**<0.001**	**Yes**	86%

+ See details in **Appendix 7.3.**

Under study condition after 28 days of use the product " Nerrish 7White Melasma cream " induce a depigmentation effect characterized by:

Depigmentation effect:

- a significant increase in L* parameter of +2% on average on D28, this effect was observed on 95% of the subjects (p<0.001);
- a significant decrease in b* parameter of -3% on average on D28, this effect was observed on 91% of the subjects (p<0.001);
- a significant increase in ITA° parameter of +15% on average on D28, this effect was observed on 86% of the subjects (p<0.001);

So, the product " Nerrish 7White Melasma cream " presents a depigmentation effect.

Variation of the colorimetric parameters on the normal skin in comparison with the initial state

				Statistical analysis		
Parameters	Kinetic	Δ (mean ± SEM)	Δ% on the average	p	Significance	% of subjects with the expected effect
L* parameter	Δ D28	+0.50 ± 0.07	+1%	**<0.001**	**Yes**	95%
b* parameter	Δ D28	-0.32 ± 0.07	-2%	**<0.001**	**Yes**	64%
ITA° parameter	Δ D28	+1.67 ± 0.16	+5%	**<0.001**	**Yes**	82%

+ See details in **Appendix 7.3.**

Under study condition after 28 days of use the product " Nerrish 7White Melasma cream " induce a whitening effect characterized by:

Whitening effect:

- a significant increase in L* parameter of +1% on average on D28, this effect was observed on 95% of the subjects (p<0.001);
- a significant decrease in b* parameter of -2% on average on D28, this effect was observed on 64% of the subjects (p<0.001);
- a significant increase in ITA° parameter of +5% on average on D28, this effect was observed on 82% of the subjects (p<0.001);

So, the product " Nerrish 7White Melasma cream " presents a whitening effect.

3.3. ILLUSTRATION VISIA® SYSTEM

The device used is the VISIA® from CANFIELD® imaging systems.

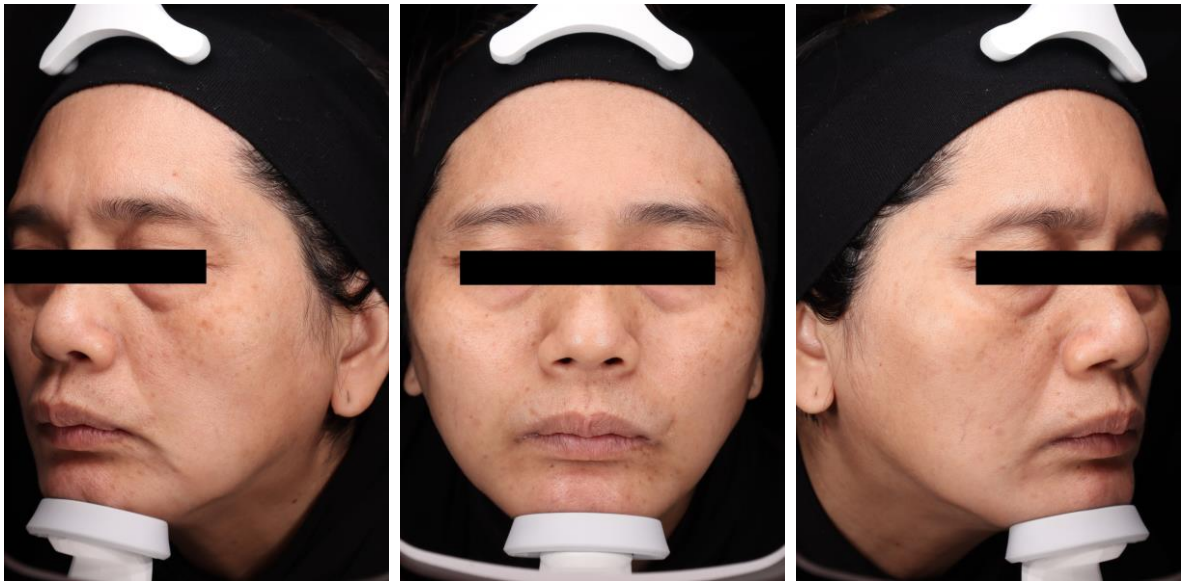
The VISIA allows to take pictures with different types of illuminations and a very rapid capture of images.
The control of the repositioning takes place directly on data-processing screen using an overlay visualization of the images at each time of acquisition.

A series of photos taken under multi-spectral imaging (white light or polarized light - parallel or crossed) allow to capture visual information affecting complexion health and appearance:

3.3.1. Illustration

An example of results obtained with product " **Nerrish 7White Melasma cream** " is presented below, for Subject #09, who the one presents the best visual observed on D0 and D28 (After 28 days of use product).

D0



D28

3.4. SUBJECTIVE EVALUATION QUESTIONNAIRE

3.4.1. Principle

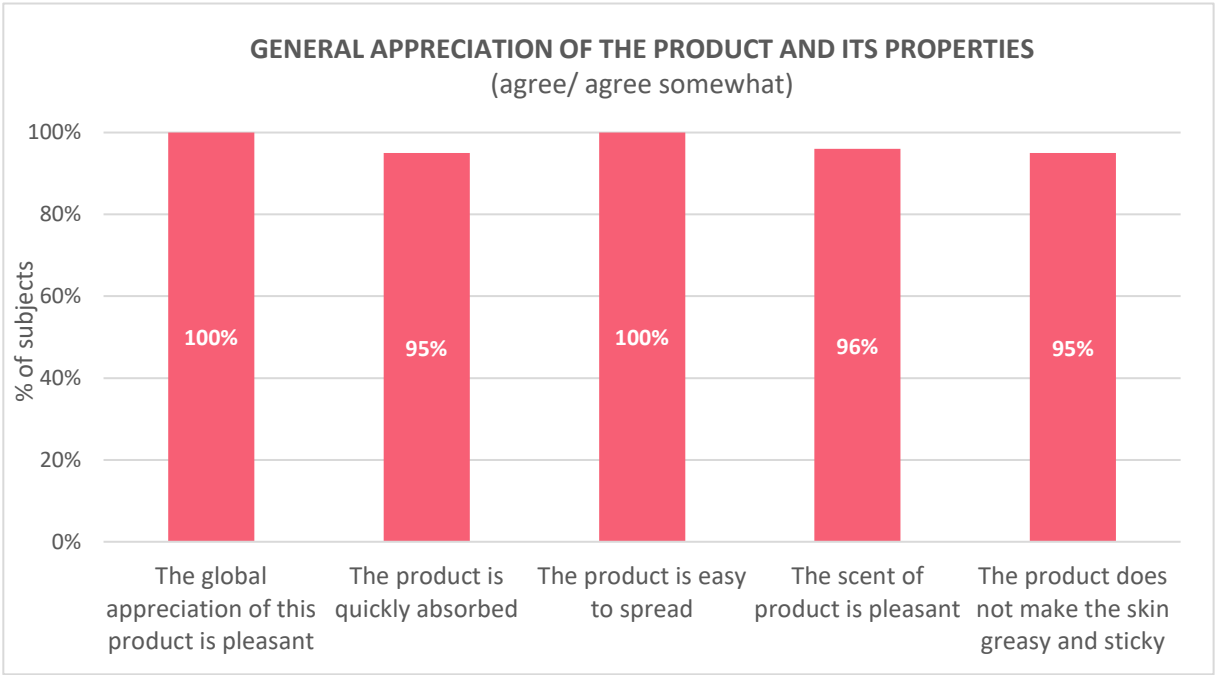
A subjective evaluation questionnaire, prepared by the clinical trial center and submitted to the sponsor is filled in by the subjects on D28 at the end of the study to subjectively evaluate the properties of the studied product, its global efficacy and its future use.

3.4.2. Summary of the results / statistical analysis

To be easier to read, the percentages are rounded off. The sum of these percentages may be different from 100%.

- **In this study (n=22), one subject represents 4.54%.**

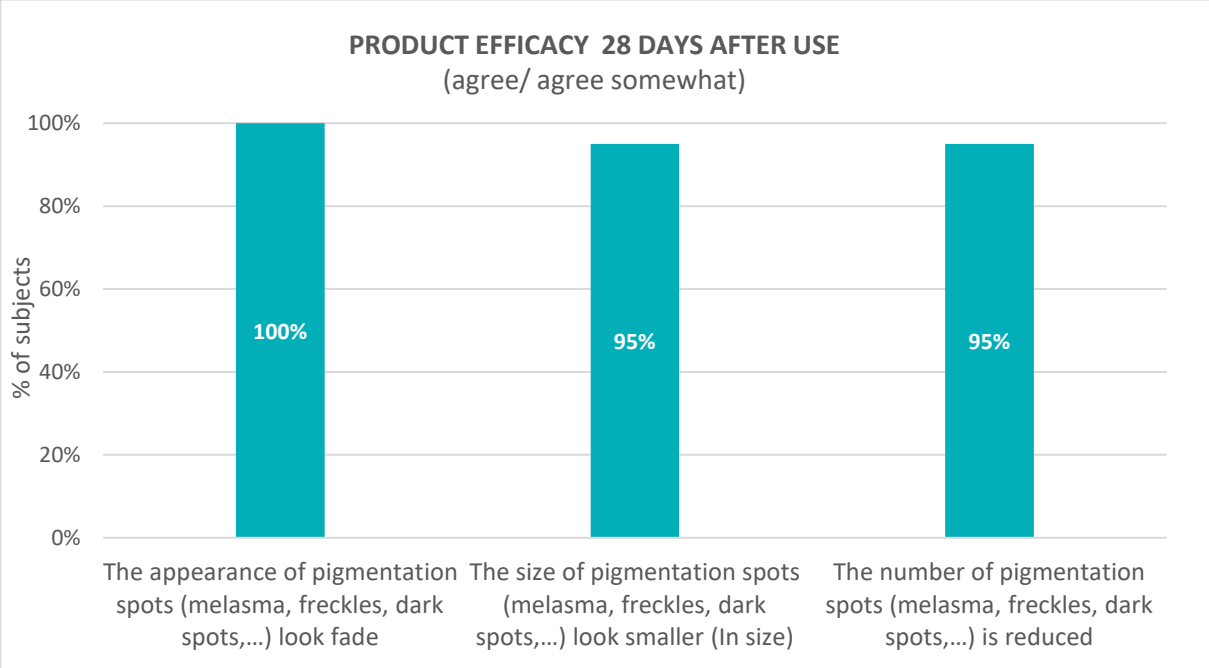
GENERAL APPRECIATION OF THE PRODUCT AND ITS PROPERTIES			
	% of subjects (agree / agree somewhat)	agree	agree somewhat
The global appreciation of this product is pleasant	**100%**	64%	36%
The product is quickly absorbed	**95%**	68%	27%
The product is easy to spread	**100%**	73%	27%
The scent of product is pleasant	**96%**	64%	32%
The product does not make the skin greasy and sticky	**95%**	68%	27%



PRODUCTS EFFICACY

AFTER 28 DAYS OF USE

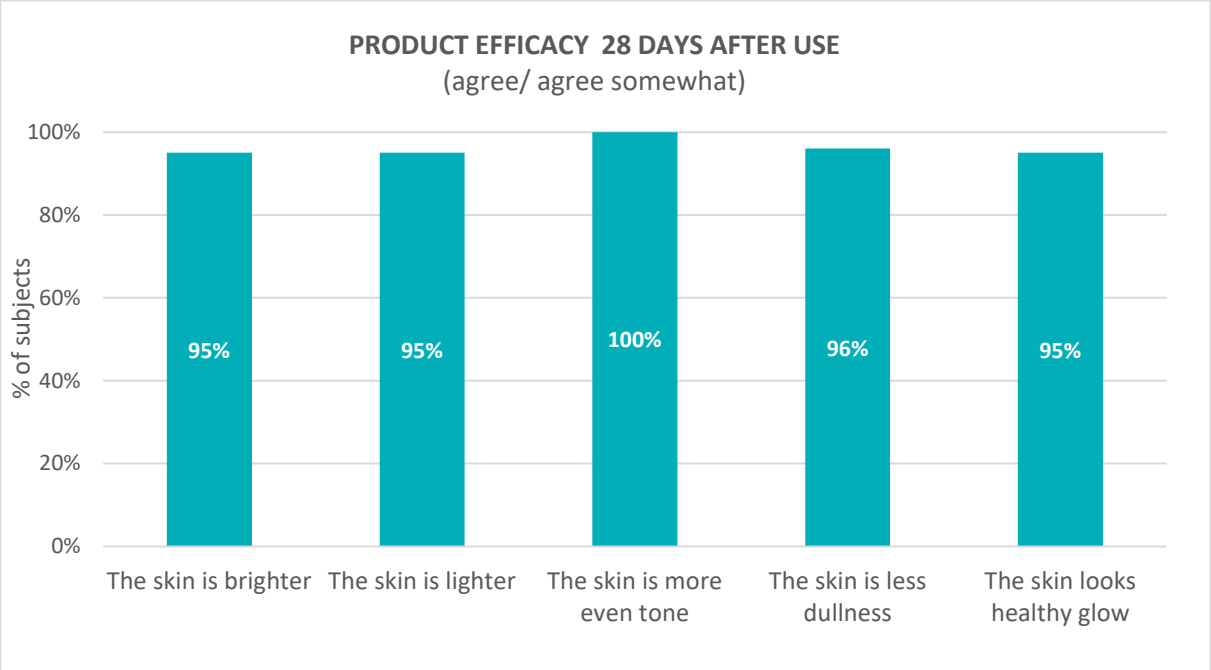
	% of subjects (agree / agree somewhat)	agree	agree somewhat
The appearance of pigmentation spots (melasma, freckles, dark spots,…) look fade	**100%**	59%	41%
The size of pigmentation spots (melasma, freckles, dark spots,…) look smaller (In size)	**95%**	59%	36%
The number of pigmentation spots (melasma, freckles, dark spots,…) is reduced	**95%**	59%	36%



PRODUCTS EFFICACY

AFTER 28 DAYS OF USE

	% of subjects (agree / agree somewhat)	agree	agree somewhat
The skin is brighter	**95%**	68%	27%
The skin is lighter	**95%**	68%	27%
The skin is more even tone	**100%**	68%	32%
The skin is less dullness	**96%**	64%	32%
The skin looks healthy glow	**95%**	68%	27%



PRODUCTS EFFICACY
AFTER 28 DAYS OF USE

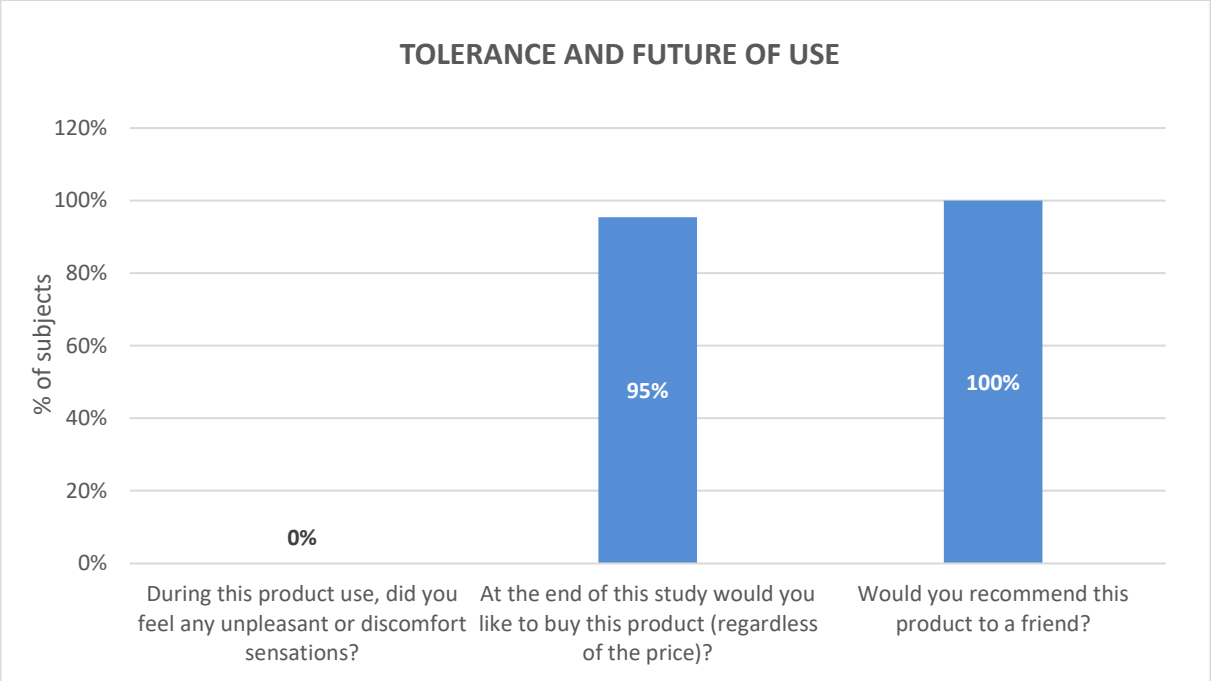
	% of subjects (agree / agree somewhat)	agree	agree somewhat
The skin is more moisturized	**95%**	68%	27%
The skin feels restored	**100%**	68%	32%
The product is suitable for your skin type	**100%**	68%	32%
The product does not cause skin irritation	**100%**	77%	23%

TOLERANCE

	% of subjects (yes)
During this product use, did you feel any unpleasant or discomfort sensations?	0%

FUTURE USE OF PRODUCT

	% of subjects (yes)
At the end of this study would you like to buy this product (regardless of the price)?	95%
Would you recommend this product to a friend?	100%



Subject	Comments
4	The texture of product is too fluid.
9	The texture of product is too fluid.

+ See details in **Appendix 7.4.**

4. CONCLUSION

Under the conditions of this study conducted under dermatological control, we observed that:

Product "Nerrish 7White Melasma cream"

DEPIGMENTATION EFFECT

Under study condition after 28 days of use the product induce a depigmentation effect characterized by:

- a significant increase in L* parameter of +2% on average on D28, this effect was observed on 95% of the subjects ($p<0.001$).
- a significant decrease in b* parameter of -3% on average on D28, this effect was observed on 91% of the subjects ($p<0.001$).
- a significant increase in ITA° parameter of +15% on average on D28, this effect was observed on 86% of the subjects ($p<0.001$).

WHITENING EFFECT

Under study condition after 28 days of use the product induce a whitening effect characterized by:

- a significant increase in L* parameter of +1% on average on D28, this effect was observed on 95% of the subjects ($p<0.001$).
- a significant decrease in b* parameter of -2% on average on D28, this effect was observed on 64% of the subjects ($p<0.001$).
- a significant increase in ITA° parameter of +5% on average on D28, this effect was observed on 82% of the subjects ($p<0.001$).

SUBJECTIVE QUESTIONNAIRES

Subjects appreciated for its properties of the product after 28 days of use:

- 100% appreciated for the global appreciation of this product is pleasant and the product is easy to spread.
- 96% appreciated for the scent of product is pleasant.
- 95% appreciated for the product is quickly absorbed and the product does not make the skin greasy and sticky.

Subjects appreciated for its efficacy of the product after 28 days of use:

- 100% appreciated for the appearance of pigmentation spots look fade, the skin is more even tone, the skin feels restored, the product is suitable for your skin type, and the product does not cause skin irritation.
- 96% appreciated for the skin is less dullness.
- 95% appreciated for the size of pigmentation spots look smaller (In size), the number of pigmentation spots is reduced, the skin is brighter, lighter and looks healthy glow, and the skin is more moisturized.

95% of the subjects at the end of this study the subject would like to buy this product (regardless of the price) and 100% of subjects recommend this product to a friend.

5. CERTIFICATION

The study is conducted according to Helsinki Declaration (1964) and its successive updates. Data are obtained using the study protocol, current internal procedures and as closely as possible to the guidance on Good Clinical Practice CPMP / ICH / 135 / 95 (R2).

This study is totally performed under the responsibility of DERMSCAN.

All the observations and numerical data collected throughout the study are reported in this document and are in accordance with the obtained results.

	PROJECT MANAGER
Name	**Pimrumpa VICHITNARK**
Date	**November 24, 2022**
Signature	

Any modifications are the sole responsibility of the author of the modification, whether he/she is acting for the Sponsor or independently.

The on-line publishing, on the Internet, of this study report with the names and signatures is strictly prohibited.

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APPENDICES:

STUDY DOCUMENTS, DETAILED RESULTS & ETHICAL REQUIREMENTS AND REGULATORY STANDARDS

7. APPENDICES – STUDY DOCUMENTS / DETAILED RESULTS

7.1. SUBJECTS' CHARACTERISTICS

Subject#	Last name	First name	Age	Sex	Phototype	Skin type	Comments	Inclusion date	End date
1	KH	O	58	F	IV	D	None	October 20, 2022	November 17, 2022
2	JU	P	49	F	III	C	None	October 20, 2022	November 17, 2022
3	SA	V	59	F	IV	N	None	October 20, 2022	November 17, 2022
4	KI	N	44	F	IV	C	None	October 20, 2022	November 17, 2022
5	SU	M	48	F	IV	C	None	October 20, 2022	November 17, 2022
6	JA	S	41	F	IV	N	None	October 20, 2022	November 17, 2022
7	SE	K	47	F	IV	D	None	October 20, 2022	November 17, 2022
8	AV	S	60	F	III	N	None	October 20, 2022	November 17, 2022
9	SA	P	53	F	IV	N	None	October 20, 2022	November 17, 2022
10	JI	S	54	F	III	C	None	October 20, 2022	November 17, 2022
11	SA	N	48	F	IV	C	None	October 20, 2022	November 17, 2022
12	AU	N	40	F	IV	C	None	October 20, 2022	November 17, 2022
13	KE	S	40	F	IV	N	None	October 20, 2022	November 17, 2022
14	PA	B	28	F	IV	N	None	October 20, 2022	November 17, 2022
15	PR	W	24	F	IV	C	None	October 20, 2022	November 17, 2022
16	MA	P	38	F	IV	C	None	October 20, 2022	November 17, 2022
17	RA	W	36	F	IV	N	None	October 20, 2022	November 17, 2022
18	PI	K	35	F	IV	G	None	October 20, 2022	November 17, 2022
19	KU	P	40	F	IV	C	None	October 20, 2022	November 17, 2022
20	PA	K	27	F	IV	N	None	October 20, 2022	November 17, 2022
21	YO	J	37	F	IV	C	None	October 20, 2022	November 17, 2022
22	IS	P	33	F	III	C	None	October 20, 2022	November 17, 2022

Mean	**43**	**F**	22	**I**	0	**N**	8
Median	41			**II**	0	**D**	2
Minimum	24			**III**	4	**C**	11
Maximum	60			**IV**	18	**G**	1
SEM	**2**						
95% CI	5						

Legend: F: female

N: normal skin
D: dry skin
C: combination skin
G: greasy skin

7.2. DAILY LOG

DAILY LOG (topical product)

THIS TABLE MUST BE COMPLETED EVERY DAY. When there is no product application, please write"0" in the column "Number"

In case of discomfort and/or intolerance, please note the **nature** (skin tension, stinging, itching, burning sensations,…), the **zone,** the **intensity** (very mild, mild, moderate, severe) and **duration** of these sensations as well as the **time of appearance** regarding product application (immediately after application, 5 minutes after…)

DAY	DATE	NUMBER OF DAILY APPLICATION(S)		DISCOMFORT AND/OR INTOLERANCE SENSATIONS FELT	MEDICATION (why?, which one? which dosage? how long?)
		Number	Comment Define if omission or other		
Ex:	05/04/2016	0	Not applicable	☐ NO ☒ YES if yes, define: ..... Light tingling / eyes / for 5 minutes at the application	☐ NO ☒ YES if yes, define:..... Headache / Paracetamol 500mg / 1 tablet
D0				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....
D1				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....
D2				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....
D3				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....
D4				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....
D5				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....
D6				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....
D7				☐ NO ☐ YES if yes, define:.....	☐ NO ☐ YES if yes, define:.....

…/ D28

7.3. SPECTROPHOTOMETER® CM700-D – INDIVIDUAL RESULTS

- L* parameter

Spot			
Subject	L* parameter		Δ (D28-D0)
	D0	D28	
1	49.54	49.73	0.19
2	61.89	63.15	1.26
3	56.94	57.57	0.63
4	56.14	56.60	0.46
5	50.94	52.41	1.47
6	54.76	55.72	0.96
7	53.67	54.60	0.93
8	62.62	63.45	0.83
9	58.69	58.66	-0.03
10	57.07	58.29	1.22
11	55.27	56.13	0.86
12	54.34	54.76	0.42
13	57.70	58.67	0.97
14	57.07	58.53	1.46
15	52.95	53.95	1.00
16	56.58	58.05	1.47
17	52.75	53.67	0.92
18	56.05	57.25	1.20
19	54.84	55.00	0.16
20	55.52	56.02	0.50
21	59.06	60.02	0.96
22	61.45	62.69	1.24
Mean	**56.17**	**57.04**	**0.87**
Median	56.10	56.93	0.95
Minimum	*49.54*	*49.73*	*-0.03*
Maximum	*62.62*	*63.45*	*1.47*
SEM	**0.70**	**0.73**	**0.09**
IC 95%	1.47	1.51	0.19
	p		**<0.001**
	Δ%		**2%**

% of subjects with the expected effect (NB : if variations ≥ 0.1)	95%

Normal			
Subject	L* parameter		Δ (D28-D0)
	D0	D28	
1	55.13	55.45	0.32
2	65.32	65.43	0.11
3	59.37	60.33	0.96
4	58.19	58.39	0.20
5	57.20	57.64	0.44
6	58.65	58.86	0.21
7	62.83	63.22	0.39
8	64.12	64.62	0.50
9	62.18	63.36	1.18
10	62.79	63.05	0.26
11	59.65	60.13	0.48
12	57.28	58.10	0.82
13	63.46	63.80	0.34
14	62.11	62.33	0.22
15	56.59	57.17	0.58
16	61.82	62.32	0.50
17	58.64	59.74	1.10
18	60.10	61.23	1.13
19	59.76	60.22	0.46
20	62.66	63.03	0.37
21	60.52	60.62	0.10
22	65.05	65.47	0.42
Mean	**60.61**	**61.11**	**0.50**
Median	60.31	60.93	0.43
Minimum	*55.13*	*55.45*	*0.10*
Maximum	*65.32*	*65.47*	*1.18*
SEM	**0.60**	**0.59**	**0.07**
IC 95%	1.26	1.23	0.15
	p		**<0.001**
	Δ%		**1%**

% of subjects with the expected effect (NB : if variations ≥ 0.1)	95%

Legend:
( )*: value not taken in the data analysis
AV: aberrant value
MV: miss value
DO: dropped out
Un: Untraceable

- b* parameter

Spot			
Subject	b* parameter		Δ (D28-D0)
	D0	D28	
1	18.98	18.42	-0.56
2	16.81	16.28	-0.53
3	18.78	17.72	-1.06
4	19.30	19.00	-0.30
5	19.00	18.01	-0.99
6	17.17	16.96	-0.21
7	18.71	18.68	-0.03
8	19.68	18.95	-0.73
9	16.27	16.87	0.60
10	17.73	16.76	-0.97
11	19.21	19.08	-0.13
12	21.04	20.38	-0.66
13	19.16	18.98	-0.18
14	18.26	17.00	-1.26
15	18.95	18.32	-0.63
16	18.02	17.42	-0.60
17	18.94	18.80	-0.14
18	18.14	17.87	-0.27
19	18.11	17.93	-0.18
20	17.46	17.23	-0.23
21	18.44	16.60	-1.84
22	15.36	15.24	-0.12
Mean	**18.34**	**17.84**	**-0.50**
Median	18.58	17.90	-0.41
Minimum	*15.36*	*15.24*	*-1.84*
Maximum	*21.04*	*20.38*	*0.60*
SEM	**0.26**	**0.25**	**0.11**
IC 95%	0.54	0.52	0.23
	p		**<0.001**
	Δ%		**-3%**

% of subjects with the expected effect (NB : if variations ≤ -0.1)	91%

Normal			
Subject	b* parameter		Δ (D28-D0)
	D0	D28	
1	19.67	19.22	-0.45
2	15.23	15.00	-0.23
3	17.26	17.20	-0.06
4	19.94	19.29	-0.65
5	17.77	17.67	-0.10
6	17.98	17.59	-0.39
7	18.02	17.27	-0.75
8	15.56	15.58	0.02
9	16.49	16.20	-0.29
10	16.03	15.95	-0.08
11	18.42	18.51	0.09
12	19.21	19.24	0.03
13	18.24	17.50	-0.74
14	17.32	16.40	-0.92
15	17.26	17.05	-0.21
16	16.84	16.50	-0.34
17	18.31	18.19	-0.12
18	17.67	17.26	-0.41
19	17.75	17.66	-0.09
20	15.66	15.32	-0.34
21	17.61	16.57	-1.04
22	15.03	14.99	-0.04
Mean	**17.42**	**17.10**	**-0.32**
Median	17.64	17.23	-0.26
Minimum	*15.03*	*14.99*	*-1.04*
Maximum	*19.94*	*19.29*	*0.09*
SEM	**0.29**	**0.28**	**0.07**
IC 95%	0.60	0.58	0.14
		p	**<0.001**
		Δ%	**-2%**

% of subjects with the expected effect (NB : if variations ≤ -0.1)	64%

Legend:
( )*: value not taken in the data analysis
AV: aberrant value
MV: miss value
DO: dropped out
Un: Untraceable

- ITA° parameter

Spot			
Subject	ITA° parameter		Δ (D28-D0)
	D0	D28	
1	-1.39	-0.83	0.56
2	35.27	38.94	3.67
3	20.28	23.14	2.86
4	17.66	19.16	1.50
5	2.83	7.63	4.80
6	15.49	18.63	3.14
7	11.09	13.83	2.74
8	32.66	35.37	2.71
9	28.09	27.17	-0.92
10	21.73	26.31	4.58
11	15.33	17.81	2.48
12	11.65	13.16	1.51
13	21.89	24.56	2.67
14	21.16	26.65	5.49
15	8.85	12.18	3.33
16	20.07	24.80	4.73
17	8.25	11.04	2.79
18	18.45	22.07	3.62
19	14.97	15.58	0.61
20	17.55	19.25	1.70
21	26.18	31.10	4.92
22	36.70	39.79	3.09
Mean	**18.40**	**21.24**	**2.84**
Median	18.06	20.66	2.83
Minimum	*-1.39*	*-0.83*	*-0.92*
Maximum	*36.70*	*39.79*	*5.49*
SEM	**2.07**	**2.14**	**0.34**
IC 95%	4.30	4.44	0.70
	p		**<0.001**
	Δ%		**15%**

Normal			
Subject	ITA° parameter		Δ (D28-D0)
	D0	D28	
1	14.61	15.83	1.22
2	45.17	45.82	0.65
3	28.49	30.99	2.50
4	22.32	23.51	1.19
5	22.04	23.39	1.35
6	25.69	26.73	1.04
7	35.46	37.43	1.97
8	42.22	43.18	0.96
9	36.44	39.51	3.07
10	38.59	39.29	0.70
11	27.65	28.69	1.04
12	20.77	22.84	2.07
13	36.43	38.26	1.83
14	34.96	36.93	1.97
15	20.91	22.80	1.89
16	35.07	36.75	1.68
17	25.27	28.17	2.90
18	29.76	33.04	3.28
19	28.81	30.06	1.25
20	38.95	40.39	1.44
21	30.85	32.65	1.80
22	45.03	45.90	0.87
Mean	**31.16**	**32.83**	**1.67**
Median	30.31	32.85	1.56
Minimum	*14.61*	*15.83*	*0.65*
Maximum	*45.17*	*45.90*	*3.28*
SEM	**1.78**	**1.76**	**0.16**
IC 95%	3.71	3.65	0.33
		p	**<0.001**
		Δ%	**5%**

% of subjects with the expected effect (NB : if variations ≥ 1)	86%

% of subjects with the expected effect (NB : if variations ≥ 1)	82%

Legend:
( )*: value not taken in the data analysis
AV: aberrant value
MV: miss value
DO: dropped out
Un: Untraceable

7.4. SUBJECTIVE EVALUATION QUESTIONNAIRE

To be easier to read, the percentages are rounded off. The sum of these percentages may be different from 100%.

- **In this study (n=22), one subject represents 4.54%.**

GENERAL APPRECIATION OF THE PRODUCT AND ITS PROPERTIES

		agree	*agree somewhat*	*disagree*	*disagree*
1	**The global appreciation of this product is pleasant**	63.6%	36.4%	0.0%	0.0%
2	**The product is quickly absorbed**	68.2%	27.3%	4.5%	0.0%
3	**The product is easy to spread**	72.7%	27.3%	0.0%	0.0%
4	**The scent of product is pleasant**	63.6%	31.8%	4.5%	0.0%
5	**The product does not make the skin greasy and sticky**	68.2%	27.3%	4.5%	0.0%

PRODUCT EFFICACY
AFTER 28 DAYS OF USE

		agree	*agree somewhat*	*disagree*	*disagree*
6	**The appearance of pigmentation spots (melasma, freckles, dark spots,…) look fade**	59.1%	40.9%	0.0%	0.0%
7	**The size of pigmentation spots (melasma, freckles, dark spots,…) look smaller (In size)**	59.1%	36.4%	4.5%	0.0%
8	**The number of pigmentation spots (melasma, freckles, dark spots,…) is reduced**	59.1%	36.4%	4.5%	0.0%
9	**The skin is brighter**	68.2%	27.3%	4.5%	0.0%
10	**The skin is lighter**	68.2%	27.3%	4.5%	0.0%
11	**The skin is more even tone**	68.2%	31.8%	0.0%	0.0%
12	**The skin is less dullness**	63.6%	31.8%	4.5%	0.0%
13	**The skin looks healthy glow**	68.2%	27.3%	4.5%	0.0%
14	**The skin is more moisturized**	68.2%	27.3%	4.5%	0.0%
15	**The skin feels restored**	68.2%	31.8%	0.0%	0.0%
16	**The product is suitable for your skin type**	68.2%	31.8%	0.0%	0.0%
17	**The product does not cause skin irritation**	77.3%	22.7%	0.0%	0.0%

TOLERANCE

18 During this product use, did you feel any unpleasant or discomfort sensations?

yes	*no*
0.0%	100.0%

FUTURE USE OF PRODUCT

19 At the end of this study would you like to buy this product (regardless of the price)?

yes	*no*
95.5%	4.5%

20 Would you recommend this product to a friend?

yes	*no*
100.0%	0.0%

Comment of the product:

Subject	Comments
4	The texture of product is too fluid.
9	The texture of product is too fluid.

8. APPENDICES - ETHICAL REQUIREMENTS AND REGULATORY STANDARDS

8.1. ADVERSE EVENT

8.1.1. Adverse Event (AE)

Any noxious symptom, occurring in a subject taking part in a clinical trial, whether or not this symptom is related to the study or the study product(s) (e.g. flu, headache, abnormal biological analysis…).

8.1.2. Undesirable Effect (UE) / Adverse Reaction (AR)

An **undesirable effect** is defined as an adverse reaction for human health attributable to the normal or reasonably foreseeable use of the cosmetic product(s).
There are 5 levels of imputability: very likely, likely, not clearly attributable, unlikely and excluded (ANSM methodology).

The severity/intensity of undesirable effects/adverse events can be graded on a three-point scale:
- **mild**: discomfort noted, that does not disturb normal daily activities;
- **moderate**: discomfort sufficient to reduce or affect normal daily activities;
- **severe**: inability to work or have normal daily activities.

8.1.3. Serious Adverse Event (SAE) / Serious Undesirable Effect (SUE)

Any event that:
- results in death (note: death is the outcome, not the event);
- is life threatening;
- requires in-patient hospitalization (at least one night) or prolongation of existing hospitalization (does not include hospitalization scheduled before the inclusion);
- results in temporary or permanent functional incapacity or disability;
- is a congenital anomaly;
- is considered like by the investigator.

8.1.4. Documentation

All concomitant treatments are reported in the CRF and the study report.

All UE are reported in the CRF and the study report.
If it requires the temporary or definitive termination of the study product, the need for a corrective treatment or the withdrawal of the subject, an Adverse Event form is completed.

All SAE are reported in the CRF and the study report.

8.1.5. Notification

The investigator declares to the Sponsor, by e-mail, the occurrence of adverse reactions according to their severity and their unexpectedness (according to the investigator's advice).

All SAE are transmitted by e-mail to the Sponsor without delay, at the latest 24 hours after knowledge of their occurrence.
A SAE declaration form signed by a physician is sent, within 48 hours, by e-mail with acknowledgement of receipt.

8.1.6. Follow-up

When an adverse event linked to the study product or the protocol persists at the end of the study, the Investigator ensures that the subject is followed up until total resolution of the event or stabilization of the symptoms without releasing the Sponsor of any obligation or responsibility.

8.1.7. Occurrence of pregnancy

The occurrence of a pregnancy (reported or diagnosed) after inclusion in the study is considered as an intercurrent event not related to the study product(s) nor the protocol and induces the immediate dropping out of the subject.
Any pregnancy that occurs during the study period is reported by e-mail to the Sponsor within 24 hours following its discovering.
A follow-up is done according to the current internal procedures until the completion/termination of the pregnancy or its interruption.

8.2. PREMATURE TERMINATION OF SUBJECT PARTICIPATION

In compliance with the Helsinki Declaration (1964) and its successive updates, subjects have the right to exit from the study at any time and for any motive.

The investigator can also interrupt the subject participation in the study prematurely in the case of a disease occurrence, a pregnancy or the occurrence of an adverse reaction.

The Sponsor can demand that any subject be excluded from the study for major infringements to the protocol, for administrative reasons or any other motive however this would need to be clearly documented with a rationale as to why.

Nevertheless, premature removal of a high percentage of subjects from the study can make it difficult or impossible to interpret. Consequently, any premature exit without valid motives should be avoided as much as possible and is carefully documented in the case report form, the final report and, if necessary, in the Adverse Event form.

Every premature exit must be classified under one of the following headings:

- presence of a non-inclusion criteria;
- Undesirable Effect / Adverse Event occurrence;
- Serious Adverse Event occurrence;
- withdrawal of consent;
- lost to follow-up;
- appearance of non-inclusion criteria;
- non-adherence to the protocol;
- other reason.

No replacement is foreseen as 10% additional subjects are planned to be included in the study.

8.3. DATA COLLECTION AND VALIDATION

An identification code is attributed to each subject for the purpose to keep his/her identity confidential. This code consists of: the first two letters of the subject's name and the first letter of his/her first name.

The personnel in charge of the study (technician, physician …) adds data to subject case report form and to a computerized data base.
The simple data entry is done from the case report forms by the designed technician(s) or operator(s), without any interpretation, in specific MS EXCEL databases.
Then the Project Manager or assistant checks the coherence between computed data and information in the study documents. He/She also checks formulas used in the EXCEL tables (calculation formulas, selected data…).
The coherence of data coming directly from measurement software(s) is also checked and validated by the Project Manager or assistant.
When all CRF are computed and all controls done, the database is locked.

8.4. QUALITY MANAGEMENT

In order to ensure that the clinical trials are in compliance with the Sponsor's requirement, Dermscan Asia has implemented a quality management system which has been certified ISO 9001: 2015.
This quality assurance system includes Good Clinical Practices (GCP) and regulation requirements.

Each study report is subjected to a quality inspection by a member of the DERMSCAN Proofreading Committee. The proofreader is chosen because he(she) is not involved in the audited study. The inspection of the study report allows to confirm that the results reflect exactly the study raw data and that the study fulfils any standard and regulatory requirements.
A certificate of quality inspection, signed by the person who checked the report is enclosed in each study.

8.5. ARCHIVES OF STUDY DOCUMENTS

<table>
<tr><th rowspan="2">STUDY DOCUMENTS AND DATA</th><th colspan="3">TIME AFTER DISPATCH OF THE FINAL REPORT:
laboratory → service provider → destruction
0 1 (maximum) 10 YEARS</th></tr>
<tr><td>Stored at the laboratory</td><td>Securely archived at an approved service provider</td><td rowspan="2">Destruction of the archives unless otherwise stipulated in writing by the Sponsor</td></tr>
<tr><td>Paper</td><td colspan="2"></td></tr>
<tr><td>Digital</td><td colspan="2">Securely archived</td></tr>
</table>