MASCOT SPINCONTROL
clinical research centre

SPINCONTROL®
au coeur de la peau...

CONFIDENTIAL REPORT

Ref: XXX-HD01-EV-AT23

Version: 01

Dated: 22/11/2023

EVALUATION & COMPARISON OF EFFICACY AND SAFETY OF SKIN CARE FORMULATION VERSUS UNTREATED CONTROL THROUGH

- **Subject Self Evaluation (SSE)**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Dermatological Evaluation: Efficacy**
- **Corneometry**

TEST PRODUCT REFERENCE:

- **Ultra Protect Fluid Sunscreen (1540) : Product D**

Study Sponsor:
Effeza Science Pvt Ltd
A/G-1, Dheeraj Heritage Residency 1,
Shastri Nagar, Linking Road Extn,
Santacruz And est, Mumbai-400054

Investigator:
MASCOT SPINCONTROL INDIA PVT. LTD.
Kohinoor Estate, 3rd Floor,
Sun Mill Compound,
Lower Parel West,
Mumbai – 400013, INDIA

NOVEMBER 2023

CONTENTS

1. EXPERIMENTATION SITE, PARTICIPANTS

1.1 EXPERIMENTATION SITE

MASCOT-SPINCONTROL India Pvt. Ltd.
Kohinoor Estate, 3rd Floor,
Sun Mill Compound, Lower Parel West,
Mumbai – 400013, INDIA
Telephone: +91-22-43349191/192
E-mail:info@mascotspincontrol.in

SPONSOR

1.2 STUDY SPONSOR

Effeza Science Pvt Ltd.
A/G-1, Dheeraj Heritage Residency 1,
Shastri Nagar, Linking Road Extn,
Santacruz And est, Mumbai-400054.

1.3 STUDY MONITOR

Mr. Gajanan Pai.
Effeza Science Pvt Ltd.
A/G-1, Dheeraj Heritage Residency 1,
Shastri Nagar, Linking Road Extn,
Santacruz And est, Mumbai-400054.
Telephone (M): +91-7700925972
E-mail: gajanan@effezascience.com

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:

1.5 PRINCIPAL INVESTIGATOR

Dr. Raji Patil
Dermatologist
Reg. No. 2004/01/330
MASCOT SPINCONTROL
Telephone: +91-22-43349191 / 192
E-mail: raji@mascotspincontrol.in

Signature:

Date:

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:

2. SUMMARY OF THE STUDY

2.1 OBJECTIVE

The objective of this study was to evaluate the in-vivo safety and efficacy of Skin Care formulation and comparison (of Treated versus Untreated Area) in terms of skin moisturization and Softness on healthy human subjects coded:

- **Ultra Protect Fluid Sunscreen(1540) : Product D**

The evaluation was performed using:

- **Subject Self Evaluation (SSE)**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Dermatological Evaluation: Efficacy**
- **Corneometry**

The study lasted 24 Hours, following the application of the product.

2.2 POPULATION

33 (17 females & 16 males) subjects were selected for this study.
The subjects selected for this study were healthy females and males aged between 19 and 38 years, having dry skin on forearms.

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

2.3 STUDY DURATION

Duration: 24 Hours following the application of the product.

Scheduled Procedures:

	Screening	T0	T+8 hours	T+24 hours
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)		■	■	■
Corneometry		■	■	■
Product Application on site		■		
AE/SAE Monitoring		■	■	■
				End of the study

Study Schedule:

T0	T+8 Hours	T+ 24 Hours
07/09/2023	**07/09/2023**	**08/09/2023**

2.4 STUDY DESIGN

- Single blind study.
- Comparative study.
- Subjects served as their own reference for the intra-group comparison (evaluation of the efficacy on time of each product) and do not served as their own reference for the inter-group comparison (comparison of the efficacy of the test product & with control).

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 and Children Assent 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 incharge.

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.

The subjects selected for the study were chosen under the supervision of the investigator and study incharge, on the basis of the inclusion/non inclusion criteria listed below.
A selection of 33 (17 females and 16 males) subjects was made for this study.
SSE, Dermatological Evaluation for Cosmetic Acceptability, Cosmetic Efficacy & Corneometry were done on 33 subjects.
The results given include 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 male & 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

- Subject having dry skin on forearms.

3.1.2 Non-inclusion criteria

Standard criteria

- For Females: Being pregnant or breastfeeding or having stopped to breastfeed in the past three months.
- Having refused to give his/her assent by not signing the consent form and Informed consent form
- Taking part in another study liable to interfere with this study
- Being known diabetic case
- Known asthma case
- Having a chronic dermatosis liable to modify the cutaneous reactivity on the tested area (except for specific studies on a determined dermatosis)
- Being known thyroid case
- Being epileptic.
- 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 or corticosteroid by any route (the only medication permitted is paracetamol)
- Known case of hypersensitivity.
- Having a diagnosed or highly probable allergy to one or several compounds of the cosmetic products.
- Having undergone a surgery requiring a general anaesthetic of more than one hour in the past 6 months.
- Having changed their cosmetic habits except those required by the protocol 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 48 hours prior study.

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 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 product to the studied areas.

Specific criteria

- Having started, changed or stopped a hormonal treatment (hormonal contraception, Hormone Replacement Therapy, thyroid…) in the past 3 months.
- Having taken an oral retinoid-based treatment in the past 6 months
- Having taken a local retinoid-based treatment on the studied areas in the previous month
- Having had beauty treatment (e.g., scrub, manicure, self-tanning product …) in the previous week
- Having practiced water activities (swimming pool, sauna, hammam, baleneotherapy etc.) in the previous week.
- Having practiced water activities (swimming pool, sauna, hammam, baleneotherapy etc.) in the previous week
- Having consumed caffeine-based products (coffee, cola, tea, …), alcohol, highly spiced food and/or not smoke in the two hours preceding the measurements
- Having practiced intensive sports during the day prior to the T0 measurements
- Having wounds, Scars, sunburns, tattoos, and piercings on test site.
- Having hair on test site.
- Having applied another product than water on the studied areas in the morning of the T0 measurements
- Having had an intensive UV exposition on the inner forearm (solariums, sun) prior to T0 measurements.
- Having used moisturizing products on the arms during 24 hours prior to T0 measurements.

Refusing to follow the restrictions below during the study:

- Do not have beauty treatment (e.g., scrub, manicure self-tanning product …)
- Do not practice water activities (swimming pool, sauna, hammam, balneotherapy etc.)
- Do not drink/ eat caffeine-based products (coffee, cola, tea, …), alcohol, highly spiced food, nor smoke.
- Do not practice sport.
- Do not apply any product on forearms including water.
- Do not wipe their forearms.
- Do not wear jewels on the wrists.
- Do not have an intensive UV exposition on the arms (solariums, sun).

Between T0 and T+24 Hour's measurements:

- Do not use skin care products on the forearms.
- Do not wash the forearms.
- Do not use Surfactant containing product on the test sites.
- Daily morning hygiene with water accepted except on forearms.

All restrictions presented above must be followed during the study. These restrictions are also presented in the informed consent form.

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	Product Code	Batch number	Mfg. Date	Expiry Date	Constituent form	Packaging	Capacity
Ultra Protect Fluid Sunscreen(1540)	**D**	**1540**	**17-08-2023**	**N/AV**	**Liquid**	**Pet jar**	**200 ml**

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.
Product was stored in an ambient temperature away from light.
At the end of the study, the product used by the volunteers or the left over product 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 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 trained CRA at Mascot Spincontrol:

Product	Application area	Frequency of application	Application duration	Conservation
Ultra Protect Fluid Sunscreen (1540)	Forearm Site	Once on site	24 Hours	At ambient temperature

Modalities of test product application:

2 site of 3 x 3 cm^2 was marked on forearm. Application was carried out on the forearm for test product and one site served as control/untreated site.

An amount of 20 µl of test Product was dispensed in the randomized site of 3 x 3 cm^2 from a disposable syringe/ micropipette on previously marked area on forearm and carefully spreaded with a finger protected by a finger cot. Afterwards kept the test site uncovered for at least 5 minutes to get absorbed into the skin. One site was served as control/untreated site.

Note :
Do not wash the forearm with water on next 24 Hours.
Do not use any other product till the end of the study.
Do not wipe/ clean the forearm.

3.3 STUDY DESIGN

- This study was carried out as a "single blind test". The subjects participating were not aware of the type of product being applied.
- This was a comparative study in which the results obtained by treated area is compared with control /untreated area respectively.
- Subjects served as their own reference for the intra-group comparison (evaluation of the efficacy on time of each product) and do not served as their own reference for the inter-group comparison (comparison of the efficacy of the test product with control).

3.4 RANDOMISATION

The selection of the areas to be treated by the product and of the untreated area was determined at random for each subject and is carried out using software designed for this purpose.

3.5 STUDY PROCEDURES

3.5.1 Subject Self Evaluation

➢ *Acquisition of source data*

- Principle

The subjects were asked to answer a self-evaluation questionnaire in order to evaluate the overall opinion and their attitude towards the efficacy of the product, product characteristics at T+8 Hours & T+24 Hours.

- Studied area: 2 sites on Forearm.

- 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 filing 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:

Questionnaires:

Product Efficacy

1. The test product made my skin moisturized/hydrated.
2. The test product made my skin soft.

Physical Characteristics of product (only at T+8 hours)

1. The fragrance of the test product is appealing.
2. The test product gets quickly absorbed in skin.

Product Acceptability

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

For each Item, the possible answers were:
Scale: 1 = Completely agree,
2 = Somewhat agree,
3 = Somewhat disagree,
4 = Completely disagree

➢ *Treatment of Raw Data*

Questionnaires was filled out manually in Paper version and all the capture data was treated and Analyzer with Microsoft Excel.

3.5.2 Dermatological Evaluation (Cosmetic Acceptability)

➢ *Acquisition of source data*

- Principle

Safety of the product was assessed by the dermatologist, through the grading on all sites on forearms of defined clinical signs (observed by the dermatologist) and functional signs (felt by the subjects and reported to the dermatologist), at T0, T+8 hours, and T+24 hours 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 at room temperature. The lighting was ensured by a ceiling lamp.

- Subject

A 20-minute period of acclimatization at room temperature was respected for the subject prior the measurements. 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: 2 sites marked on forearm.

- Measures

The dermatologist assessed each descriptor using the dedicated scale and reports 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.

3.5.3 Dermatological Evaluation by a Dermatologist (Efficacy)

➢ *Acquisition of source data*

- Principle

The overall product efficacy was assessed by the dermatologist, through the grading at T0, T+8 hours, and T+24 hours visit of the following parameters:

- 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)

➢ *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%).

- 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: 2 sites marked on forearm.

- Measures

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

➢ *Treatment of raw data*

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.

3.5.4 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

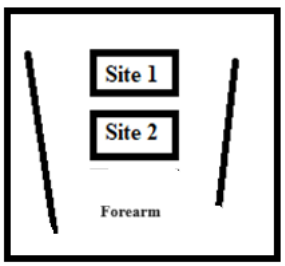
Prior to each series of measurements, the calibration of the device was checked according to the procedure supplied by the manufacturer.

- 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 towards technician.

- Studied areas and marking.

The measurements was performed on all the marked sites on forearms. The site to be measured at each kinetics was reproducible. The site was determined by a cutaneous marking at T0 with the help of gauge.



- Measurements

At T0, T+8 hours, and T+24 hours the measurements were carried out on the control/untreated area and on each treated areas, after wiping delicately the skin with an absorbent paper.
3 measurements were performed on the study areas for each subject and at 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 given 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 effect of the product was evaluated over 24 Hours following the application of the product. The scheduled measurement procedures were as follows:

Screening

- Registration
- Protocol Briefing
- Consent for screening
- Concomitant Medication
- Demographics
- Clinical Observation
- Habit Questionnaire
- History Questionnaire
- Routine Check-up
- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 mins.
- 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
- Corneometry
- Weighing of the product
- Product application.
- Adverse Event/ Serious Adverse Event Monitoring

At T+8 hours after product application

- Subject Self evaluation (SSE)
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Corneometry
- Adverse Event/ Serious Adverse Event Monitoring.

At T+24 hours after product application

- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 mins.
- Proscription & Restriction
- Concomitant Medication
- Subject Self evaluation (SSE)
- Dermatological Evaluation: Cosmetic Acceptability
- Dermatological Evaluation: Efficacy
- Corneometry
- 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 for cosmetic acceptability)

Carried out by Study Incharge at Mascot Spincontrol India Pvt. Ltd.

The results include:

- Raw values for each subject at each examination.
- Differences, in relation to T0 for each subject during the study (Tn – T0).
- 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.

Comparison in time for product:

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

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

Comparison of the treated site (test product) with untreated site (control):

The normality of the distributions was checked using Shapiro-Wilk test, threshold at 1% for the comparison between the treated area and untreated area at T0 and at Tn-T0. The statistical comparison between the treated area and untreated area at T0 and on the differences (Tn-T0), for each of the measured parameters, was performed with the Student test (normality of distributions checked) or the Wilcoxon test (normality of the distributions rejected). The significance threshold was fixed at 5%.

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 were 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 were 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 was evaluated using the Chi-squared test at 5%.

Note: All statistical analysis was 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

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 121200/48/2023/6655).

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 the protocol and the current procedures.
Schedule of Audit:

Sr. No.	Audit Report	Date of Auditing
1.	Audit of study protocol	30/08/2023
2.	Audit of the CRF's	06/09/2023
3.	Audit of the Raw Data & Results	14/09/2023
4.	Audit report of the Trial Master File	14/09/2023
5.	Audit of the Study Report	22/09/2023, 22/11/2023

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 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS

At T0, 33 subjects were recruited

Considering the information previously mentioned in the paragraph 5.1, 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+8 hours after product application	T+24 hours after product application
Subject Self Evaluation	**N/AP**	**33**	**33**
Dermatological Evaluation (Cosmetic Acceptability)	**33**	**33**	**33**
Dermatological Evaluation (Efficacy)	**33**	**33**	**33**
Corneometry	**33**	**33**	**33**

5.3 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of 33 (17 females & 16 males) Healthy Indian subjects, aged between 19 and 38 years old, (average age: 25.1 years old; standard deviation in year 5.3 and median age is 23 please see details in appendix 1) and **having dry skin with corneometer reading ≤30 on forearms.**

5.4 RESULTS OF THE SUBJECT'S SELF EVALUATION

5.4.1. Table of results:

The table below summarises the agreement percentages recorded for each suggested item for Product D after **T+ 8 hours & T+24hours,** of product application, as well as their statistical significance evaluated using Chi-squared test at 5%.

➢ **Product D:**

Product D
SUBJECT SELF-EVALUATION QUESTIONNAIRE

		T+8 hours after product application		T+24 hours after product application	
	Number of subjects	*33*		*33*	
		% agreement	*Significant ? (5%)*	*% agreement*	*Significant ? (5%)*
1	The test product made my skin moisturized/hydrated.	100%	Yes	97%	Yes
2	The test product made my skin soft.	100%	Yes	97%	Yes
3	The fragrance of the test product is appealing	82%	Yes	-	-
4	The test product gets quickly absorbed in skin	73%	Yes	-	-
5	The test product does not cause itching.	100%	Yes	100%	Yes
6	The test product does not cause stinging.	100%	Yes	100%	Yes
7	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

All the suggested items are significantly and highly recognized by the panel, at T+ 8 hours & T+24hours of study with 73% to 100% of agreement for Product D for all the items.

- Concerning the **product efficacy**, test product D is well appreciated for **moisturizing the skin** & making skin soft with 100% agreement at **T+ 8 hours** & 97% agreement at T+ 24 hours hours after product application.
- Concerning the **physical characteristics**, test product D is well appreciated throughout the study for its **appealing fragrance with 82% agreement** and for **quick absorption** with 73% agreement.
- Concerning the **product acceptability**, test product D is well appreciated for not causing itching, irritation and burning sensation to the skin with 100% agreement at **T+ 8 hours & T+24hours** after product application.

5.5 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 evaluation was performed using the following scale:

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

5.5.1 Observed results for Product D

The dermatologist recorded no occurrence of clinical & functional signs for any of subject out of 33 for the test product.

The average of all the parameters is 0 out of 3 which signifies no occurrence of Erythema, Oedema, Dryness, Scaling, Peeling, Itching and Tingling till T+24 hours after product application for the test **Product D**.

5.6 DERMATOLOGICAL EVALUATION BY A DERMATOLOGIST (EFFICACY)

The product efficacy, was assessed by the dermatologist, through the grading at T0,T+8 hours after product application & T+24 hours after product application after product application visit of the following parameters:

- 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).

5.6.1 Observed Results: For Skin Softness

➢ **Raw values**

The following table summarizes the means and standard deviations of the raw values of the studied parameter, observed on forearm treated with test Product D & untreated control at **T0, T+8 hours after product application & T+24 hours after product application,** 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%).

			RAW VALUES		
			T0	T+8 hours after product application	T+24 hours after product application
Skin Softness	Product D	N	33	33	33
		Mean	3.58	2.77	3.23
		Standard deviation	*0.28*	*0.47*	*0.38*
		Significant at 5 % (T0 vs Tn)		Yes	Yes
		p=		*<0.001*	*<0.001*
		Test		*Wilcoxon*	*Wilcoxon*
	Control	N	33	33	33
		Mean	3.58	3.58	3.56
		Standard deviation	*0.28*	*0.28*	*0.27*
		Significant at 5 % (T0 vs Tn)		No	No
		p=		*1.00E+00*	*1.00E+00*
		Test		*Wilcoxon*	*Wilcoxon*

Yes: Significant difference in favor of the product

No: No significant difference

Yes*: Significant difference in disfavor of the product

➢ **Evolutions (Tn-T0)**

The following table presents the means and the standard deviations of the evolutions (Tn-T0) of the studied parameter, observed on the Forearm sites treated with test Product D and untreated control.

			EVOLUTION OF THE Tn-T0	
			T+8 hours after product application - T0	T+24 hours after product application - T0
Skin Softness	Product D	Mean Standard deviation	**-0.80** *0.37*	**-0.35** *0.34*
	Control	Mean Standard deviation	**0.00** *0.00*	**-0.02** *0.09*

➢ **Variations (Tn-T0)/T0 (%)**

The following table summarizes the average percentages of the variation (Tn-T0)/T0 of the studied parameter, observed on the forearm treated with Product D and untreated control, calculated from the average values.

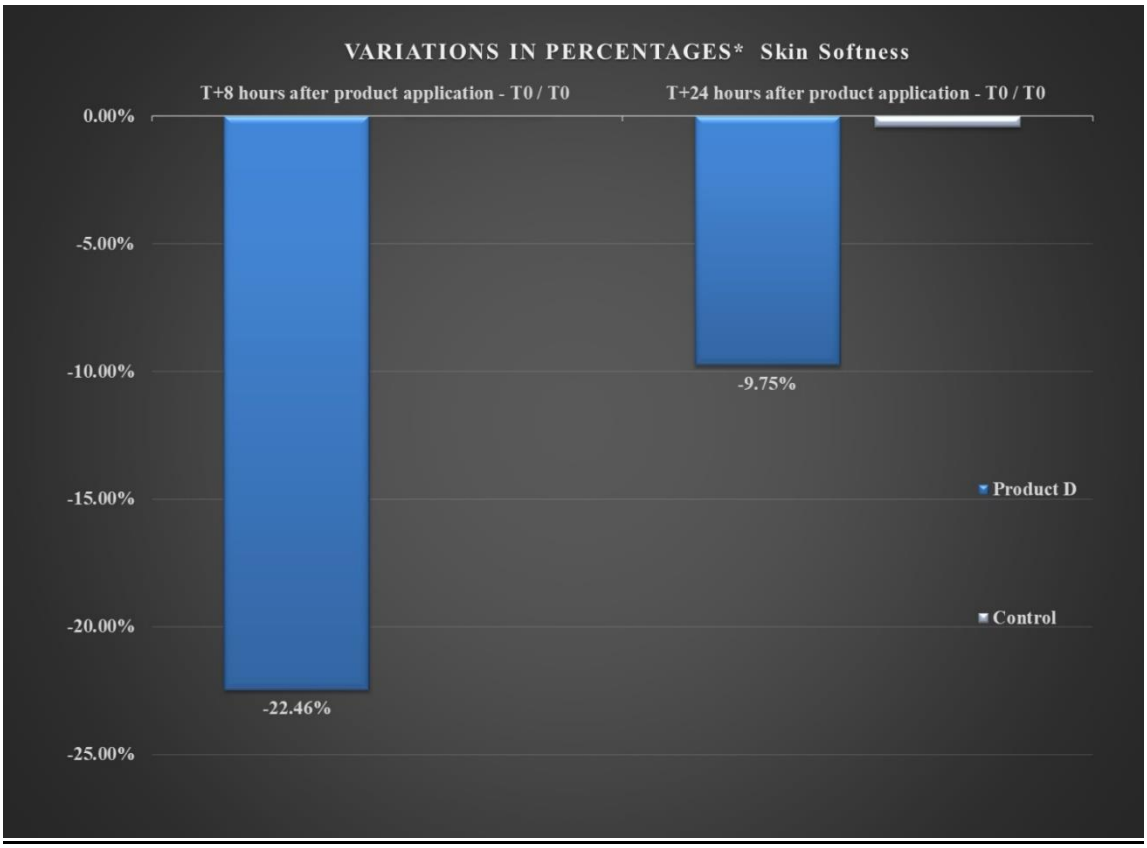
			VARIATIONS IN PERCENTAGES* Skin Softness	
			T+8 hours after product application - T0 / T0	T+24 hours after product application - T0 / T0
Skin Softness	Product D	Mean	**-22.46%**	**-9.75%**
	Control	Mean	**0.00%**	**-0.42%**

➢ **Analysis**

For Product D

- The statistical analysis shows a significant decrease in the score for skin softness shows an effect of the product in terms of skin softness at *T+8 hours after product application & T+24 hours after product application* by **-22.46% & -9.75%** respectively.
- An improvement in studied parameter by **-0.80 and -0.35 grade out of 9,** on average on whole panel **respectively** at T+8 hours after product application & T+24 hours after product application.
- **97% & 58%** of the panel presented an improvement in the studied parameter **respectively** at T+8 hours after product application & T+24 hours after product application.

➢ **Graphical Representation**



5.6.2 Comparison of Test Product D versus Untreated Control

- **Comparison at T0**

The following table presents the statistical results on the comparison of the studied parameter, observed between Product D versus Untreated control at T0 (Student test, two tailed, for independent samples or Mann-Witney test at 5%, after checking the normality of the distributions by a Shapiro-Wilk test at 1%).

Comparision at T0

			COMPARSION AT T0
Skin Softness	Product D Vs Control	Significant at 5 % p= Test	No 1.00E+00 *Rank Sum Test*

Yes: Significant difference in favor of the product

No: No significant difference

Yes*: Significant difference in disfavor of the product

No significant difference between Product D versus Untreated control site is noted at T0 for the studied parameter. Both the sites are therefore comparable.

- **Comparison at Tn**

The following table presents the statistical results on the comparison of the studied parameter, observed between Product D versus Untreated control at Tn (Student test, two tailed, for independent samples or Mann-Witney test at 5%, after checking the normality of the distributions by a Shapiro-Wilk test at 1%).

			COMPARISON FROM THE DIFFERENCES (Tn-T0)	
			T+8 hours after product application	T+24 hours after product application
Skin Softness	Product D Vs Control	Significant at 5 % p= Test	Yes *<0.001* Rank Sum Test	Yes *<0.001* Rank Sum Test

Yes: Significant difference in favor of the product

No: No significant difference

Yes*: Significant difference in disfavor of the product

On comparing test product versus untreated control, significant difference between test Product D versus Untreated control site is noted at T+8 hours after product application & T+24 hours after product application in favour of test Product D.

5.7 CORNEOMETRY

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

5.7.1. Observed results:

→ Raw values

The following table summarizes the means and standard deviations of the raw values of capacitance, observed on the forearm with test Product D at T0, T+8 hours after product application & T+24 hours after product application 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%).

			RAW VALUES		
			T0	T+8 hours after product application	T+24 hours after product application
Capacitance	Product D	N	33	33	33
		Mean	**21.49**	**39.80**	**31.15**
		Standard deviation	*4.32*	*8.55*	*6.72*
		Significant at 5 % (T0 vs Tn)		Yes	Yes
		p=		*<0.001*	*<0.001*
		Test		*Student Paired t-test*	*Wilcoxon*
	Control	N	33	33	33
		Mean	**23.29**	**23.42**	**23.58**
		Standard deviation	*3.77*	*4.04*	*4.10*
		Significant at 5 % (T0 vs Tn)		No	No
		p=		*4.60E-01*	*2.18E-01*
		Test		*Student Paired t-test*	*Wilcoxon*

Yes: Significant difference in favor of the product

No: No significant difference

Yes*: Significant difference in disfavor of the product

→ Evolutions (Tn-T0)

The following table presents the means and the standard deviations of the evolutions (Tn-T0) of capacitance, observed on the forearm treated with test Product D.

			EVOLUTION OF THE Tn-T0	
			T+8 hours after product application - T0	T+24 hours after product application - T0
Capacitance	Product D	Mean	**18.31**	**9.65**
		Standard deviation	*5.70*	*5.04*
	Control	Mean	**0.13**	**0.29**
		Standard deviation	*0.97*	*1.02*

→ Variations (Tn-T0)/T0 (%)

The following table summarises the average percentages of the variation (Tn-T0)/T0 of the capacitance, observed on the forearm treated with test Product D.

			VARIATIONS IN PERCENTAGES* Capacitance	
			T+8 hours after product application - T0 / T0	T+24 hours after product application - T0 / T0
Capacitance	Product D	Mean	85.20%	44.92%
	Control	Mean	0.54%	1.23%

→ Analysis

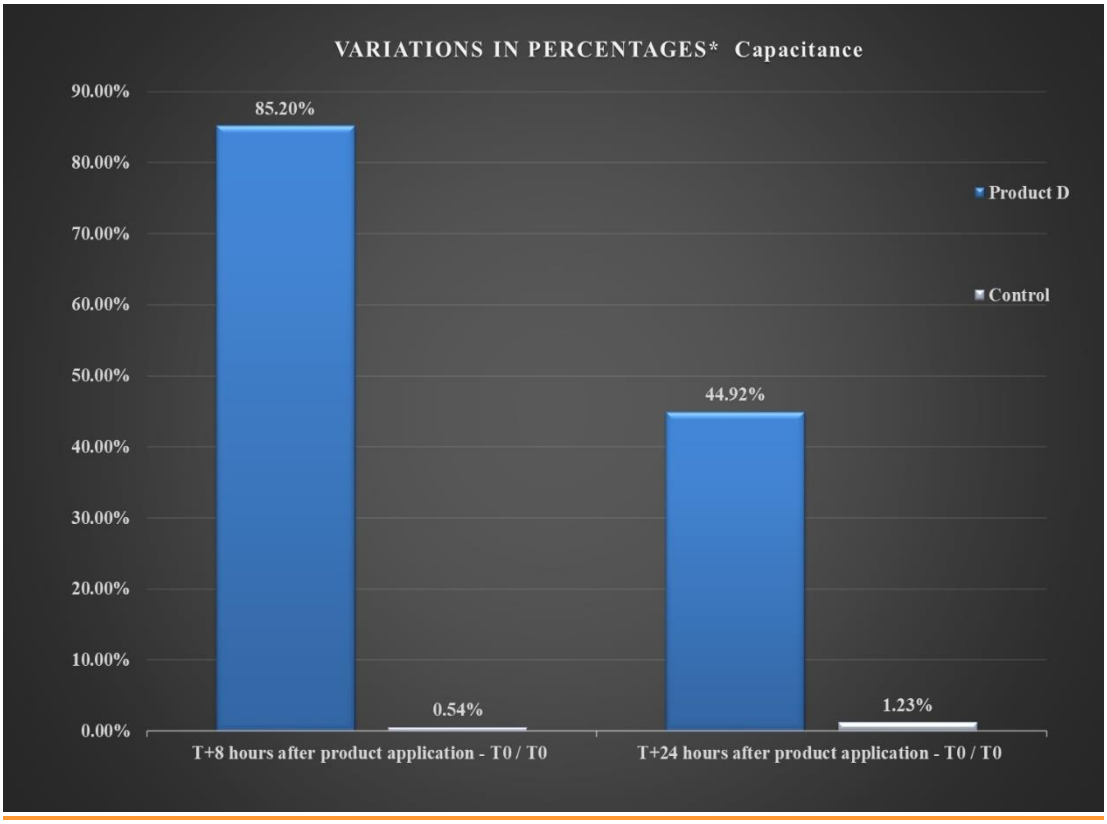
For Product D:

- The statistical analysis shows **a significant increase in capacitance** parameter by **+85.20%, & +44.92%** on the forearm treated with test Product D on average on whole panel respectively at T+ 8 hours & T+24 hours after product application.
- **100% o**f the panel presented an improvement in the studied parameter **at T+ 8 hours & T+24 hours after product application**.

For Untreated Control:

- The statistical analysis shows no significant difference in capacitance parameter on average on whole panel at any given time points.

→ Graphical Representation



5.7.2. Comparison of Test Product versus Untreated Control

➢ Comparison at T0

The following table presents the statistical results on the comparison of the studied parameter, observed between Product D versus Untreated control at T0 (Student test, two tailed, for independent samples or Mann-Witney test at 5%, after checking the normality of the distributions by a Shapiro-Wilk test at 1%).

Comparision at T0

			COMPARSION AT T0
Capacitance	**Product D Vs Control**	Significant at 5 % p= Test	**No** *7.59E-02* *Student t test (two-tailed)*

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

No significant difference between Product D versus Untreated control site is noted at T0 for the studied parameter. Both the sites are therefore comparable.

➢ Comparison at Tn

The following table presents the statistical results on the comparison of the studied parameter, observed between Product D versus Untreated control at Tn (Student test, two tailed, for independent samples or Mann-Witney test at 5%, after checking the normality of the distributions by a Shapiro-Wilk test at 1%).

			COMPARISON FROM THE DIFFERENCES (Tn-T0)	
			T+8 hours after product application	**T+24 hours after product application**
Capacitance	**Product D Vs Control**	Significant at 5 % p= Test	**Yes** *<0.001* Student t test (two-tailed)	**Yes** *<0.001* Rank Sum Test

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

On comparing test product versus untreated control, significant difference between test Product D versus Untreated control site is noted at all time points in favour of test Product D.

6. DISCUSSION AND CONCLUSION

The once on site application of the product coded **Ultra Protect Fluid Sunscreen(1540): Product D** on the forearm by a panel of 33 (17 females & 16 males) subjects, **having dry skin with corneometer reading ≤30 on forearms**, leads to the following results after 24 hours 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 at T+8 hours after product application, & T+24 hours after product application for test Product D.

***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 till T+24 hours after product application for the test product D at all the given time points.

✓ **Dermatological Evaluation for Efficacy:**

➢ **Skin Softness**

- The statistical analysis shows a significant improvement in skin softness on the sites treated with **Product D** at T+8 hours after product application & T+24 hours after product application by **-22.46% & -9.75%** respectively.
- On comparing test product versus untreated control, **significant improvement is observed in favour of test Product D**.

✓ **Corneometry:**

- The statistical analysis shows **a significant increase in capacitance** parameter shows **a moisturizing effect** by **+85.20%, & +44.92%** on the randomized forearm treated with test Product D on average on whole panel respectively at T+ 8 hours & T+24 hours after product application.
- On comparing test product versus untreated control, **significant improvement is observed in favour of test Product D**.

To conclude, in the experimental conditions of the study, after 24 hours of application of the product coded: Ultra Protect Fluid Sunscreen(1540): Product D, the following points have been demonstrated.

- Dermatological evaluation for efficacy shows a significant improvement in Skin Softness upto T+24 hours of application of the test product D.

- A significant increase in capacitance parameter through Corneometry, shows effect of the product in terms of skin moisturization upto T+24 hours of application test Product D.

- **On comparing test product versus untreated control, significant improvement is observed in favour of test Product D.**

- Appreciation from the panel is obtained for Product D through subject self-evaluation, especially in terms the skin moisturization, skin softness, appealing fragrance, quick absorption, & for not causing itching, irritation and burning sensation to the skin after 24 hours of product application.

-Dermatological Evaluation for cosmetic acceptability showed no occurrence of clinical and functional signs for the Product D at all studied timepoints.

7. APPENDICES

APPENDIX 1:

QUALITY ASSURANCE STATEMENT

Quality Assurance Statement

This study (XXX-HD01-EV-AT23) 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-HD01-EV-AT23-AU01	30/08/2023
2.	Audit of the CRF's	XXX-HD01-EV-AT23-AU02	06/09/2023
3.	Audit of the Raw Data & Results	XXX-HD01-EV-AT23-AU03	14/09/2023
4.	Audit report of the Trial Master File	XXX-HD01-EV-AT23-AU04	14/09/2023
5.	Audit of the Study Report	XXX-HD01-EV-AT23-AU05	22/09/2023, 22/11/2023

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 THE STUDY PROTOCOL

SUMMARY: XXX-HD01-EV-AT23
Test Product: Ultra Protect Fluid Sunscreen (1540): Product D

DESCRIPTION OF THE STUDY:

EVALUATION & COMPARISON OF EFFICACY AND SAFETY OF SKIN CARE FORMULATION VERSUS UNTREATED AREA

THROUGH:

- **Subject Self Evaluation (SSE)**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Dermatological Evaluation: Efficacy**
- **Corneometry**

NATURE OF THE TESTED PRODUCT AND METHODOLOGY:

Product reference	*Ultra Protect Fluid Sunscreen (1540): Product D*
Study design	*It was a single blinded and comparative study. Subjects served as their own reference for the intra-group comparison (evaluation of the efficacy on time of each product) and did not serve as their own reference for the inter-group comparison (comparison of the efficacy of test product & with control).*
Total duration of the study	*24 hours*
Kinetic	*T0, T +8 hours after product application & T+24 hours after product application.*
Product application	*Once at site on forearm.*
Number of volunteers	*33 (17 females & 16 males) subjects*
Special selection criteria	*Having dry skin on forearms with corneometer reading ≤ 30*

RESULTS AND CONCLUSION:

The once on site application of the product coded **Ultra Protect Fluid Sunscreen(1540): Product D** on the forearm by a panel of 33 (17 females & 16 males) subjects, **having dry skin with corneometer reading ≤30 on forearms**, leads to the following results after 24 hours 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 at T+8 hours after product application, & T+24 hours after product application for test Product D.

***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 till T+24 hours after product application for the test product D at all the given time points.

✓ **Dermatological Evaluation for Efficacy:**

➢ **Skin Softness**

- The statistical analysis shows a significant improvement in skin softness on the sites treated with **Product D** at T+8 hours after product application & T+24 hours after product application by **-22.46% & -9.75%** respectively.
- On comparing test product versus untreated control, **significant improvement is observed in favour of test Product D**.

✓ **Corneometry:**

- The statistical analysis shows **a significant increase in capacitance** parameter shows **a moisturizing effect** by **+85.20%, & +44.92%** on the forearm treated with test Product D on average on whole panel respectively at T+ 8 hours & T+24 hours after product application.
- On comparing test product versus untreated control, **significant improvement is observed in favour of test product i.e., Product D**.

To conclude, in the experimental conditions of the study, after 24 hours of application of the product coded: Ultra Protect Fluid Sunscreen(1540): Product D, the following points have been demonstrated.

- Dermatological evaluation for efficacy shows a significant improvement in Skin Softness upto T+24 hours of application of the test product D.

- A significant increase in capacitance parameter through Corneometry, shows effect of the product in terms of skin moisturization upto T+24 hours of application test Product D.

- **On comparing test product versus untreated control, significant improvement is observed in favour of test product i.e., Product D.**

- Appreciation from the panel is obtained for Product D. through subject self-evaluation, especially in terms the skin moisturization, skin softness, appealing fragrance, quick absorption, & for not causing itching, irritation and burning sensation to the skin after 24 hours of product application.

-Dermatological Evaluation for cosmetic acceptability showed no occurrence of clinical and functional signs for the Product D at all studied timepoints.