

SPINCONTROL®
au coeur de la peau...

CONFIDENTIAL REPORT

XXX-NF01-CO-JY25

Version: 01

Dated: 02/05/2026

**EVALUATION OF THE IN-VIVO SAFETY AND EFFICACY OF A SKIN CARE
FORMULATION THROUGH:**

- **Subject Self Evaluation**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Dermatological Evaluation: Efficacy**
- **Chromametry**
- **Corneometry**

TEST PRODUCT REFERENCE:

- **ClayCo. Rice & Sake Sleep Mask : Product A**

Study Sponsor:

ClayCo. Cosmetics Pvt. Ltd.

Floor-1, 109, Plot-16,
Vithaldas Chamber,
Mumbai Samachar Marg,
Bombay Stock Exchange,
Fort, Mumbai.
Maharashtra – 400001

Investigator:

MASCOT SPINCONTROL INDIA PVT. LTD

Sea Breeze Building, 9th Floor,
Appasaheb Marathe Marg,
Century Bazaar, Prabhadevi,
Mumbai, Maharashtra 400025.

FEBRUARY 2026



CONTENTS

1. EXPERIMENTATION SITE, PARTICIPANTS.....	4
1.1 EXPERIMENTATION SITE	4
1.2 STUDY SPONSOR.....	4
1.3 STUDY MONITOR	4
1.4 STUDY DIRECTOR.....	4
1.5 PRINCIPAL INVESTIGATOR	5
1.6 QUALITY ASSURANCE MANAGER	5
2. SUMMARY OF THE STUDY	6
2.1 OBJECTIVE.....	6
2.2 POPULATION	6
2.3 STUDY DURATION	6
2.4 STUDY DESIGN	7
3. STUDY PROTOCOL	8
3.1 SUBJECT SELECTION.....	8
3.2 THE PRODUCT	12
3.3 STUDY DESIGN	13
3.4 RANDOMIZATION	13
3.5 STUDY PROCEDURES	14
3.6 EXAMINATION SCHEDULE.....	22
3.7 DATA ANALYSIS AND STATISTICS	24
4. ETHICAL AND LEGAL CONSIDERATIONS	25
4.1 STUDY PERSONNEL.....	25
4.2 DATA ARCHIVING.....	25
4.3 ANONYMITY OF THE SUBJECTS.....	25
4.4 CONSENT TO PARTICIPATE IN THE STUDY.....	25
4.5 USE OF IMAGE	25
4.6 CONFIDENTIALITY	25
4.7 QUALITY ASSURANCE.....	26
4.8 CTRI REGISTRATION	26
4.9 REGULATIONS	26



4.10 PRACTICAL CONSIDERATIONS	26
5. RESULTS.....	27
5.1 DEVIATIONS FROM THE STUDY PROTOCOL	27
5.2 ABSENCES.....	27
5.3 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS	27
5.4 DESCRIPTION OF THE EXPLOITED PANEL	27
5.5 RESULTS OF THE SUBJECT’S SELF ASSESSMENT QUESTIONNAIRE	28
5.6 DERMATOLOGICAL EVALUATION: COSMETIC ACCEPTABILITY	29
5.7 DERMATOLOGICAL EVALUATION : EFFICACY	30
5.8 CHROMAMETRY.....	35
5.9 CORNEOMETRY.....	36
6. DISCUSSION and CONCLUSION.....	37
7. APPENDICES:.....	38
1. QUALITY ASSURANCE STATEMENT	
2. COPY OF THE STUDY PROTOCOL	
3. REPRESENTATIVE IMAGES	





1. EXPERIMENTATION SITE, PARTICIPANTS

1.1 EXPERIMENTATION SITE

MASCOT-SPINCONTROL India Pvt. Ltd.

Sea Breeze Building, 9th Floor,
AppaSaheb Marathe Marg,
Century Bazaar, Prabhadevi,
Mumbai, Maharashtra 400025

SPONSOR

1.2 STUDY SPONSOR

ClayCo. Cosmetics Pvt. Ltd.

Floor-1, 109, Plot-16,
Vithaldas Chamber,
Mumbai Samachar Marg,
Bombay Stock Exchange,
Fort, Mumbai.
Maharashtra – 400001

1.3 STUDY MONITOR

Manali Kadam

Product Head

ClayCo. Cosmetics Pvt. Ltd.

Floor-1, 109, Plot-16,
Vithaldas Chamber,
Mumbai Samachar Marg,
Bombay Stock Exchange,
Fort, Mumbai. Maharashtra – 400001
E-mail: product@clayco.in
Phone number: 8652084238

MASCOT SPINCONTROL INDIA

1.4 STUDY DIRECTOR

Mr. Mohit Lalvani

MD

MASCOT SPINCONTROL

Telephone: +91-22-43349191 / 192

E-mail: mohit@mascotspincontrol.in

Signature:

Date: 05/02/2026





MASCOT SPINCONTROL
Contract Research Organization

1.5 PRINCIPAL INVESTIGATOR

Dr. Niharika Salian

Dermatologist

Reg. No. 2011/05/1530

MASCOT SPINCONTROL

Telephone: +91-22-43349191/ 92

Signature:

Date: 05/02/2026

1.6 QUALITY ASSURANCE MANAGER

Ms. Shraddha Jadhav

General Manager- Quality Assurance

MASCOT-SPINCONTROL

Telephone: +91-22-43349191 / 192

E-mail: shraddhajadhav@mascotspincontrol.in

Signature:

Date: 05/02/2026





2. SUMMARY OF THE STUDY

2.1 OBJECTIVE

The objective of this study was to evaluate the in-vivo safety and efficacy of a skin care formulation in terms of Skin Brightening, Skin Smoothness, Skin Softness, Skin Glow and Skin Hydration on healthy human subjects coded:

- **ClayCo. Rice & Sake Sleep Mask : Product A**

The evaluation was performed using:

- **Subject Self Evaluation**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Dermatological Evaluation: Efficacy**
- **Chromametry**
- **Corneometry**

The study lasts 28 days following the first application of the product on the whole face.

2.2 POPULATION

36 (18 females and 18 male) subjects were selected for the study. The subjects selected for this study will be healthy males and females, aged between **18 and 45 years** old, having wheatish to dark complexion and dry skin.

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

2.3 STUDY DURATION

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





Scheduled Procedures:

	Screening	T0	T+7 Days (± 1 day)	T+14 Days (± 1 day)	T+28 Days (± 1 day)
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		■	■	■	■
Corneometry		■	■	■	■
Distribution of Product, Product Instruction & Diary Sheet		■			
Product Application on site		■			
AE/SAE Monitoring		■	■	■	■
Product Retrieval					■
					End of the study

Study Schedule:

Study Kinetics	Screening + T0	T+7 Days	T+14 Days	T+28 Days
Dates	29/10/2025	05/11/2025	12/11/2025	26/11/2025

2.4 STUDY DESIGN

- Double Blind 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 Organisation as soon as the subject is accepted into the study by the study manager.

The subject must respect 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, and/or English language: i.e. only Hindi, Marathi, 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 (18 females and 18 male)** subjects was made for this study.

SSE, Dermatological Evaluation for Cosmetic Acceptability, Dermatological Evaluation: Efficacy, Chromametry and Corneometry was done on **36 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 and male 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 45 years of age.
- Skin is healthy on the studied anatomic unit (free of eczema, wounds, inflammatory scar....).

Specific criteria

- Having wheatish to dark complexion.
- Having dry skin.

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 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 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 (only face cleaned with water is accepted).





Refusing to follow the restrictions below during the study:

- 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 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 (only usual cleanser/soap is accepted)
- The day of the measurements: No test product must be used (only face 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 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
- Having a suntanned skin on the studied areas which could interfere with the evaluations of the study.





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 the days of study.
- Do not expose yourself to the sun by respecting a strict photo-protection.

All restrictions presented above must be followed during the study.



3.2 THE PRODUCT

3.2.1 Presentation of the product

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

Reference of the product	Batch	Mfg. Date	Expiry Date	Constituent form	Packaging	Capacity
ClayCo. Rice & Sake Sleep Mask: Product A	N/AV	N/AV	N/AV	N/AV	N/AV	N/AV

The study sponsor is 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 agrees 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 is 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
ClayCo. Rice & Sake Sleep Mask: Product A	Whole Face	Once in a day	28 days	At an ambient temperature

Modalities of application:

A sufficient amount of the product was taken and applied evenly, avoiding the eyes and lips. Spread a thin, uniform layer across the forehead, cheeks, nose, and chin. Left overnight without washing off. Used daily as part of the night time skin care routine. The test product was applied daily at night for a period of 28 days.

Note:

The usual cleanser/ soap was kept during the study.

Face was washed only with water on study visits i.e. T+7 days, T+14 days & T+28 days in the morning. The test product was not applied on T+7 days, T+14 days & T+28 days in the morning i.e., on the day of visit.

The test product was applied after going home on T+7 days & T+14 days.

3.3 STUDY DESIGN

- This study was carried out as an “double blind study”. The subjects participating and the investigational site 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 RANDOMIZATION

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+7 days, T+14 days and T+28 days** visit to evaluate the overall opinion and their attitude towards the safety and efficacy of the product and at **T+7 days** for physical characteristics of product under test.

- Studied area: Whole Face

- Procedure

The questionnaires were filled in the Mascot Spincontrol office.

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

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

Product Efficacy

1. The product visibly brightens my skin.
2. The product leaves my skin feeling deeply hydrated.
3. The product improves the smoothness of my skin.
4. The product makes my skin feel soft and supple.
5. The product enhances my skin's natural glow.

Physical Characteristics (only at T+7 days)

6. The fragrance of the test product is appealing.
7. The test product spreads properly on the face.

Product Safety

1. The test product does not cause itching on the skin.
2. The test product does not cause irritation on the skin.
3. The test product does not give burning sensation to the skin.

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 whole face of defined clinical signs (observed by the dermatologist) and functional signs (felt by the subjects and reported to the dermatologist), at T0, T+7 days, T+14 days and 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 of 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+7 days, T+14 days and T+28 days** visit of the following parameters:

- Skin Smoothness (Scale: 0 to 9; 0= very rough skin to 9 = very smooth skin)
- Skin Softness (Scale: 0 to 9; where 0=Very Soft, 0.5 to 3.5=slightly more resistance to pressure, 4 to 7.5= moderate resistance to pressure & 8 to 9=hard like a callous)
- Skin Glow (Scale: 0 to 9, where 0=Facial skin is smooth to touch, without uneven skin tone in any areas (cheeks, forehead, perioral), spots of light present on whole face whatever the angle of observation, 0.5-2.5 = Facial skin shows 1 or more areas (cheeks, forehead, perioral) of slight roughness, slight patches of uneven skin tone (red/brown), spots of light present on 75% -95% of whole face whatever the angle of observation, 3-4.5= Facial skin shows 2 or more areas (cheeks, forehead, perioral) of mild roughness, minimal patches of uneven skin tone (red/brown), spots of light present on 45% -65% of whole face whatever the angle of observation, 5-7= Facial skin shows 2 or more areas (cheeks, forehead, perioral) of moderate roughness, moderate patches of uneven skin tone (red/brown), spots of light present on 15% -35% of whole face whatever the angle of observation & 7.5-9= Facial skin shows all 3 areas (cheeks, forehead, perioral) of significant roughness, severe patches of uneven skin tone (red/ brown), no spots of light present on whole face whatever the angle of observation.

➤ 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 the measurements (temperature: 20°C to 25°C, hygrometry: 50 ±10%).

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

The subject was positioned just below a lamp of 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, for each studied area, using the dedicated scale and reported the grade in the CRF.





➤ Treatment of raw data

• **For Skin Smoothness**

The result was given in terms of a score from 0 to 9 for Skin Smoothness.

- The significant increase in the score for skin smoothness parameter shows an effect of the product in terms of Skin Smoothness.

• **For Skin Softness**

The result was given in terms of a score from 0 to 9 for Skin Softness.

- The significant decrease in the score for Skin Softness parameter shows an effect of the product in terms of Skin Softness.

• **For Skin Glow**

The result was given in terms of a score from 0 to 9 for Skin Glow.

- The significant decrease in the score for Skin Glow parameter shows an effect of the product in terms of Skin Glow.





3.5.4 Chromametry

➤ Acquisition of raw data

- Principle

Tristimulus colorimeters are made of a control unit and a measurement headline associated. The measurement head line takes the measurements from a zone of 8mm in diameter and uses 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 %).

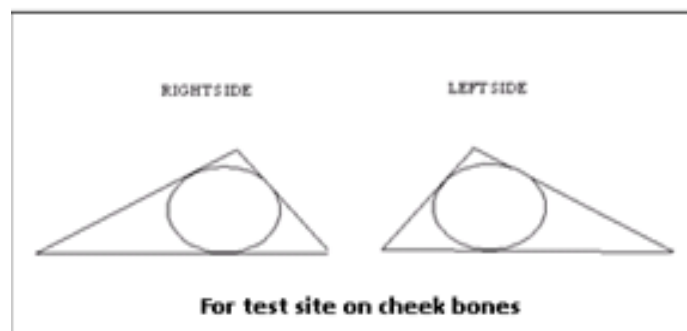
- Subject

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 cheeks, the subject was seated on a chair.

- Studied areas and marking

The measurements were performed **on cheek bones for skin brightening** 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, is made on a transparent film.



- Measurements

Three measurements were carried out on the study areas, for each subject at each examination time. **T0**, **T+7 days**, **T+14 days** and **T+28 days** visits.





- Parameters

The absolute measurement was expressed in the form L^*

- 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 for each site.

A significant increase in L^* **parameter** corresponds to an improvement in **Skin Brightening**.



3.5.5 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.

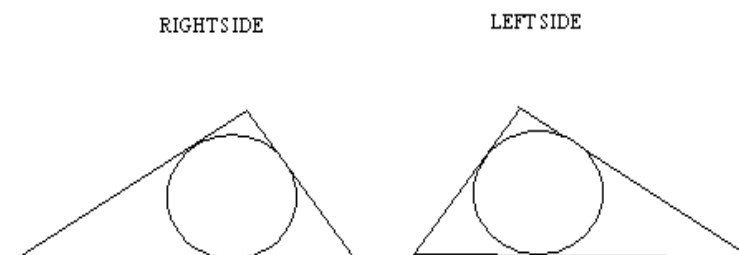
- Subject

A 20-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 was sitting on a chair facing the technician.

- Studied areas and marking.

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



- Measurements

At T0, T+7 days, T+14 days and T+28 days visits the measurements were carried out on both the cheek bones, after wiping delicately 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 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 & was 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.





3.6 EXAMINATION SCHEDULE

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

Screening

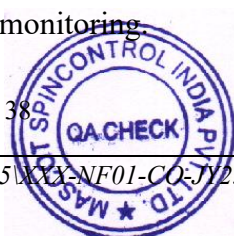
- Registration
- Protocol Briefing
- Consent for screening
- Demographics
- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 mins.
- Concomitant Medication
- Habit Questionnaire
- Clinical observations
- History Questionnaire
- Routine Check-up
- Checking of the inclusion/non-inclusion criteria by dermatologist

At T0

- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 mins.
- 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
- Corneometry
- Weighing of the product
- 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+7 Days: (± 1 day)

- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 mins.
- Proscriptions and Restrictions
- Concomitant Medication
- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Corneometry
- 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 mins.
- Proscriptions and Restrictions
- Concomitant Medication
- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Corneometry
- Adverse Event / Serious Adverse Event monitoring.

At T+28 days: (+ 1 day)

- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 mins.
- Proscriptions and Restrictions
- Concomitant Medication
- Subject Self Evaluation
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Chromametry
- Corneometry
- Retrieval of the Product, Product Instruction & Diary Sheet
- 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 A:

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 product 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%.

Note: All statistical analysis will be done using SigmaStat 3.5 and PAST 4.03.



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

Electronic files are archived on large capacity USB hard disks, which are 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.

4.3 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.

4.4 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.

4.5 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.

4.6 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.



4.7 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.

Audit Schedule:

Sr. No.	Audit Report	Date of Auditing
1.	Audit of study protocol	11/09/2025
2.	Audit of the CRF's	28/10/2025
3.	Audit report of the Trial Master File	09/12/2025
4.	Audit of the Raw Data & Results	09/12/2025
5.	Audit of the Study Report	10/12/2025, 28/01/2026, 05/02/2026

4.8 CTRI REGISTRATION

The study will be registered with Clinical Trials Registry of India (CTRI) after approval from Ethics committee. The subject recruitment started on that site after the CTRI registration of the study.

CTRI Registration Date: 24/09/2025

CTRI Number: CTRI/2025/09/095327

4.9 REGULATIONS

This study is carried out in conformity with the most recent recommendations of the World Medical Association (75th WMA Declaration of Helsinki, Finland, October 2024).

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° 017 INHP3** did not report to the study site on T+7 days visit till T+28 days visit.
The data for this subject is not exploited in the global study results.

➤ **Subject n° 030 PAN88** did not report to the study site on T+28 days visit.
The data for this subject is exploited till T+14 days 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+7 Days	T+14 Days	T+28 Days
Subject Self Evaluation	N/AP	35	35	34
Dermatological Evaluation: Cosmetic Acceptability	36	35	35	34
Dermatological Evaluation: Efficacy	36	35	35	34
Chromametry	36	35	35	34
Corneometry	36	35	35	34

5.4 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of **35 Healthy Indian (18 males and 17 female) subjects**, aged between **18 and 45** years old, (Mean age: **29.5 years old**; SD: **10.1 years old**; Median: **32 years old**) having wheatish to dark complexion and dry skin.



5.5 RESULTS OF THE SUBJECT'S SELF ASSESSMENT QUESTIONNAIRE

The detailed results of the self-assessment questionnaire.

The table below summarizes the agreement percentages recorded for each suggested item for tested product at T+7 days, T+14 days and T+28 days as well as their statistical significance evaluated using Chi-squared test at 5%.

		T+7 Days		T+14 Days		T+28 Days	
Number of subjects		35		35		34	
		% agreement	Significant? (5%)	% agreement	Significant? (5%)	% agreement	Significant? (5%)
1	The product visibly brightens my skin.	69%	Yes	86%	Yes	97%	Yes
2	The product leaves my skin feeling deeply hydrated.	89%	Yes	97%	Yes	100%	Yes
3	The product improves the smoothness of my skin.	71%	Yes	77%	Yes	88%	Yes
4	The product makes my skin feel soft and supple.	77%	Yes	83%	Yes	91%	Yes
5	The product enhances my skin's natural glow.	74%	Yes	89%	Yes	94%	Yes
6	The fragrance of the test product is appealing.	100%	Yes	-	-	-	-
7	The test product spreads properly on the face.	100%	Yes	-	-	-	-
8	The test product does not cause itching on the skin.	100%	Yes	100%	Yes	100%	Yes
9	The test product does not cause irritation on the skin.	100%	Yes	100%	Yes	100%	Yes
10	The test product does not give burning sensation to the skin.	100%	Yes	100%	Yes	100%	Yes

Yes: Significant difference in favor of the product

No: No significant difference

Yes*: Significant difference in disfavor of the product

For test Product A, **all the suggested items are significantly and highly recognized by the panel, after 28 days with 69% to 100% of agreement.**

- Concerning the **product efficacy**, test product A is well appreciated for visibly brightening the skin with **69% to 97% of agreement**, for leaving the skin feeling deeply hydrated with **89% to 100% of agreement**, for improving smoothness of the skin with **71% to 88% of agreement**, for making the skin feel soft and supple with **77% to 91% of agreement** and for enhancing the skin's natural glow with **74% to 94% of agreement** respectively after 28 days of application.
- Concerning the **physical characteristics**, test product A is well appreciated for its appealing fragrance and for proper spreadability on the face with **100% agreement** at given time point (at T+14 days).
- Concerning the **product safety**, test product A is well appreciated for not causing itching, irritation and burning sensation to the skin with **100% agreement** at all the given time points.



5.6 DERMATOLOGICAL EVALUATION: COSMETIC ACCEPTABILITY

The detailed results of the 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:

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 at any given time point for test product A.



5.7 DERMATOLOGICAL EVALUATION : EFFICACY

The detailed results of the Dermatological Evaluation of Efficacy. The studied parameters were:

- Skin Smoothness (Scale: 0 to 9; 0= very rough skin to 9 = very smooth skin)

The significant increase in the score for skin smoothness parameter shows an effect of the product in terms of Skin Smoothness.

- Skin Softness (Scale: 0 to 9; where 0=Very Soft, 0.5 to 3.5=slightly more resistance to pressure, 4 to 7.5= moderate resistance to pressure & 8 to 9=hard like a callous)

The significant decrease in the score for Skin Softness parameter shows an effect of the product in terms of Skin Softness.

- Skin Glow (Scale: 0 to 9, where 0=Facial skin is smooth to touch, without uneven skin tone in any areas (cheeks, forehead, perioral), spots of light present on whole face whatever the angle of observation, 0.5-2.5 = Facial skin shows 1 or more areas (cheeks, forehead, perioral) of slight roughness, slight patches of uneven skin tone (red/brown),spots of light present on 75% -95% of whole face whatever the angle of observation, 3-4.5= Facial skin shows 2 or more areas (cheeks, forehead, perioral) of mild roughness, minimal patches of uneven skin tone (red/brown), spots of light present on 45% -65% of whole face whatever the angle of observation, 5-7= Facial skin shows 2 or more areas (cheeks, forehead, perioral) of moderate roughness, moderate patches of uneven skin tone (red/brown), spots of light present on 15% -35% of whole face whatever the angle of observation &7.5-9= Facial skin shows all 3 areas (cheeks, forehead, perioral) of significant roughness, severe patches of uneven skin tone (red/ brown), no spots of light present on whole face whatever the angle of observation.

The significant decrease in the score for Skin Glow parameter shows an effect of the product in terms of Skin Glow.



5.7.1 Observed Results: Skin Smoothness

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of the **Skin Smoothness** observed on whole face treated with test product A at T0, T+7 days, T+14 days and 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%).

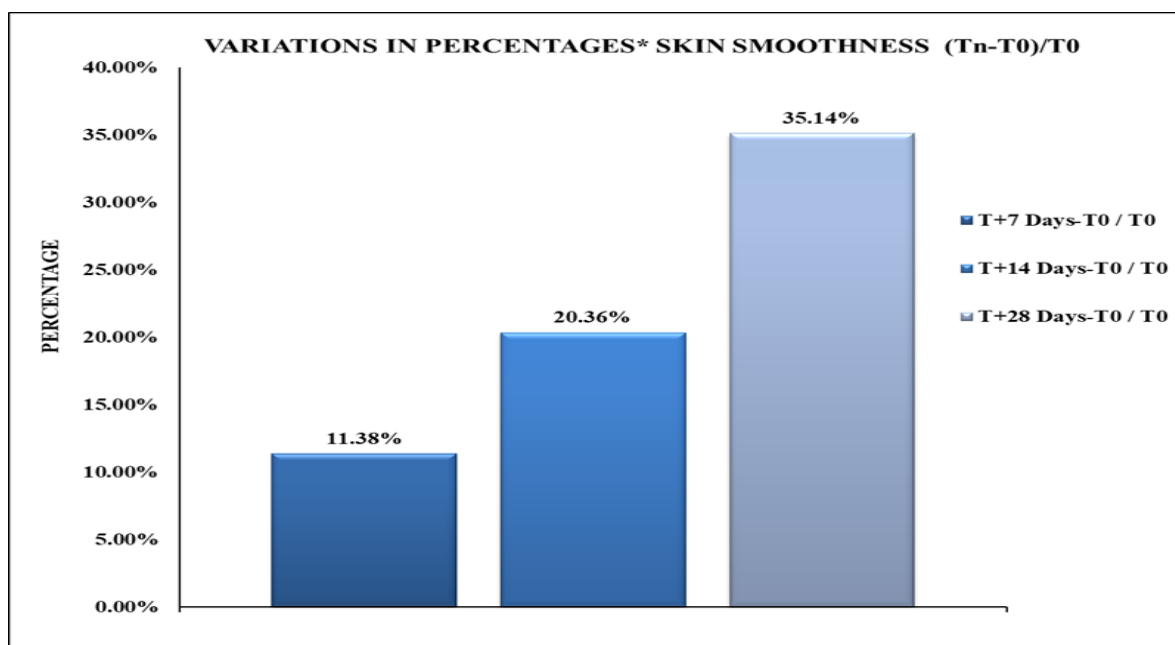
Dermat Efficacy		Skin Smoothness			
		T0	T+7 Days	T+14 Days	T+28 Days
RAW VALUES	N	35	35	35	34
	Mean	4.77	5.31	5.74	6.50
	Standard deviation	0.84	1.05	1.04	1.05
	Significant at 5 % (T0 vs Tn)		Yes	Yes	Yes
	p=		<0.001	<0.001	<0.001
	Test		Wilcoxon	Wilcoxon	Wilcoxon
EVOLUTION OF THE SKIN SMOOTHNESS PARAMETERS(Tn-T0)	Mean		0.54	0.97	1.68
	Standard deviation		0.51	0.57	0.73
VARIATIONS IN PERCENTAGES* SKIN SMOOTHNESS (Tn-T0)/T0	Mean		11.38%	20.36%	35.14%
Yes: Significant difference in favor of the product No: No significant difference Yes*: Significant difference in disfavor of the product		*Calculated based on mean value			

→ Analysis

- The statistical analysis shows a **significant increase in Skin Smoothness by 11.38%, 20.36% & 35.14%** on the whole face treated with test product A on average on whole panel respectively at T+7 days, T+14 days and T+28 days.
- **54%, 83% & 94%** of the panel presented an improvement in the studied respectively at T+7 days, T+14 days and T+28 days.
- **The significant increase in the score for studied parameter shows an effect of the product in terms of Skin Smoothness.**

→ Graphical Representation





5.7.2 Observed Results: Skin Softness

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of the **Skin Softness** observed on whole face treated with test product A at T0, T+7 days, T+14 days and 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%).

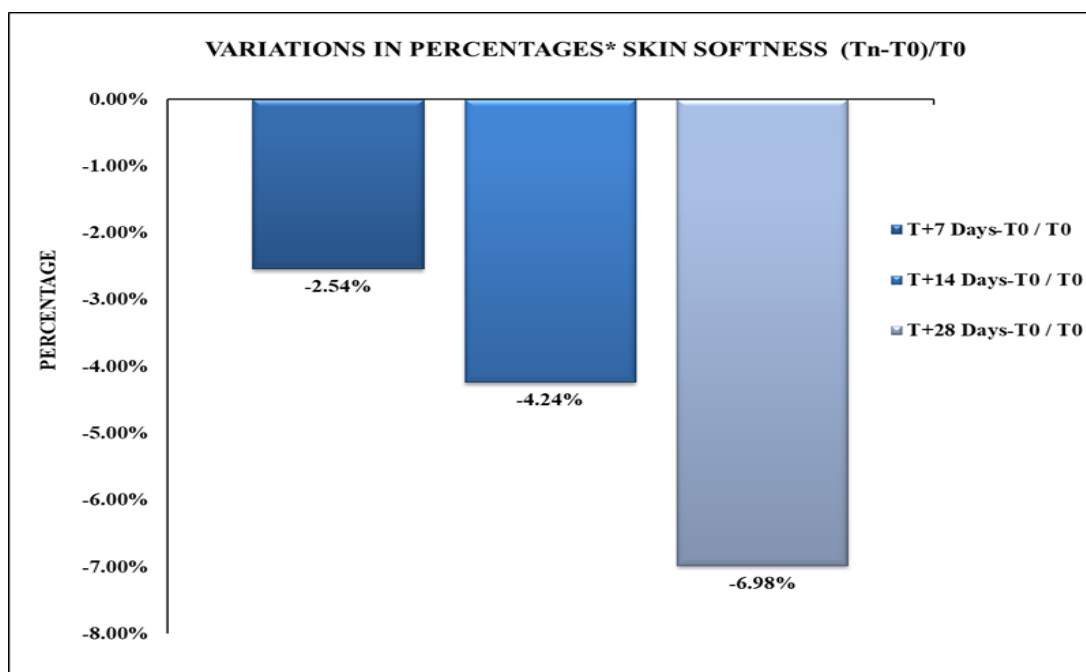
Dermat Efficacy		Skin Softness			
		T0	T+7 Days	T+14 Days	T+28 Days
RAW VALUES	N	35	35	35	34
	Mean	3.37	3.29	3.23	3.13
	Standard deviation	0.51	0.50	0.56	0.55
	Significant at 5 % (T0 vs Tn)		Yes	Yes	Yes
	p=		0.0310	0.0040	<0.001
	Test		Wilcoxon	Wilcoxon	Wilcoxon
EVOLUTION OF THE SKIN SOFTNESS PARAMETERS (Tn-T0)	Mean		-0.09	-0.14	-0.24
	Standard deviation		0.19	0.26	0.33
VARIATIONS IN PERCENTAGES* SKIN SOFTNESS (Tn-T0)/T0		Mean	-2.54%	-4.24%	-6.98%
Yes: Significant difference in favor of the product		*Calculated based on mean value			
No: No significant difference					
Yes*: Significant difference in disfavor of the product					

→ Analysis

- The statistical analysis shows a **significant decrease** in the score by **-2.54%, -4.24% & -6.98%** on the whole face treated with test product A which in terms shows improvement in **Skin Softness** at T+7 days, T+14 days and T+28 days after application of test product A.
- 17%, 26% & 38%** of the panel presented an improvement in the studied parameter respectively at T+7 days, T+14 days and T+28 days.

→ Graphical Representation





5.7.3 Observed Results: Skin Glow

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of the **Skin Glow** observed on whole face treated with test product A at T0, T+7 days, T+14 days and 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 Glow			
		T0	T+7 Days	T+14 Days	T+28 Days
RAW VALUES	N	35	35	35	34
	Mean	3.90	3.81	3.63	3.35
	Standard deviation	0.93	0.94	0.92	1.00
	Significant at 5 % (T0 vs Tn)		Yes	Yes	Yes
	p=		0.0310	<0.001	<0.001
	Test		Wilcoxon	Wilcoxon	Wilcoxon
EVOLUTION OF THE SKIN GLOW PARAMETERS(Tn-T0)	Mean		-0.09	-0.27	-0.54
	Standard deviation		0.19	0.28	0.45
VARIATIONS IN PERCENTAGES* SKIN GLOW (Tn-T0)/T0	Mean		-2.20%	-6.96%	-13.95%

Yes: Significant difference in favor of the product

*Calculated based on mean value

No: No significant difference

Yes*: Significant difference in disfavor of the product

→ Analysis

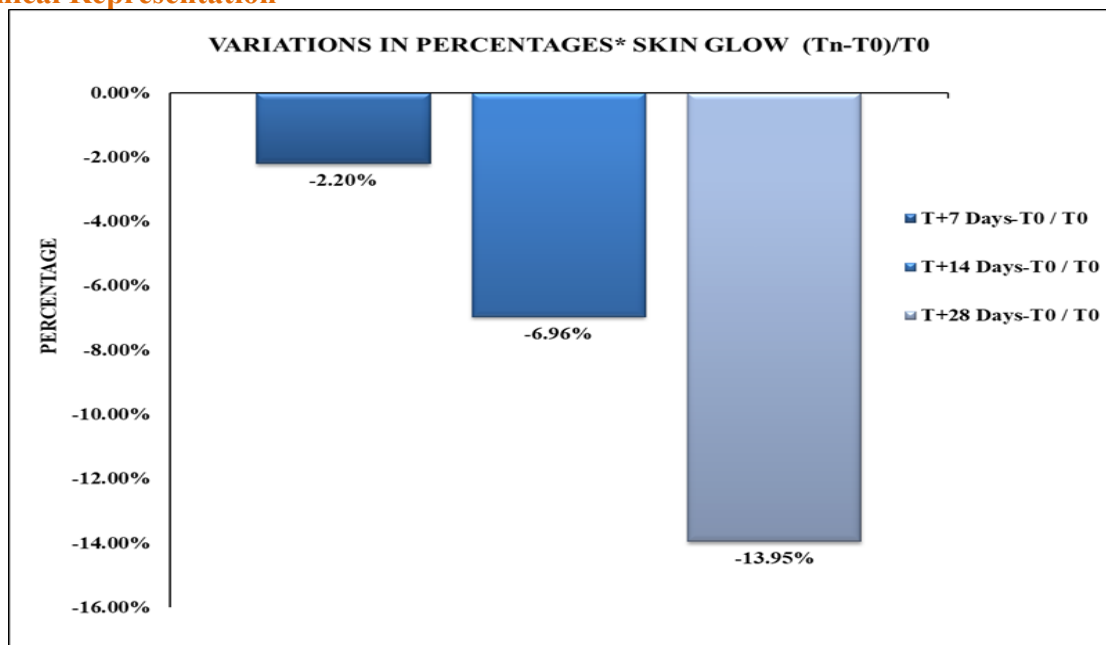
- The statistical analysis shows a **significant decrease** in the score by **-2.20%**, **-6.96%** & **-13.95%** on the whole face treated with test product A which in terms shows improvement in **Skin Glow** at T+7 days, T+14 days and T+28 days after application of test product A.
- 17%**, **51%** & **68%** of the panel presented an improvement in the studied respectively at T+7 days, T+14 days and T+28 days.





- The significant decrease in the score for studied parameter shows an effect of the product in terms of Skin Glow.

→ Graphical Representation



5.8 CHROMAMETRY

The detailed results of the skin colour analysis through Chromametry.

The studied parameter is L*.

A significant increase in the L* shows an effect of the product in terms of Skin Brightening.

5.8.1 Observed results for L*:

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of L* observed on the whole face treated with test product A at T0, T+7 days, T+14 days and 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%).

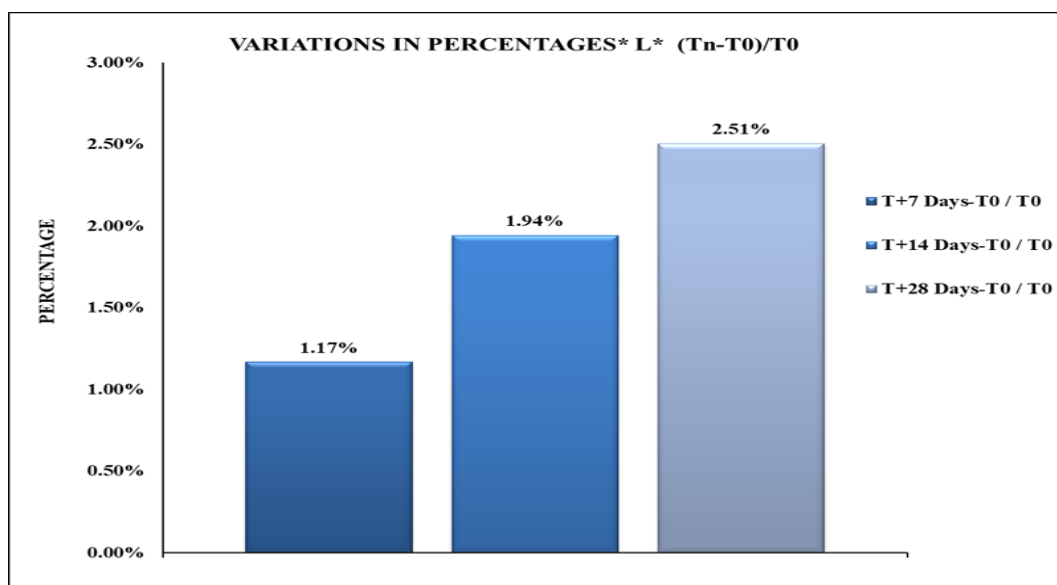
Chromametry		L*			
		T0	T+7 Days	T+14 Days	T+28 Days
RAW VALUES	N	35	35	35	34
	Mean	51.81	52.42	52.82	53.04
	Standard deviation	3.46	3.56	3.52	3.51
	Significant at 5 % (T0 vs Tn) p= Test		Yes <0.001 Paired Student t test	Yes <0.001 Paired Student t test	Yes <0.001 Wilcoxon
EVOLUTION OF THE L* PARAMETERS (Tn-T0)	Mean		0.60	1.01	1.30
	Standard deviation		0.28	0.53	0.96
VARIATIONS IN PERCENTAGES* L* (Tn-T0)/T0	Mean		1.17%	1.94%	2.51%
<p>Yes: Significant difference in favor of the product</p> <p>No: No significant difference</p> <p>Yes*: Significant difference in disfavor of the product</p>		*Calculated based on mean value			

→ Analysis

- The statistical analysis shows a **significant increase in L* parameter by 1.17%, 1.94% & 2.51%** on the whole face treated with test product A on average on whole panel respectively at T+7 days, T+14 days and T+28 days.
- **100%** of the panel presented an improvement in the studied parameter respectively at T+7 days, T+14 days and T+28 days.
- **A significant increase in L* parameter shows an improvement in Skin Brightening.**

→ Graphical Representation





5.9 CORNEOMETRY

The detailed results of the Corneometry measurements.

The studied parameter is the Capacitance. A significant increase in capacitance shows a Moisturizing Effect of the product.

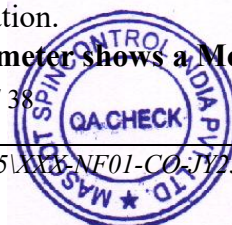
5.9.1 Observed results:

The following table summarises the means and standard deviations of the raw values, evolution & percent variation of the of the **Capacitance** parameter, observed on whole face treated with test product A at T0, T+7 days, T+14 days and 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+7 Days	T+14 Days	T+28 Days
RAW VALUES	N	35	35	35	34
	Mean	44.00	50.30	56.21	62.22
	Standard deviation	3.86	3.72	4.06	5.82
	Significant at 5 % (T0 vs Tn) p= Test		Yes <0.001 Wilcoxon	Yes <0.001 Paired Student t test	Yes <0.001 Paired Student t test
EVOLUTION OF THE CAPACITANCE PARAMETERS(Tn-T0)	Mean		6.30	12.21	17.99
	Standard deviation		2.44	4.60	6.78
VARIATIONS IN PERCENTAGES* CAPACITANCE (Tn-T0)/T0	Mean		14.31%	27.76%	40.89%
Yes: Significant difference in favor of the product		*Calculated based on mean value			
No: No significant difference					
Yes*: Significant difference in disfavor of the product					

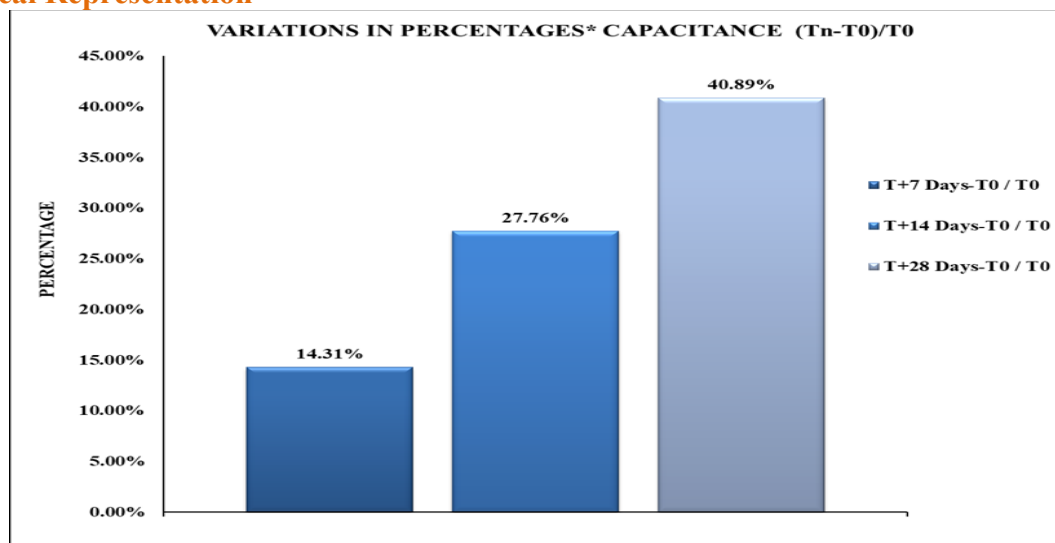
→ Analysis

- The statistical analysis shows a **significant increase in capacitance** parameter by **14.31%, 27.76% & 40.89%** on whole face treated with test product A on average on whole panel respectively after T+7 days, T+14 days and T+28 days of application.
- **100%** of the panel presented an improvement in the studied parameter respectively after T+7 days, T+14 days and T+28 days of product application.
- A **significant increase in capacitance parameter shows a Moisturizing Effect of the product.**





→ Graphical Representation



6. DISCUSSION and CONCLUSION

Once a day application of the test product coded **ClayCo. Rice & Sake Sleep Mask: Product A**, on a panel of **35 Healthy Indian (18 males and 17 female) subjects** aged between **18 and 45 years** old, having wheatish to dark complexion and dry skin, leads to the following results after 28 days of test.

✓ 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, on the whole panel, no occurrence of the clinical and functional signs was observed after 28 days of application of test product A.

✓ Dermatological Evaluation (Efficacy):

- The statistical analysis shows a **significant increase in Skin Smoothness** by **11.38%, 20.36% & 35.14%** respectively after 7 days, 14 days & 28 days on the whole face treated with test product A on average on whole panel, shows an **effect of the product in terms of Skin Smoothness**.
- The statistical analysis shows a **significant decrease** in the score by **-2.54%, -4.24% & -6.98%** on the whole face treated with test product A which in terms shows improvement in **Skin Softness** at T+7 days, T+14 days and T+28 days after application of test product A.
- The statistical analysis shows a **significant decrease** in the score by **-2.20%, -6.96% & -13.95%** on the whole face treated with test product A which in terms shows **improvement in Skin Glow** at T+7 days, T+14 days and T+28 days after application of test product A.

✓ Chromametry

- The statistical analysis shows a **significant increase in the L* parameter** by **1.17%, 1.94% & 2.51%** on the whole face treated with test product A on average on whole panel respectively after 7 days, 14 days & 28 days which shows an effect of the product in terms of **Skin Brightening**.

✓ Corneometry:

- The statistical analysis shows a **significant increase in capacitance** parameter by **14.31%, 27.76% & 40.89%** on the whole face treated with test product A on average on whole panel respectively after 7 days, 14 days & 28 days which shows **Moisturizing Effect** of the product.





To conclude, in the experimental conditions of the study, after 28 days for test product coded ClayCo. Rice & Sake Sleep Mask: Product A, the following points have been demonstrated.

- A significant increase in the grade of skin smoothness parameter through Dermat Efficacy, shows effect of the product in terms of Skin Smoothness after 28 days of application of test product A.
 - A significant decrease in the grade of skin softness & skin glow parameter through Dermat Efficacy, shows effect of the product in terms of Skin Softness & Skin Glow after 28 days of application of test product A.
 - A significant increase in L* through Chromametry, shows effect of the product in terms of Skin Brightening after 28 days of application of test product A.
 - A significant increase in capacitance through Corneometry, shows Moisturizing Effect of the product after 28 days of application of test product A.
 - Appreciation from the panel is obtained for test product A through subject self-evaluation for product efficacy, product characteristics & product acceptability.
- Moreover, no unfavourable aggravation of clinical & functional sign was observed after 28 days of application of test product A.

7. APPENDICES:





APPENDIX 1:
QUALITY ASSURANCE STATEMENT



Quality Assurance Statement

This study (XXX-NF01-CO-JY25) 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:

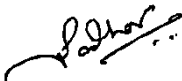
Sr. No.	Audit Report	Audit Report Number	Date of Audits
1.	Audit of study protocol	XXX-NF01-CO-JY25-AU01	11/09/2025
2.	Audit of the CRF's	XXX-NF01-CO-JY25-AU02	28/10/2025
3.	Audit report of the Trial Master File	XXX-NF01-CO-JY25-AU03	09/12/2025
4.	Audit of the Raw Data & Results	XXX-NF01-CO-JY25-AU04	09/12/2025
5.	Audit of the Study Report	XXX-NF01-CO-JY25-AU05	10/12/2025, 28/01/2026, 05/02/2026

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: 05/02/2026
Auditor(s)

Signature: N/AP
Auditor(s)-



Signature: 05/02/2026
Quality Assurance Manager





APPENDIX 2:
COPY OF PROTOCOL





STUDY SUMMARY: XXX-NF01-CO-JY25
Test Product: ClayCo. Rice & Sake Sleep Mask: Product A

DESCRIPTION OF THE STUDY:

EVALUATION OF THE SAFETY AND EFFICACY OF A SKIN CARE FORMULATION THROUGH:

- **Subject Self Evaluation**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Dermatological Evaluation: Efficacy**
- **Chromametry**
- **Corneometry**

NATURE OF THE TESTED PRODUCT AND METHODOLOGY:

Test Product reference	<i>ClayCo. Rice & Sake Sleep Mask: Product A</i>
Study design	<i>It was a double blinded, non-comparative study. Subjects served as their own reference.</i>
Total duration of the study	<i>28 days following the first application of product.</i>
Kinetic	<i>T0, T+7 days, T+14 days and T+28 days</i>
Product application	<i>Once a day on whole face</i>
Number of volunteers	<i>35 Healthy Indian (18 Males & 17 Female) subjects</i>
Special selection criteria	<i>Having wheatish to dark complexion and dry skin</i>

RESULTS AND CONCLUSION

Once a day application of the test product coded **ClayCo. Rice & Sake Sleep Mask: Product A**, on a panel of **35 Healthy Indian (18 males and 17 female) subjects** aged between **18 and 45 years** old, having wheatish to dark complexion and dry skin, leads to the following results after 28 days of test.

✓ **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, on the whole panel, no occurrence of the clinical and functional signs was observed after 28 days of application of test product A.

✓ **Dermatological Evaluation (Efficacy):**

- The statistical analysis shows a **significant increase in Skin Smoothness** by **11.38%, 20.36% & 35.14%** respectively after 7 days, 14 days & 28 days on the whole face treated with test product A on average on whole panel, shows an **effect of the product in terms of Skin Smoothness**.
- The statistical analysis shows a **significant decrease** in the score by **-2.54%, -4.24% & -6.98%** on the whole face treated with test product A which in terms shows improvement in **Skin Softness** at T+7 days, T+14 days and T+28 days after application of test product A.
- The statistical analysis shows a **significant decrease** in the score by **-2.20%, -6.96% & -13.95%** on the whole face treated with test product A which in terms shows **improvement in Skin Glow** at T+7 days, T+14 days and T+28 days after application of test product A.

✓ **Chromametry**

- The statistical analysis shows a **significant increase in the L* parameter** by **1.17%, 1.94% & 2.51%** on the whole face treated with test product A on average on whole panel respectively after 7 days, 14 days & 28 days which shows an effect of the product in terms of **Skin Brightening**.

✓ **Corneometry:**





- The statistical analysis shows a **significant increase in capacitance** parameter by **14.31%, 27.76% & 40.89%** on the whole face treated with test product A on average on whole panel respectively after 7 days, 14 days & 28 days which shows **Moisturizing Effect** of the product.

To conclude, in the experimental conditions of the study, after 28 days for test product coded ClayCo. Rice & Sake Sleep Mask: Product A, the following points have been demonstrated.

- A significant increase in the grade of skin smoothness parameter through Dermat Efficacy, shows effect of the product in terms of Skin Smoothness after 28 days of application of test product A.
- A significant decrease in the grade of skin softness & skin glow parameter through Dermat Efficacy, shows effect of the product in terms of Skin Softness & Skin Glow after 28 days of application of test product A.
 - A significant increase in L* through Chromametry, shows effect of the product in terms of Skin Brightening after 28 days of application of test product A.
- A significant increase in capacitance through Corneometry, shows Moisturizing Effect of the product after 28 days of application of test product A.
- Appreciation from the panel is obtained for test product A through subject self-evaluation for product efficacy, product characteristics & product acceptability.
- Moreover, no unfavourable aggravation of clinical & functional sign was observed after 28 days of application of test product A.





APPENDIX 3:

REPRESENTATIVE IMAGES





MASCOT SPINCONTROL
Contract Research Organization

SUBJECT NO :001 (WHOLE FACE)



T0



T+7 DAYS



T+14 DAYS



T+28 DAYS





MASCOT SPINCONTROL
Contract Research Organization

SUBJECT NO :001 (LEFT HALF FACE)



T0



T+7 DAYS



T+14 DAYS



T+28 DAYS





SUBJECT NO :001 (RIGHT HALF FACE)



T0



T+7 DAYS



T+14 DAYS



T+28 DAYS





MASCOT SPINCONTROL
Contract Research Organization

SUBJECT NO :002 (WHOLE FACE)



T0



T+7 DAYS



T+14 DAYS



T+28 DAYS





MASCOT SPINCONTROL
Contract Research Organization

SUBJECT NO :002 (LEFT HALF FACE)



T0



T+7 DAYS



T+14 DAYS



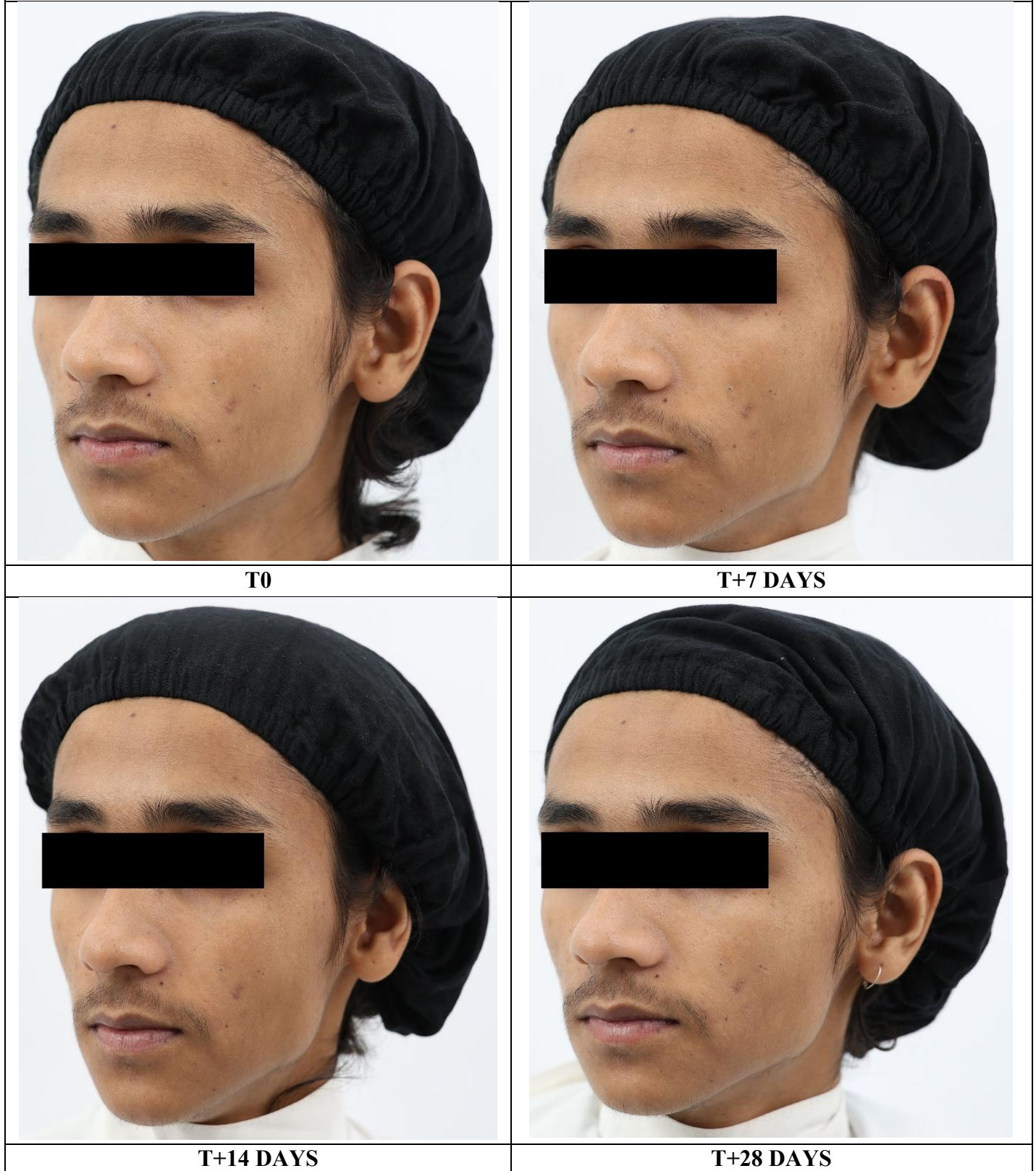
T+28 DAYS





MASCOT SPINCONTROL
Contract Research Organization

SUBJECT NO :002 (RIGHT HALF FACE)





SUBJECT NO :003 (WHOLE FACE)



T0



T+7 DAYS



T+14 DAYS



T+28 DAYS





MASCOT SPINCONTROL
Contract Research Organization

SUBJECT NO :003 (LEFT HALF FACE)



T0



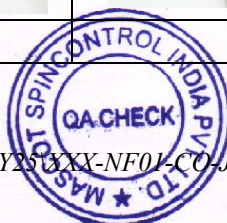
T+7 DAYS



T+14 DAYS



T+28 DAYS





MASCOT SPINCONTROL
Contract Research Organization

SUBJECT NO :003 (RIGHT HALF FACE)



T0



T+7 DAYS



T+14 DAYS



T+28 DAYS

