



MASCOT SPINCONTROL
clinical research centre

SPINCONTROL®
— au coeur de la peau...

CONFIDENTIAL REPORT

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EVALUATION OF THE IN-VIVO SAFETY AND EFFICACY OF A SKIN CARE FORMULATION IN TERMS OF SKIN BRIGHTENING & REDUCTION IN INTENSITY OF DARK SPOTS

THROUGH:

- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Mexametry
- Corneometry
- Illustrative photographs of whole face under diffused light

TEST PRODUCT REFERENCE:

- Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122) :Product A

Study Sponsor:

PUREPLAY SKIN SCIENCES (I) PVT. LTD.

9th floor, Lodha I-Think Techno Campus,
Behind Viviana Mall, Chirag Nagar,
Thane (w) 400607.

Investigator:

MASCOT SPINCONTROL INDIA PVT. LTD

Kohinoor Estate, 3rd Floor,
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JANUARY 2023



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1. EXPERIMENTATION SITE, PARTICIPANTS

1.1 EXPERIMENTATION SITE

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SPONSOR

1.2 STUDY SPONSOR

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1.6 QUALITY ASSURANCE MANAGER

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2. SUMMARY OF THE STUDY

2.1 PRIMARY OBJECTIVE

The objective of this study was to assess the in-vivo safety & efficacy of a skin care formulation in terms of skin brightening and reduction in intensity of dark spot on healthy female subjects.

2.2 SECONDARY OBJECTIVE

To evaluate the in-vivo safety and efficacy in terms of tan reduction & skin moisturization on healthy female subjects.

Product Reference:

- Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122) : Product A

The evaluation was performed using:

- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Mexametry
- Corneometry
- Illustrative photographs of whole face under diffused light

The study lasted 28 days following the first application of the product.

2.3 POPULATION

36 female subjects were selected for the study. The subjects selected for this study were healthy females, aged between 18 and 34 years old having wheatish to dark tanned skin and having at least one acne PIH of size 3.5mm.

These subjects were selected according to the inclusion/ non-inclusion criteria listed in paragraph 3.1.

2.4 STUDY DURATION

Duration: 28 days following the first application of the product.



Scheduled Procedures:

	Screening	T0	T+14 days	T+28 days
Registration	■			
Protocol Briefing	■			
Consent	■			
ICF		■		
Demographics	■			
Inclusion and Non-Inclusion criteria by the Dermatologist	■	■		
Habits Questionnaire	■			
Clinical Observations	■			
History Questionnaire	■			
Routine check up	■			
Concomitant Medication	■	■	■	■
Proscriptions and Restrictions			■	■
Subject Self Evaluation			■	■
Dermatological Evaluation: (Cosmetic Acceptability)		■	■	■
Dermatological Evaluation (Efficacy)		■	■	■
Chromametry		■	■	■
Mexametry		■	■	■
Corneometry		■	■	■
Illustrative photographs of whole face under diffused light		■	■	■
Product Weighing		■		■
Distribution of Products, Products Instruction & Diary Sheet		■		
Product Application on site		■		
Product Retrieval				■
AE/SAE Monitoring		■	■	■
				End of the study

Study Schedule:

Batch	Screening + T0	T+14 Days	T+28 Days
Batch 1	22/11/2022	06/12/2022	20/12/2022
Batch 2	30/11/2022	14/12/2022	28/12/2022



2.5 STUDY DESIGN

- Single Blinded study.
- Non-Comparative study.
- Subjects served as their own references.



3. STUDY PROTOCOL

3.1 SUBJECT SELECTION

Mascot Spincontrol's subject panel is composed of subjects selected on the basis of a questionnaire filled in by the investigator for subjects, prior to the study that provides details of their medical history, possible allergies, skin-care and make-up habits, as well as a certain amount of administrative information.

The selection procedures are elaborated in order to guarantee that the subjects receive all possible information about the aims of the study and the consequences of their participation.

This selection procedure includes:

- A preliminary interview, during which the following points are explained to the subjects: the study's modalities, its practical considerations, possible payment, as well as any possible cosmetic benefits, inconveniences or potential risks.
- The information form which is specific to the study, including all essential information is then given to the subject to read.
- The consent form is read, approved, and signed by the subject to substantiate the fact that they freely accept the conditions of the study which has been described to them.
- The informed consent form which is filled in freely and intentionally by the subject after it had been fully explained to them, in the event of any claims for damages, enables them to benefit from the terms of the insurance policies taken out by Clinical Research Organization as soon as the subject is accepted into the study by the study manager.

The subject respected the following conditions: (as well as those already mentioned)

- Available for the entire duration of the study
- Motivated to freely participate in the study
- Willing to follow the full product application procedure
- Able to justify a permanent address
- Able to understand Hindi, Marathi, Gujarati and/or English language: i.e. only Hindi, Marathi, Gujarati and/or English speaking subjects capable of reading the consent documents and able to accept the participation conditions.
- No individual sentenced to imprisonment by a court decision or by an administrative decision, or hospitalized without consent, or admitted in a medical or social establishment.
- No minor as well as individual of age benefiting from a legal protection measure or enable to express his consent.

The subjects selected for the study were chosen under the supervision of the investigator and study manager, on the basis of the inclusion/non-inclusion criteria listed below.

A selection of 36 (females) subjects was made for this study.

SSE, Dermatological Evaluation for Cosmetic Acceptability, Dermatological Evaluation (Efficacy), Chromametry, Mexametry, Corneometry and Illustrative photographs of whole face under diffused light were done on 36 female subjects.

The results given included all of the present and assessable subjects at each examination.



3.1.1 Inclusion criteria

The study was conducted on subjects who fulfilled the following criteria:

Standard criteria

- Indian / Asian female subjects
- Healthy subjects (no infectious and evolutive pathology which could make the subject vulnerable and stop the study, no pathology which could interfere with the study, no symptom in the process of an exploratory checkup)
- Between 18 and 40 years of age
- Skin is healthy on the studied anatomic unit (free of eczema, wounds, inflammatory scar....)

Specific criteria

- Having wheatish to dark tanned skin.
- Having at least one acne PIH of size 3.5mm

3.1.2 Non-inclusion criteria

Standard criteria

- Being pregnant or breastfeeding or having stopped to breastfeed in the past three months
- Having refused to give his/her assent by signing the consent form
- Taking part in another study liable to interfere with this study
- Having a chronic dermatosis liable to modify the cutaneous reactivity on the tested area
- Being insulin-dependent diabetic or non-insulin-dependent diabetic with a recent therapy (less than 6 months)
- Having a progressive asthma (either under treatment or last fit in the last 2 years)
- Being epileptic
- Having non-stabilized thyroid problems (requirement of a stabilized treatment for at least 6 months)
- Having cutaneous hypersensitivity
- Having a diagnosed or highly probable allergy to one or several compounds of the cosmetic products or food products or to latex
- Following a chronic medicinal treatment comprising any of the following products: aspirin-based products, anti-inflammatories, anti-histamines, corticotherapy, taken by general or local routes (the only medication permitted is paracetamol)
- Having undergone a surgery requiring a general anaesthetic of more than one hour in the past 6 months.
- Having changed his/her cosmetic habits in the 14 days preceding the start of the study on the studied anatomic unit
- Having applied a cosmetic product (included make-up) on the studied areas the first day of the study.

Refusing to follow the restrictions below during the study:

- For Female: Do not take part in any family planning activities leading to pregnancy and breastfeeding
- Do not take part in another study liable to interfere with this study
- Do not take medicinal treatment comprising any of the following products: aspirin-based products, anti-inflammatories, anti-histamines, corticotherapy, taken by general or local routes (the only medication permitted is paracetamol)



- Do not change his/her cosmetic habits apart from the particular conditions mentioned in the protocol, on the studied anatomic unit
- During the study: Do not use other cosmetic products than the tested products to the studied areas
- The day of the measurements: No test product must be used (only test area cleaned with water is accepted)

Specific criteria

- Having started, changed or stopped a hormonal treatment (hormonal contraception, Hormone Replacement Therapy) in the past 3 months.
- Having started, changed or stopped his/her tobacco consumption (for smokers consuming more than 10 cigarettes per day) in the previous 6 months
- Having taken a medicinal treatment which could lead to hyper pigmentation (phenytoin, amiodarone, metals, minocycline...) in the previous 6 months
- Taking oral supplements with major or minor effect on whitening of skin (e.g. vitamin C, beta-carotene...)
- Having had beauty treatment (e.g. skin cleansing, exfoliation, scrub, mask ...) or having applied self-tanning products in the week preceding the start of the study
- Having applied products with anti-wrinkle action (Retinoic acid, retinol, retinaldehyde, isotretinoin, A.H.A...) in the 2 weeks preceding the start of the study
- Having applied products with a depigmenting action (hydroquinone or derivatives...) in the 4 weeks preceding the start of the study.
- Having undergone physical and/or chemical treatments of the spots (liquid nitrogen, dry ice, pulsed flash lamp, dermabrasion, chemical peel ...) in the previous 6 months.

Refusing to follow the restrictions below during the study:

- Do not start, change or stop a hormonal treatment (hormonal contraception, Hormone Replacement Therapy).
- Do not start a medicinal treatment which could lead to hyper pigmentation
- Do not take oral supplements with major or minor effect on whitening of skin (e.g. vitamin C, beta-carotene...).
- Do not start an oral or local retinoid-based treatment
- Do not have beauty treatment (e.g. skin cleansing, exfoliation, scrub, mask ...) or apply self-tanning products.
- Do not use products or techniques or surgery with a depigmenting action.
- Do not practice water activities (swimming pool, sauna, hammam, balneotherapy).
- Do not practice sport on the days of study.
- Do not expose yourself to the sun by respecting a strict photo-protection.



3.2 THEPRODUCT

3.2.1 Presentation of the products

The test product was supplied free of charge by the study sponsor.

Reference of the products	Batch	Mfg. Date	Expiry Date	Constituent form	Packaging	Capacity of
Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122)	RD011 122	11/22	11/23	Cream	Tube	N/AV
Neutral Cleanser (035)	035	04/22	03/23	Emulsion	Tube	N/AV

The study sponsor was in charge of product manufacturing and packaging. He/ She is responsible for the study sponsor was in charge of product manufacturing and packaging. He/ She was responsible for product identification, purity determination, composition, innocuousness, and any other characteristics of each product to be tested prior to the beginning of the study.

For this study, the study sponsor agreed to supply:

The appropriate quantity of the product required to treat all of the subjects;

A sufficient quantity of the product for any additional subjects participating in the study;

One product unit per reference and per batch to be retained in the sample cabinet of MASCOT-SPINCONTROL.

Products were stored in an ambient temperature away from light.

At the end of the study, the products used by the volunteers or the left-over products can be sent back to the sponsor if he has asked for it on the document attached to the quotation or by mail.

On the other hand, the Principal Investigator proceeds to eliminate the remaining products according to the method of their choice described in their procedures.

The cost of the products' destruction by the Principal Investigator was charged to the sponsor.

On the other hand, the investigator proceeds to eliminate the remaining product according to the method of their choice described in their procedures.

The cost of the product destruction by the investigator was charged to the sponsor.



3.2.2 Product application

The application was carried out by the subjects themselves at home; except the first application of test product was carried out at Mascot Spincontrol under the guidance of the CRA:

Product	Application area	Frequency of application	Application duration	Conservation
Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122)	Whole Face	Twice a day	28 days	At an ambient temperature
Neutral Cleanser (035)	Whole Face	Twice a day	28 days	At an ambient temperature

Modalities of application:

Face was washed with provided cleanser and pat dry. Approx. 1 gm of the test product was taken and applied dot wise on the whole face. Gently spreaded the test product using only fingers in outward direction. It was ensured that the subject don't rub the product into their skin. The product was applied twice a day in morning and afternoon with a gap of minimum 4 hours in between two applications on whole face for the period of 28 days.

Note:

No other soap/ cleanser was used during the study.

Face was washed only with water on study visits i.e. T+14 days and T+28 days in morning.

The test product was not applied on study visits i.e. T+14 days and T+28 days in morning.

The test product was applied after going home on T+14 days visit.

3.3 STUDY DESIGN

- This study was carried out as a “single blind study”. The subjects participating were not aware of the type of products being applied.
- This was a non-comparative study.
- The subjects served as their own reference and results obtained at various assessment times were compared with those obtained at T0.

3.4 RANDOMISATION

There was no randomization in the study.



3.5 STUDY PROCEDURES

3.5.1 Subject Self Evaluation

➤ Acquisition of source data

- Principle

The subjects were asked to answer self-evaluation questionnaire at **T+14 days & T+28 days** in order to evaluate the overall opinion and their attitude towards the safety and efficacy of the product under test

- Studied area: whole face

- Procedure

The questionnaires were filled in the Mascot Spincontrol office.

The subjects were filled in the questionnaire individually without any extrinsic influences (other volunteers and results of technical measurements). The filing of the questionnaires was performed under control of the CRA who checked the acquisition according to standard procedure.

The questionnaires were carried out in accordance with the promoter as follows:

Product Efficacy at T+14 days & T+28 days.

1. The test product helps in brightening my skin.
2. The test product helps in reducing intensity of dark spots.
3. The test product helps in reducing tanning of skin.
4. The test product helps to moisturize my skin.

Physical Characteristics at T+14 days

1. The fragrance of test product is appealing.
2. The texture of the test product is appealing.
3. The test product spreads properly on the face.
4. The test product gets absorbed quickly in the skin.

Product Safety at T+14 days & T+28 days

1. The test product does not cause itching.
2. The test product does not cause irritation.
3. The test product does not give burning sensation.

For each Item, the possible answers were:

- 1 = Completely agree
- 2 = Somewhat agree
- 3 = Somewhat disagree
- 4 = Completely disagree

➤ Treatment of Raw Data

Questionnaires were filled out manually in paper version and all the captured data was entered in Microsoft Excel.



3.5.2 Dermatological Evaluation by a Dermatologist (Cosmetic Acceptability)

➤ Acquisition of source data

- Principle

Safety of the product was assessed by the dermatologist, through the grading on the affected area of defined clinical signs (observed by the dermatologist) and functional signs (felt by the subjects and reported to the dermatologist), at **T0, T+14 days & T+28 days visits**, as follows:

Clinical Signs: Functional signs:

- | | |
|------------|------------|
| - Erythema | - Itching |
| - Oedema | - Tingling |
| - Dryness | |
| - Scaling | |
| - Peeling | |

The evaluation was performed using the following scale:

- 0: None
- 1: Slight
- 2: Moderate
- 3: Severe

➤ Acquisition methodology

- Environmental conditions

The evaluation was carried out under a controlled temperature and relative humidity (temperature: 20°C to 25°C, hygrometry: 50 ±10%). The lighting was ensured by a ceiling lamp.

- Subject

A 20-minute period of acclimatization in the air-conditioned room was respected for the subject prior to the measurements (temperature: 20°C to 25°C, hygrometry: 50 ±10%).

The subject was sitting on a chair facing the test site towards dermatologist.

The subject was positioned just below a lamp in the ceiling. All the shutters of the room were closed, and the only light was provided by the lamp of the ceiling.

- Studied areas: Whole Face
- Measures

The dermatologist assessed each descriptor using the dedicated scale and reported the grade in the CRF.

➤ Treatment of raw data

The result was given in terms of a score from 0 to 3 for each studied descriptor.

The evaluation of the cosmetic acceptability was not submitted to a statistical analysis (descriptive analysis only).



3.5.3 Dermatological Evaluation by a Dermatologist (Efficacy)

➤ Acquisition of source data

- Principle

The product efficacy, was assessed by the dermatologist, through the grading at T0, T+14 days & T+28 days visit of the following parameters:

- Skin Brightening using shade card (Scale: 1 to 10; 1=Dark Skin & 10=Fair Skin)

➤ Acquisition methodology

- Environmental conditions

The evaluation was carried out under a controlled temperature and relative humidity (temperature: 20°C to 25°C, hygrometry: 50 ±10%). The lighting was ensured by a ceiling lamp.

- Subject

A 20-minute period of acclimatization in the air-conditioned room was respected for the subject prior to the measurements (temperature: 20°C to 25°C, hygrometry: 50 ±10%).

The subject sat on a chair facing the test site towards the dermatologist.

The subject was positioned just below a lamp in the ceiling. All the shutters of the room were closed and the only light was provided by the lamp on the ceiling.

- Studied areas: Whole Face

- Measures

The dermatologist assessed each descriptor, for each studied area, using the dedicated scale and reported the grade in the CRF.

➤ Treatment of raw data

- **For Skin Brightening**

The result was given in terms of a score from 1 to 10 for skin brightening.

- The increase in the score showed an effect of the product in terms of skin brightening.



3.5.4 Chromametry

➤ Acquisition of raw data

- Principle

Tristimulus colorimeters are made of a control unit and a measurement head line associated. The measurement head line takes the measurements from a zone of 8mm in diameter and uses a diffuse lighting as well as an angle of 0° (including specular component). The headline measurement has a light with a pulsed xenon arch lamp. A double beam system measures the incident light and the reflected light by means of six photocells. The used material is a Chromameter CR-400 (Minolta).

➤ Acquisition methodology

- Checking of the calibration

A calibration was made for each supply of electricity to the device according to the recommendations of the manufacturer, by means of a white ceramic plate CR-A44, supplied with the device.

- Environmental conditions

The evaluation was carried out under a controlled temperature and relative humidity (temperature: 20°C - 25°C, hygrometry: 50±10 %).

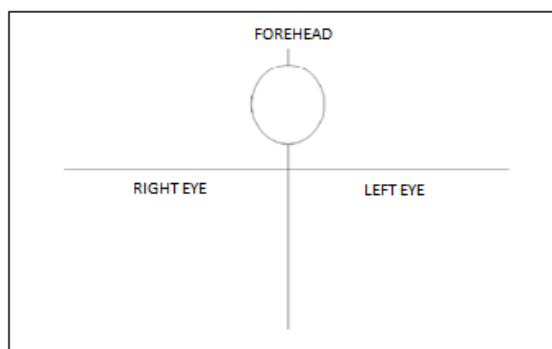
- Subject

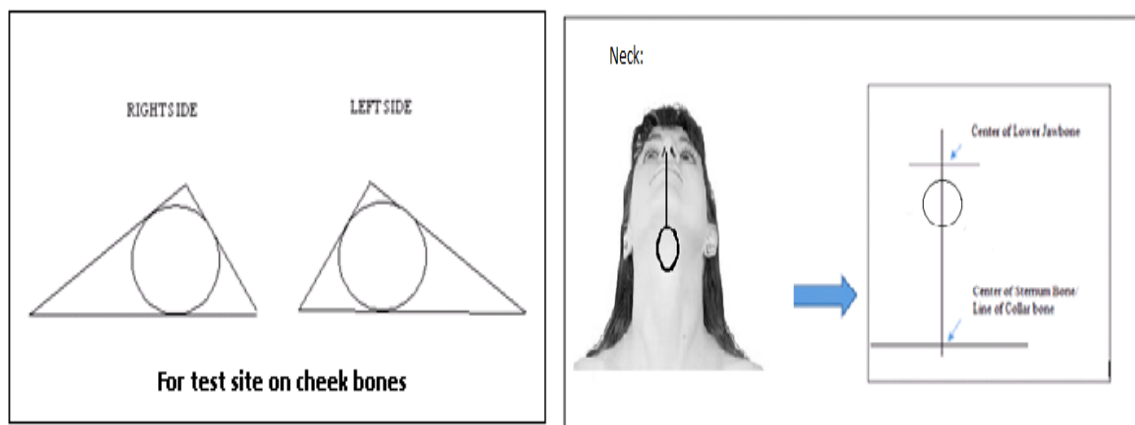
A 20-minute period of acclimatization in the air-conditioned room was respected for the subjects prior to the measurements (temperature: 20°C - 25°C, hygrometry: 50±10 %).

For the measurement on affected area, the subject was seated on a chair.

- Studied areas and marking

The measurements were performed **on forehead, on both cheek bones and below the chin, on neck (unexposed area) for calculating difference between both skin (ΔE^*)** as shown in the below image. The site of the instrumental measurements and their location at the different points of the kinetics was strictly the most reproducible. The location was determined by a cutaneous marking on the instrumental measurement sites at T0. In order to reposition this marking accurately while the measurements were taken, a mapping of the skin's surface, for the measurement site and for each subject, was made on a transparent film.





Measurements

Three measurements were carried out on the study areas, for each subject at each examination time at T0, T+14 days and T+28 days visits.

- Parameters

The absolute measurements were expressed in the form L*, a*, b* and ΔE^* (unexposed area)

ΔE^* represents the relative difference in colour between two given areas

$\Delta E^* = [(L^*_{si} - L^*_{sj})^2 + (a^*_{si} - a^*_{sj})^2 + (b^*_{si} - b^*_{sj})^2]^{1/2}$, Where si and sj means two different sites defined on the face & L* represents the relative brightness from total black ($L^*=0$) to total white ($L^*=100$).

➤ Treatment of Raw Data

All the captured data was entered in excel manually from CRFs & was calculated subsequently, on Microsoft Excel file. As the data was captured manually the mean of the three measurements were performed.

L* parameter signifies improvement in skin brightening effect.

The color differences between the different investigated sites was calculated and plotted.

A significant decrease in the ΔE^* parameter correspond to decrease in color difference of tanned skin (Whole Face) and unexposed site (below the chin, on neck) showed an effect of the product in terms of Tan Reduction.



3.5.5 Mexametry

➤ Acquisition of source data

- Principle

Mexametry is the technique used to determine the melanin content of the skin. This method is based on absorption/reflection. The probe of the Mexameter® MX 18 emits 3 specific light wavelengths. A receiver measures the light reflected by the skin. The positions of emitter and receiver guarantee that only diffuse and scattered light is measured. As the quantity of emitted light is defined, the quantity of light absorbed by the skin can be calculated. The apparatus used is a MX 18 (Courage and Khazaka, Germany).

➤ Acquisition methodology

- Environmental conditions

The evaluation was carried out under a controlled temperature (20°C to 25°C) and relative hygrometry (50± 10%).

- Subject

A 20-minute period of acclimatization in the air-conditioned room was respected for the subject prior the measurements (temperature: 20°C to 25°C, hygrometry: 50±10 %).

The subject was seated on a chair.

- Studied areas and Marking

The measurements were performed on **one visible dark spot**. The site of the instrumental measurements and their location at the different points of the kinetics was strictly the most reproducible. The location was determined by a cutaneous marking on the instrumental measurement sites at T0 by calculating the distance of the spot from the nose and eyes. In order to reposition this marking accurately while the measurements were taken, a mapping of the skin's surface, for the measurement site and for each subject, was recorded in the case report form.

- Measurement

Three measurements were carried out on the selected dark spot, for each subject and each examination time on **T0, T+14 days and T+28 days visits**.

- Parameters

The results obtained for melanin were expressed in arbitrary units.

➤ Treatment of Raw Data

All the captured data was entered in excel manually from CRFs & were calculated subsequently on Microsoft Excel file. As the data was captured manually the mean of the three measurements were performed.

The significant decrease in the melanin readings showed an effect of the product in terms of reduction in melanin content (intensity) of the spot.



3.5.6 Corneometry

➤ Acquisition of source data

- Principle

Corneometry is a technique used to determine the level of moisture in the outer layers of the stratum corneum. This method is based on the relationship between the electrical properties of skin tissues and their moisture content. The principle of corneometry consists in passing a high frequency electric current through the skin between two electrodes. The electric field produced in the epidermis is function to the geometry and the dielectric constant of the electrodes and of the capacitance of the skin in contact with the probe. A moisturizing variation of the skin is traduced by a modification of the total capacitance of the system. The apparatus used is a CM 825 (Courage and Khazaka, Germany).

➤ Acquisition methodology

- Environmental conditions

The evaluation was carried out under a controlled temperature and relative humidity (temperature: 20°C to 25°C, hygrometry: 50±10%).

- Checking the calibration

Prior to each series of measurements, the calibration of the device was checked according to the procedure supplied by the manufacturer.

- Subject

A 30-minute period of acclimatization in the air-conditioned room was respected for the subjects prior to the measurements (temperature: 20°C to 25°C, hygrometry: 50±10%).

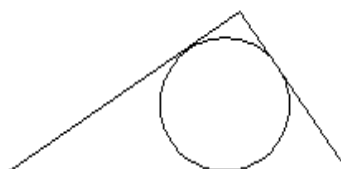
The subject sat on a chair facing towards technician

Studied areas and marking

The measurements were performed on both cheek bones. The site to be measured at each kinetics was reproducible. The site was determined by a cutaneous marking at T0 with the help of transparency.

RIGHTSIDE

LEFT SIDE



- Measurements

At T0, T+14 days & T+28 days visits the measurements were carried out on both the cheek bones, after delicately wiping the skin with an absorbent paper.

3 measurements were performed on the study areas for each subject and each examination time.



- Influence of the operator behaviour on the technique

This technique was considered as operator-dependent: for a given subject, the measurements were performed by the same technician at all the kinetics time points.

- Treatment of Raw Data

All the captured data was entered in excel manually from CRFs & were calculated subsequently, on Microsoft Excel file.

The studied parameter was the capacitance, expressed in arbitrary units. An increase in the value of the parameter shows a moisturizing effect of the product.



3.5.7 Illustrative Images of whole face under Diffused Light

➤ Acquisition of source data

- Principle

This technique consists of obtaining high resolution photographs of the whole face completely reproducible lighting conditions, in diffused light for illustration.

The acquisitions are carried out with a high resolution camera. The lens used is a Nikkor 60 mm equipped with a filter. Lighting is provided by one flash light. The flash head is fitted with filter slot to hold polarising gel (HN32 Sarelec, France).

The filter on the lens is oriented to a 90° angle in comparison with the filter on the flash. The polarised light, emitted by the flash and reflected by the face at the moment the photo is taken, is “cut” by the filter. These reflections do not appear on the photograph when it is obtained enabling a better visualisation of the changes in skin colour on the various studied areas.

➤ Acquisition methodology

- Environmental conditions

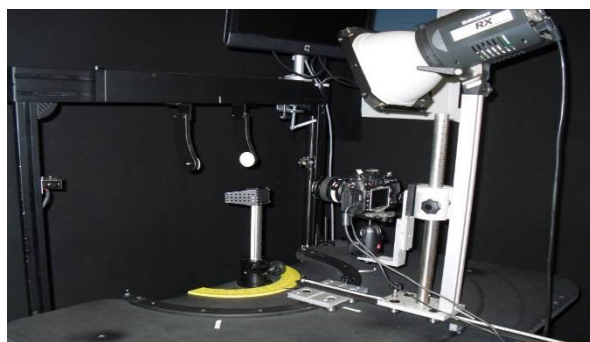
The evaluation was carried out in a dark room under a controlled temperature (20 to 25°C) and relative hygrometry (50 ± 10 %).

- Subject

A 20-minute period of acclimatization in the air-conditioned room was respected for the subject prior the measurements (temperature: 20°C - 25°C, hygrometry: 50±10 %).

The subject wore a black paper cap and a black cloth in order to avoid the potential influence of extrinsic colors. They had opened eyes during the acquisitions.

To ensure a good reproducibility of the acquisition conditions, the photographs of the face were carried out on an optical measurement bench especially developed by Spincontrol (Visio-Face®). This bench allows to keep the face in the same position and the photographic acquisition system in perfectly defined positions.



Face retention bench (VisioFace®) for the acquisition of photography of the face.

- Measurements

The camera was positioned in portrait.



Photograph of each of whole face was taken on the studied area. At Tn, the visualization of the initial digital photograph (T0) ensured a good repositioning of the subject was taken in diffused light.

Photographs of the subjects were taken at T0, T+14 days and T+28 days visits for all subjects

The visualization of the initial digital photograph (T0), at Tn ensured a good repositioning of the subject.



➤ Treatment of source data

No treatment was performed. The photographs were used only for illustrative aim.



3.6 EXAMINATION SCHEDULE

The effects of the product was evaluated over a 28 days period. The scheduled measurement procedures were as follows:

Screening

- Registration
- Protocol Briefing
- Consent for screening
- Demographics
- Concomitant Medication
- Habit Questionnaire
- History Questionnaire
- Routine Check-up
- Checking of the inclusion/non-inclusion criteria by dermatologist

At T0

- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 minutes.
- Acknowledgement, reading and signature of the ICF
- Concomitant Medication
- Checking of the inclusion/non-inclusion criteria by dermatologist
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Mexametry
- Corneometry
- Illustrative Images of whole face under Diffused Light
- Distribution of product, product instruction and diary sheet.
- Product application with instructions and recording in information and in diary sheet.
- Adverse Event / Serious Adverse Event monitoring

At T+14 Days: (± 1 Day)

- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 minutes.
- Proscription & Restrictions
- Concomitant Medication
- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Mexametry
- Corneometry
- Illustrative Images of whole face under Diffused Light
- Adverse Event/ Serious Adverse Event Monitoring



At T+28 Days: ($\pm$ 1 Day)

- Acclimatization at RH 50 $\pm$ 10% and temperature 20°C to 25°C for 20 minutes.
- Proscription & Restrictions
- Concomitant Medication
- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Mexametry
- Corneometry
- Illustrative Images of whole face under Diffused Light
- Product Accountability
- Adverse Event/ Serious Adverse Event Monitoring
- End of test product application subjects are indemnified.

Comment: The questionnaires were filled in by the subjects before carrying out any measurements to avoid influencing their judgment about the test product.



3.7 DATA ANALYSIS AND STATISTICS

3.7.1 Data analysis of technical data (not for dermatological evaluation of safety)

Carried out by statistician at Mascot Spincontrol India

The results include:

- Raw values for each subject at each examination.
- Differences, in relation to T0 for each subject during the study ($T_n - T_0$).
- Means, medians, maximum, minimum and standard deviations of the raw values and of the differences in relation to T0 obtained by the entire panel.
- Variations, in relation to T0 expressed as a percentage calculated from the mean values. (except for the dermatological evaluation for efficacy)
- Numbers and percentages of subjects presenting an improvement (dermatological grading only).

Comparison in time for product:

The normality of the distributions is checked using Shapiro-Wilk test, threshold at 1%.

The statistical analysis of the evolution of the measured parameters during the study is performed using the Student test (normality of distributions checked) or with the Wilcoxon test (normality of the distributions rejected). The significance threshold is fixed at 5%.

Remark: To make the statistical treatment easier, it's possible to perform the student t test directly if the number of subjects is ≥ 30 except for the clinical evaluation by the dermatologist for which the preliminary checking of normality of the distribution is required.

3.7.2 Data analysis of Self-evaluation

The analysis involves establishing frequency tables that take into account the number of responses and calculate the frequency of the different possible answers (given as percentage) to each qualitative question. For each question, results are shown in tabular form (number of individuals and frequency).

To evaluate the efficacy and the appreciation of the products for each item, two percentages Z1 and Z2 are calculated as follows:

Z1 = favourable opinion (Ex: "Completely agree" + "Somewhat agree")

Z2 = unfavourable opinion (Ex: "Completely disagree" + "Somewhat disagree")

The statistical difference in frequencies (%) between favourable and unfavourable opinions is evaluated using the Chi-squared test at 5%.



4. ETHICAL AND LEGAL CONSIDERATIONS

4.1 STUDY PERSONNEL

The investigator assures that the study manager and everyone who participates in this study have the required qualifications and abilities to carry it out.

4.2 DATA ARCHIVING

The documents are archived for a period as per recommendation of sponsor or 5 years. Dual archiving is ensured by using both paper and IT storage media.

Paper files are archived by Mascot Spincontrol until the end of the archiving period.

Electronics files are archived on 1 large capacity USB hard disks. The disk is stored for 5 years. The investigator keeps a copy of the protocol signed by both himself and by the Study Sponsor as well as the original case report form, questionnaires and all associated documents, the consent forms, and all project-related documents of any type for a 5-year period following delivery of the final report.

All these documents are accessible upon request for inspection by the study sponsor, their representative or by administrative authorities.

The investigator informs the study sponsor of his intention to proceed with their destruction after the 5 years period.

4.3 INSURANCE POLICY

The damages caused by the failure of the investigator or a third party shall be imputable to Mascot Spincontrol.

Adequate insurance cover of the subject for liability arising from any serious event or death during the conduct of the study will be taken by Mascot Spincontrol India Pvt. Ltd. through an insurance contract with The Oriental Insurance Company Limited, Mumbai, India. (Insurance policy number 121200/48/2022/7027).

4.4 ANONYMITY OF THE SUBJECTS

The subjects are identified for the study sponsor using a five-character alphanumeric code and a number. The investigator makes a commitment not to raise the anonymity of the subjects.

The study sponsor cannot have access to the confidential data relative to the subjects registered in the data base of Mascot-Spincontrol.

4.5 CONSENT TO PARTICIPATE IN THE STUDY

An information form is given to each subject providing full details about the study and:

- its objectives, methods, and duration;
- possible expected aesthetic benefits, constraints, and potential risks;
- the non-inclusion criteria, the amount of the payment, the right of access to data files and their later destruction.

This information enables the subjects to sign their participation consent form freely and unequivocally, in the knowledge that they are fully aware of the testing details.



4.6 USE OF IMAGE

If the study involves the use of photographs, the volunteers are informed, in the consent form, that their image without direct identification may be used by Mascot-Spincontrol all over the world, with no time limit on this usage. The volunteers are also informed that Mascot-Spincontrol may also provide images to the sponsor for publishing or duplication.

4.7 CONFIDENTIALITY

All the information, data, and results of the study are confidential. Everyone having access to such data are informed of their confidentiality.

Any medical information concerning a subject's state of health and the results of the clinical examinations carried out during the recruitment, selection and admission phases before a study is subject to the medical secrecy regulations, in no case should such information be communicated to the study sponsor using a subject's identity.

4.8 QUALITY ASSURANCE

Our quality system has been developed to meet guidelines relevant to our type of activity for ingredients and cosmetic product efficiency and tolerance testing.

As such, our Quality System is in full compliance with ICH-E6 -Good Clinical Practice (GCP) guidelines in our test companies: Mascot spin control (India) and Tours (France).

The entire dossier of a study (protocol, results, report, and any other study-related documents) is subject to a Quality Management audit which conforms to the regulatory texts and procedures in force. Verifications of data generated in this study are performed in accordance with the Quality Assurance of the studies documents.

The investigator cooperates in ensuring any additional auditing required by the study sponsor to ensure that the study progresses in accordance with regards to the protocol and the current procedures.

Sr. No.	Audit Report	Date of Auditing
1.	Audit of study protocol	15/11/2022
2.	Audit of the CRF's	21/11/2022
3.	Audit report of the Trial Master File	04/01/2023
4.	Audit of the Raw Data & Results	05/01/2023
5.	Audit of the Study Report	10/01/2023

4.9 REGULATIONS



This study is carried out in conformity with the most recent recommendations of the World Medical Association (64th WMA Declaration of Helsinki, Fortaleza, Brazil, October 2013).

This study complies with the “Schedules of the Drugs and Cosmetics Act”.

4.10 PRACTICAL CONSIDERATIONS

A preliminary agreement between the Investigator and the study sponsor, concerned by the present contract, is necessary for any publication or communication directly concerning the two parties. They must both take the initiative to inform each other if a change is to occur.



5. RESULTS

5.1 DEVIATIONS FROM THE STUDY PROTOCOL

The protocol has been respected as a whole.

5.2 ABSENCES

- **Subject n° 006 KAM37 & Subject n° 034 DHONI** did not reported to the study site on T+28 days visit
The data for these subjects was exploited till T+14 days in the global study results.
- **Subject n° 017 TOPVA** did not report to the study site from T+14 days visit till T+28 days visit.
The data for this subject is not exploited in the global study results.

5.3 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS

At T0, 36 subjects were recruited,

Considering the information previously mentioned in the paragraphs 5.1 & 5.2 the number of subjects considered in the expression of the results, at each examination time, for each technique, is presented in the following table:

Techniques / Times	T0	T+14 Days	T+28 days
Subject Self Evaluation	N/AP	35	33
Dermatological Evaluation (Cosmetic Acceptability)	36	35	33
Dermatological Evaluation (Efficacy)	36	35	33
Chromametry	36	35	33
Mexametry	36	35	33
Corneometry	36	35	33
Illustrative photographs of whole face under diffused light	36	35	33

5.4 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of **35 Healthy Indian female subjects**, aged between **18 and 34** years old, (Mean age: **22.9 years old**; SD: **4.2 years old**; Median: **22.0 years old**) having wheatish to dark tanned skin and at least one acne PIH of size 3.5mm.



5.5 RESULTS OF THE SUBJECT'S SELF ASSESSMENT QUESTIONNAIRE

The table below summarises the agreement percentages recorded for each suggested item for test product A at T+14 days & T+28 days after product application, as well as their statistical significance evaluated using Chi-squared test at 5%.

		T+14 Days		T+28 Days	
Number of subjects		35		33	
		% agreement	Significant ? (5%)	% agreement	Significant ? (5%)
1	The test product helps in brightening my skin	100%	Yes	100%	Yes
2	The test product helps in reducing intensity of dark spots	97%	Yes	100%	Yes
3	The test product helps in reducing tanning of skin	97%	Yes	100%	Yes
4	The test product helps to moisturize my skin	100%	Yes	100%	Yes
5	The fragrance of test product is appealing	100%	Yes	-	-
6	The texture of the test product is appealing	97%	Yes	-	-
7	The test product spreads properly on the face	100%	Yes	-	-
8	The test product gets absorbed quickly in the skin	97%	Yes	-	-
9	The test product does not cause itching	100%	Yes	100%	Yes
10	The test product does not cause irritation	100%	Yes	100%	Yes
11	The test product does not give burning sensation	100%	Yes	100%	Yes

Yes: Significant difference in favor of the product
No: No significant difference
Yes*: Significant difference in disfavor of the product

5.5.1. Observed results

For test product A, **all the suggested items are significantly and highly recognized by the panel, at T+14 days & T+28 days with 97% to 100% of agreement for all the items.**

- Concerning the **product efficacy**, test product A is well appreciated for helping in brightening the skin and for helping to moisturize the skin with 100% agreement, for helping in reducing the intensity of dark spots and for helping in reducing tanning of skin with 97% to 100% agreement after T+14 days and T+28 days of product application.
- Concerning the **physical characteristics**, test product A is well appreciated for its appealing fragrance and proper spreadability with 100% agreement and for its appealing texture and for quick absorption in the skin with 97% agreement at given time point.
- Concerning the **product acceptability**, test product A is well appreciated for not causing itching, irritation & burning sensation to the skin with 100% of agreement respectively after T+14 days and T+28 days of product application.



5.6 DERMATOLOGICAL EVALUATION: COSMETIC ACCEPTABILITY.

The studied parameters are:

1. Erythema
2. Oedema
3. Dryness
4. Scaling
5. Peeling
6. Itching
7. Tingling

The intensity of each parameter was evaluated according to a scale from 0 to 3 (0=None, 1=Slight, 2=Moderate, 3=Severe)

5.6.1 Observed results:

(Grading Scale: 0: None, 1: Slight, 2: Moderate, 3: Sever)

The appearance of clinical & functional signs was noticed are as follows:

Dryness: **Subject n° 011 VISKI & Subject n° 015 PALT2** experienced slight dryness of grade 1 on T+14 days visit after product application.

Nevertheless, the reaction for all the clinical & functional signs were equal to 1 (slight) reaction, on an average there was no unfavorable reaction observed by the dermatologist.



5.7 DERMATOLOGICAL EVALUATION : EFFICACY

The studied parameter was:

- Skin Brightening using shade card (Scale: 1 to 10; 1=Dark Skin & 10=Fair Skin)

5.7.1. Observed results

➤ Skin Brightening

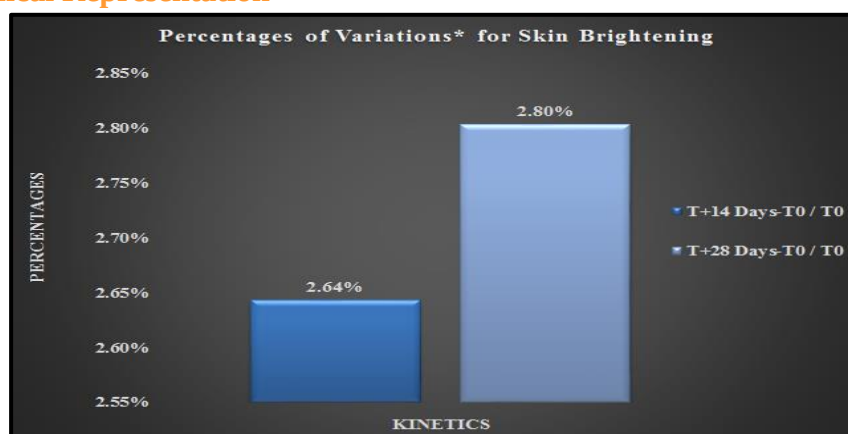
The following table summarises the means and standard deviations of the raw values, evolution & percent variation of the **Skin Brightening** observed on whole face treated with test product coded **Product A** at T0, T+14 days & T+28 days, as well as the corresponding statistical results for the evolution in time (Student test or Wilcoxon test, two-tailed for paired groups at 5%, after checking the normality of the distributions by a Shapiro-Wilk test at 1%).

Dermat Efficacy		Skin Brightening		
		T0	T+14 Days	T+28 Days
RAW VALUES	N	35	35	33
	Mean	6.49	6.66	6.58
	Standard deviation	1.29	1.24	1.20
	Significant at 5 % (T0 vs Tn) p= Test		Yes 0.0310 Wilcoxon	Yes 0.0310 Wilcoxon
EVOLUTION OF THE PARAMETERS (Tn-T0)			0.17	0.18
			0.38	0.39
VARIATIONS IN PERCENTAGES* (Tn-T0)/T0			2.64%	2.80%
Yes: Significant difference in favor of the product No: No significant difference Yes*: Significant difference in disfavor of the product				

→ Analysis

- The statistical analysis shows a significant increase in Skin Brightening parameter by 2.64% & 2.80% on whole face treated with test Product A on average of whole panel at T+14 days & T+28 days respectively.
- An improvement in studied parameter by 0.17 & 0.18 grade out of 10, on average on whole panel at T+14 days & T+28 days respectively.
- 17% & 18% of the panel presented an improvement in the studied parameter at T+14 days & T+28 days respectively.

→ Graphical Representation





5.8 CHROMAMETRY

The studied parameters are the L* & ΔE (unexposed area) of the skin without spot. A significant increase in the L*, showed an effect of the product in terms of skin brightening. A significant decrease in ΔE (unexposed area) values shows an effect of the product in terms of Tan Reduction.

5.8.1. Observed results

→ Raw values

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of L* and ΔE (unexposed area) observed on the whole face treated with test Product A at T0, T+14 days & T+28 days, as well as the corresponding statistical results for the evolution in time (Student t test, two-tailed for paired groups at 5%).

Chromametry		L*		
		T0	T+14 Days	T+28 Days
RAW VALUES	N	35	35	33
	Mean	51.88	52.59	52.61
	Standard deviation	3.37	3.47	3.59
	Significant at 5 % (T0 vs Tn)		Yes	Yes
		p=	<0.001	<0.001
		Test	Paired Student t test	Paired Student t test
EVOLUTION OF THE PARAMETERS (Tn-T0)	Mean		0.71	0.81
	Standard deviation		0.61	0.75
VARIATIONS IN PERCENTAGES* (Tn-T0)/T0	Mean		1.37%	1.56%

Yes: Significant difference in favor of the product
No: No significant difference
Yes*: Significant difference in disfavor of the product

Chromametry		ΔE		
		T0	T+14 Days	T+28 Days
RAW VALUES	N	35	35	33
	Mean	6.13	5.39	5.16
	Standard deviation	2.03	2.10	2.42
	Significant at 5 % (T0 vs Tn)		Yes	Yes
		p=	<0.001	<0.001
		Test	Wilcoxon	Wilcoxon
EVOLUTION OF THE PARAMETERS (Tn-T0)	Mean		-0.74	-0.84
	Standard deviation		1.04	1.26
VARIATIONS IN PERCENTAGES* (Tn-T0)/T0	Mean		-12.05%	-13.77%

Yes: Significant difference in favor of the product
No: No significant difference
Yes*: Significant difference in disfavor of the product



→ Analysis

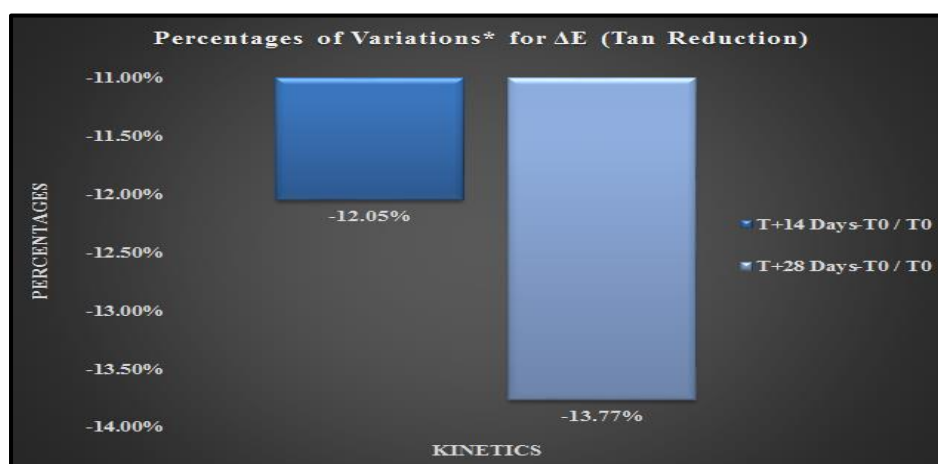
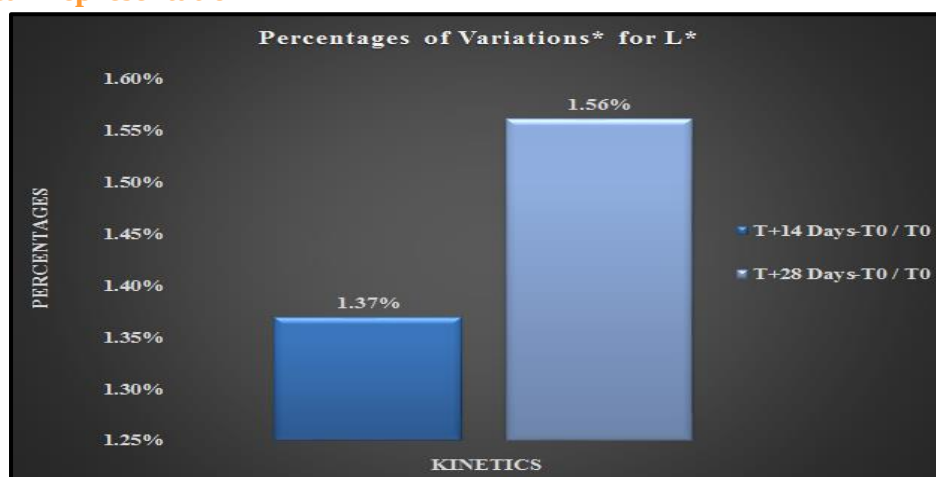
➤ L* parameter:

- The statistical analysis shows a **significant increase in L* parameter by 1.37% & 1.56%** on the whole face treated with test Product A on average on whole panel at T+14 days & T+28 days respectively.
- **89% & 88%** of the panel presented an improvement in the studied parameter at T+14 days & T+28 days respectively.

➤ ΔE parameter:

- The statistical analysis shows a **significant decrease in ΔE (unexposed area) by -12.05% & -13.77%** on the whole face treated with test Product A on average on whole panel at T+14 days & T+28 days respectively.
- **80% & 79%** of the panel presented an improvement in the studied parameter at T+14 days & T+28 days respectively.

→ Graphical Representation





5.9 MEXAMETRY

The studied parameter is melanin content of the studied dark spot, expressed in arbitrary units. A significant decrease in the melanin content shows reduction in melanin content (intensity) of the spot.

5.9.1. Observed results

→ Raw values

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of the studied parameter, observed on whole face treated with product A at T0, T+14 days & T+28 days, as well as the corresponding statistical results for the evolution in time (Student t test or Wilcoxon test, two-tailed for paired groups at 5% after checking the normality of the distributions by a Shapiro-Wilk test at 1%).

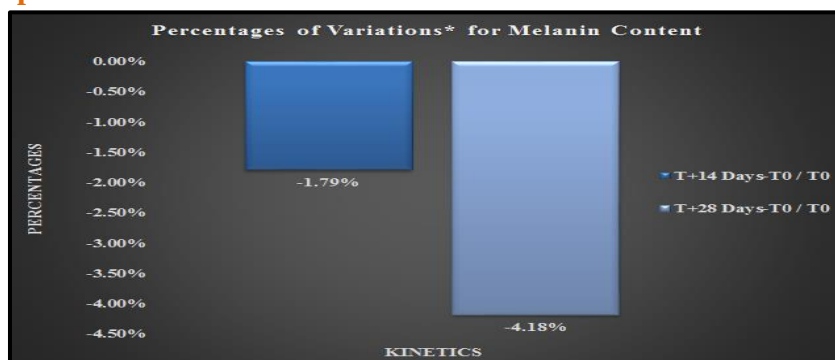
Mexametry		Melanin (arbitrary unit)		
		T0	T+14 Days	T+28 Days
RAW VALUES	N	35	35	33
	Mean	486.59	477.89	472.91
	Standard deviation	92.57	94.19	92.03
	Significant at 5 % (T0 vs Tn) p= Test		Yes <0.001 Wilcoxon	Yes <0.001 Wilcoxon
EVOLUTION OF THE PARAMETERS (Tn-T0)	Mean		-8.70	-20.34
	Standard deviation		8.24	15.33
VARIATIONS IN PERCENTAGES* (Tn-T0) / T0	Mean		-1.79%	-4.18%

Yes: Significant difference in favor of the product
No: No significant difference
Yes*: Significant difference in disfavor of the product

→ Analysis

- The statistical analysis shows a **significant decrease in melanin content of the studied dark spot** by **-1.79% & -4.18%** on the whole face treated with test Product A on average on whole panel at T+14 days & T+28 days respectively.
- 97% & 100%** of the panel presented an improvement in the studied parameter at T+14 days & T+28 days respectively.

→ Graphical Representation





5.10 CORNEOMETRY

The studied parameter is the Capacitance. A significant increase in the capacitance shows an effect of the product in terms of Skin Moisturization.

5.10.1. Observed results

→ Raw values

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of the of the studied parameter, observed on whole face treated with product A at T0, T+14 days & T+28 days, as well as the corresponding statistical results for the evolution in time (Student test or Wilcoxon test, two-tailed for paired groups at 5%, after checking the normality of the distributions by a Shapiro-Wilk test at 1%).

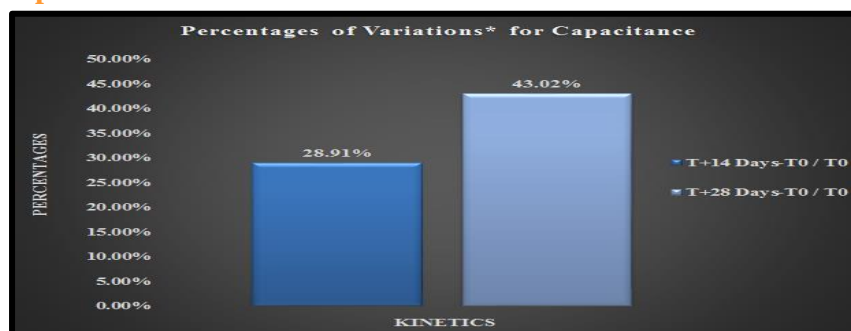
Corneometry		Capacitance		
		T0	T+14 Days	T+28 Days
RAW VALUES	N	35	35	33
	Mean	40.75	52.53	58.39
	Standard deviation	3.11	5.01	6.82
	Significant at 5 % (T0 vs Tn) p= Test		Yes <0.001 Paired Student t test	Yes <0.001 Paired Student t test
EVOLUTION OF THE PARAMETERS (Ta-T0)	Mean		11.78	17.53
	Standard deviation		4.70	6.53
VARIATIONS IN PERCENTAGES* (Ta-T0)/T0	Mean		28.91%	43.02%

Yes: Significant difference in favor of the product
No: No significant difference
Yes*: Significant difference in disfavor of the product

→ Analysis

- The statistical analysis shows a **significant increase in capacitance** parameter by **28.91% & 43.02%** on the whole face treated with test Product A on average on whole panel at T+14 days & T+28 days respectively.
- **100%** of the panel presented an improvement in the studied parameter at T+14 days & T+28 days respectively.

→ Graphical Representation





6. DISCUSSION and CONCLUSION

Twice a day application of the test product coded **Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122): Product A**, on a panel of 35 Indian female subjects, aged between **18 and 34 years old, having wheatish to dark tanned skin and having at least one acne PIH of size 3.5mm** leads to the following results after 28 days of product application:

✓ **Subject's Self Evaluation:**

On the basis of subject self-evaluation all the claims related to product efficacy, physical characteristics & product acceptability, are significantly validated by the panel after 28 days of application of test product A.

***No claims can be made based on SSE alone.**

✓ **Dermatological Evaluation for Cosmetic Acceptability:**

On the basis of Dermatological Evaluation for Cosmetic Acceptability, it has been observed that there is no occurrence of Erythema, Oedema, Dryness, Scaling, Peeling, Itching and Tingling (*except for Dryness for 2 subjects*) at any given time point for the test Product A.

✓ **Dermatological Evaluation for Efficacy:**

On the basis of Dermatological Evaluation for efficacy, **a significant increase in Skin Brightening parameter** by **2.64% & 2.80%** was observed after T+14 days & T+28 days of application of Product A.

✓ **Chromametry**

• **A significant increase in the L* parameter** by **1.37% & 1.56%** respectively after T+14 days & T+28 days of application of Product A, shows effect of the product in terms of **Skin Brightness**.

• **A significant decrease in the ΔE (unexposed area) parameter** by **-12.05% & -13.77%** respectively after T+14 days & T+28 days of application of Product A, shows effect of the product in terms of **Tan Reduction**.

✓ **Mexametry**

A significant decrease in melanin content by **-1.79% & -4.18%** respectively after T+14 days & T+28 days of application of Product A, shows effect of the product in terms of reduction in melanin content (intensity) of the spot.

✓ **Corneometry:**

A significant increase in capacitance parameter by **28.91% & 43.02%** respectively after T+14 days & T+28 days of application of Product A, shows effect of the product in terms of **Skin Moisturization**.

To conclude, in the experimental conditions of the study, after 28 days of application of the test product coded: Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122): Product A the following points have been demonstrated:

- **A significant increase in L* through Chromametry, shows effect of the product in terms of skin brightening after 28 days of application of product A.**
- **A significant decrease in ΔE (unexposed area) through Chromametry, shows effect of the product in terms of tan reduction after 28 days of application of product A.**
- **A significant decrease in melanin content through Mexametry, shows effect of the product in terms of reduction in melanin content (intensity) of the spot after 28 days of application of product A.**
- **A significant increase in capacitance parameter through Corneometry, shows effect of the product in terms of skin moisturization after 28 days of application of product A.**
- **Appreciation from the panel is obtained for product A through subject self-evaluation for product efficacy, product characteristics & product acceptability.**
- **Moreover, no unfavourable aggravation of clinical & functional sign (except for Dryness for 2 subjects) was observed after 28 days of application of product A.**

7. APPENDICES :



MASCOT SPINCONTROL
clinical research centre

APPENDIX 1:

QUALITY ASSURANCE STATEMENT

Quality Assurance Statement

This study (XXX-NF01-PD-OR22) has been regularly monitored by the quality assurance department by way of periodic audits as recommended by Good Clinical Practice and applicable regulations. The dates of these audits and the subsequent reports to the management are listed here:

Audit Schedule:

Sr. No.	Audit Report	Audit Report Number	Date of Audits
1.	Audit of study protocol	XXX-NF01-PD-OR22-AU01	15/11/2022
2.	Audit of the CRF's	XXX-NF01-PD-OR22-AU02	21/11/2022
3.	Audit report of the Trial Master File	XXX-NF01-PD-OR22-AU03	04/01/2023
4.	Audit of the Raw Data & Results	XXX-NF01-PD-OR22-AU04	05/01/2023
5.	Audit of the Study Report	XXX-NF01-PD-OR22-AU05	10/01/2023

This report has been audited by the quality assurance department and was found to be an accurate description of such methods and procedures as were used during the conduct of the study and an accurate reflection of the raw data.

Signature: _____
Auditor(s)

Signature: _____
Auditor(s)

Signature: _____
Quality Assurance Manager

APPENDIX 2:

COPY OF PROTOCOL

STUDY SUMMARY: XXX-NF01-PD-OR22
Test Product: Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122): Product A

DESCRIPTION OF THE STUDY:

EVALUATION OF THE IN-VIVO SAFETY AND EFFICACY OF A SKIN CARE FORMULATION IN TERMS OF SKIN BRIGHTENING & REDUCTION IN INTENSITY OF DARK SPOTS THROUGH:

- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Mexametry
- Corneometry
- Illustrative photographs of whole face under diffused light

NATURE OF THE TESTED PRODUCTS AND METHODOLOGY:

Product reference	Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122): Product A
Study design	It was a single blinded non-comparative study. Subjects served as their own reference.
Total duration of the study	28 days following the first application of product.
Kinetic	T0, T+14 days & T+28 days.
Product application	Twice a day on Whole face for the period of 28 days.
Number of volunteers	35 Females Subjects.
Special selection criteria	Having wheatish to dark tanned skin and having at least one acne PIH of size 3.5mm

RESULTS AND CONCLUSION

Twice a day application of the test product coded **Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122): Product A**, on a panel of 35 Indian female subjects, aged between **18 and 34 years old, having wheatish to dark tanned skin and having at least one acne PIH of size 3.5mm** leads to the following results after 28 days of product application:

✓ **Subject's Self Evaluation:**

On the basis of subject self-evaluation all the claims related to product efficacy, physical characteristics & product acceptability, are significantly validated by the panel after 28 days of application of test product A.

***No claims can be made based on SSE alone.**

✓ **Dermatological Evaluation for Cosmetic Acceptability:**

On the basis of Dermatological Evaluation for Cosmetic Acceptability, it has been observed that there is no occurrence of Erythema, Oedema, Dryness, Scaling, Peeling, Itching and Tingling (except for Dryness for 2 subjects) at any given time point for the test Product A.

✓ **Dermatological Evaluation for Efficacy:**

On the basis of Dermatological Evaluation for efficacy, a **significant increase in Skin Brightening parameter** by **2.64% & 2.80%** was observed after T+14 days & T+28 days of application of Product A.

✓ **Chromametry**

- A **significant increase in the L* parameter** by **1.37% & 1.56%** respectively after T+14 days & T+28 days of application of Product A, shows effect of the product in terms of **Skin Brightness**.
- A **significant decrease in the ΔE (unexposed area) parameter** by **-12.05% & -13.77%** respectively after T+14 days & T+28 days of application of Product A, shows effect of the product in terms of **Tan Reduction**.

✓ **Mexametry**

A **significant decrease in melanin content** by **-1.79% & -4.18%** respectively after T+14 days & T+28 days of application of Product A, **shows effect of the product in terms reduction in melanin content (intensity) of the spot.**

✓ **Corneometry:**

A **significant increase in capacitance parameter** by **28.91% & 43.02%** respectively after T+14 days & T+28 days of application of Product A, **shows effect of the product in terms of Skin Moisturization.**

To conclude, in the experimental conditions of the study, after 28 days of application of the test product coded: Plum Rice Water Niacinamide 2% Hybrid Sunscreen (RD011122): Product A the following points have been demonstrated:

- A significant increase in L* through Chromametry, shows effect of the product in terms of skin brightening after 28 days of application of product A.
- A significant decrease in ΔE (unexposed area) through Chromametry, shows effect of the product in terms of tan reduction after 28 days of application of product A.
- A significant decrease in melanin content through Mexametry, shows effect of the product in terms of reduction in melanin content (intensity) of the spot after 28 days of application of product A.
- A significant increase in capacitance parameter through Corneometry, shows effect of the product in terms of skin moisturization after 28 days of application of product A.
- Appreciation from the panel is obtained for product A through subject self-evaluation for product efficacy, product characteristics & product acceptability.
- Moreover, no unfavourable aggravation of clinical & functional sign (except for Dryness for 2 subjects) was observed after 28 days of application of product A.