MASCOT SPINCONTROL
clinical research centre

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au coeur de la peau...

CONFIDENTIAL REPORT

Ref: XXX-6F01-EV-MY23

Version: 01

Dated: 16/06/2023

EVALUATION OF THE OF OPHTHALMOLOGICAL SAFETY OF SKIN CARE FORMULATIONS THROUGH:

- **Subject Self Evaluation (SSE)**
- **Ophthalmological Evaluation: Safety**

TEST PRODUCTS REFERENCES:

- **Mineral Sunscreen SPF 50 (sport) (1219) : Product A**

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

Investigator:
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Mumbai – 400013, INDIA

JUNE 2023

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK 16/06/2023

CONTENTS

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1.3 STUDY MONITOR

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Date: 16/06/2023

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Date: 16/06/2023

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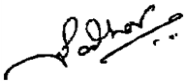
Signature: 

Date: 16/06/2023

2. SUMMARY OF THE STUDY

2.1 OBJECTIVE

The objective of this study was to evaluate Ophthalmological safety of skincare formulation involving subjects of normal eye conditions on healthy female subjects coded:

- **Mineral Sunscreen SPF 50 (sport) (1219) :Product A**

The evaluation was performed using:

- **Subject Self Evaluation (SSE)**
- **Ophthalmological Evaluation: Safety**

The study lasts 4 days following the first application of the product.

2.2 POPULATION

33 Females were selected for the study.

The subjects selected for this study were healthy female subjects, aged between 18 to 40 years, **having normal eye conditions.**

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

2.3 STUDY DURATION

Duration: The study lasts 3 days following the first application of the product.

Scheduled Procedures:

	Screening	T0	T+30 minutes after product application	T+1 days	T+3 days
Registration	■				
Protocol Briefing	■				
Consent	■				
ICF		■			
Demographics	■				
Inclusion and Non Inclusion criteria by the Dermatologist	■	■			
Habits Questionnaire	■				
Clinical Observation	■				
Concomitant Medication	■	■		■	■
History Questionnaire	■				
Routine check up	■				
Proscriptions and Restrictions				■	■
Subject Self Evaluation			■	■	■
Ophthalmological Evaluation (Safety)		■	■	■	■
Distribution of Product and Product Instruction & Diary Sheet		■			
Product Application on site		■			
Product Retrieval					■
AE/SAE Monitoring		■	■	■	■
					End of the study

Study Schedule

Screening +T0	T+1 day	T+3 days
06/06/2023	**07/06/2023**	**09/06/2023**

2.4 STUDY DESIGN

- Single blind study.
- Non-Comparative study.
- Subjects serve 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, skincare, and make-up habits, as well as a certain amount of administrative information.

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

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

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 her/his consent.

The subjects selected for the study were chosen under the supervision of the investigator and study in charge, on the basis of the inclusion/non-inclusion criteria listed below.
A selection of 33 female subjects were made for this study.
Subject's Self Evaluation, Ophthalmological Evaluation for Safety was 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 will fulfill the following criteria:

Standard criteria

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

Specific criteria

- Having normal eye conditions.

3.1.2 Non-inclusion criteria

Standard criteria

- Being pregnant or breastfeeding or having stopped to breastfeed in the past three months.
- Having refused to give his/her assent by not signing the consent form.
- Taking part in another study liable to interfere with this study.
- 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.
- 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) or skin care product 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, antihistamines, 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 eye related and/ or eye makeup than the tested products to the studied areas. (only test cleanser is accepted).
- The day of the measurements: No test product or any other eye makeup must be used (only face cleaned with water is accepted).

Specific criteria

- Having started, changed, or stopped a hormonal treatment (hormonal contraception, cyproterone acetate …)
- Having taken an oral retinoid-based treatment
- Having undergone a physical (phototherapy, laser..) or chemical (peeling) treatment for acne
- Having had a local benzoyl-peroxide-based treatment or a local retinoid-based treatment
- Having had an oral treatment with a base of cimetidine, zinc (zinc gluconate) or spironolactone
- Having applied cosmetic products with anti-seborrheic aims or cosmetics for oily skin
- Having had oral or local antibiotic treatment for acne.
- Having had beauty treatment (e.g., skin cleansing, exfoliation, scrub, mask …)
- Having a suntanned skin on the studied areas which could interfere with the evaluations of the Study
- Having practiced water activities (swimming pool, sauna, hammam, balneotherapy etc.) in the previous week.

Refusing to follow the restrictions below during the study:

- Do not start, change, or stop a hormonal treatment (hormonal contraception, cyproterone acetate …).
- Do not apply cosmetic products with anti-seborrheic aims or cosmetics for oily skin or for skin with imperfections.
- Do not have beauty treatment (e.g., skin cleansing, exfoliation, scrub, mask …).
- Do not start a local or general treatment acting on seborrhoea.
- Do not expose to the sun with the intention to sunbath (activities outside which do not last too much time are authorized.
- Do not itch the eyes.
- Do not wear lenses till the end of the study.
- Do not use any eye drops or any eye treatment/ surgery during the study.

3.2 THE PRODUCT

3.2.1 Presentation of the product

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

Reference of the product	Batch	Mfg. Date	Expiry Date	Constituent form	Packaging	Capacity
Mineral Sunscreen SPF 50 (sport) (1219)	**1219**	**16-05-2023**	**N/AV**	**Cream**	**Tube**	**40gm**

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.
The study sponsor was responsible for supplying the appropriate amount of product needed to carry out the study.

For this study, the study sponsor agreed to supply:
The appropriate quantity of the products required to treat all of the subjects;
A sufficient quantity of the products 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 subjects themselves at home; however, the first application (T0) was carried out at Mascot Spincontrol under the guidance of the CRA:

Product	Application area	Frequency of application	Duration of study	Conservation
Mineral Sunscreen SPF 50 (sport) (1219)	Whole face	Once in a day	3 days	At an ambient temperature

Modalities of application:

The face was cleansed with water. Approximately 0.1 to 0.2 gm of the product A was taken on fingertip. Applied dot wise around the eye area and whole face. Then spread it using only fingers gently. **Ensured that the product was not rubbed into the eyes.** The application of test product was carried out once a day for the period of 3 days.

Note:

Don't use the test product on study visit i.e., at T+1 day and T+3 days in morning.

Wash the face only with water on study visits i.e., at T+1 days and T+3 days in morning.

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 non-comparative study
- The subjects serve as their own references.

3.4 RANDOMISATION

There is no randomization for this 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+30 minutes after product application, T+1 days and T+3 days in order to evaluate the overall opinion and their attitude towards the safety of the product under test.

- Studied area: Both under eye area.

- 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 were performed under control of the CRA who checked the acquisition according to standard procedure.

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

Product Characteristics

1. The test product is easy to apply.

Product Safety

1. The test product does not cause irritation to eyes & under eye area
2. The test product does not cause itching to eyes & under eye area
3. The test product does not cause watering of eyes.
4. The test product does not cause redness to eyes & under eye area
5. The test product does not cause dryness of eyes & under eye area

For each Item, the possible answers are:

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 treated and analyzed with Microsoft Excel.

3.7.1 Ophthalmological Evaluation (Safety)

➢ *Acquisition of source data*

- Principle

The evaluation of the ocular acceptability carried out by the ophthalmologist at T0, T+30mins, T+1 day and T+3 days is based on the discussion with the subject and on a clinical examination.

Parameters:

1. Redness
2. Watery eyes
3. Dryness
4. Itching
5. Irritation
6. Burning of eyes.

The evaluation is 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 the measurements (temperature: 20°C to 25°C, hygrometry: 50 ±10%).
The subject sat on a chair facing the test site towards ophthalmologist.
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: Both eye
- Measures

The ophthalmologist assesses 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.
The evaluation of the Safety was not submitted to a statistical analysis (descriptive analysis only).

3.6 EXAMINATION SCHEDULE

The effect of the product was evaluated after 3 days of application. 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
- 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
- Ophthalmological Evaluation: Safety
- Weighing of the product
- Distribution of the test product and product instruction and diary sheet.
- Product application with instructions and recording information in diary sheet.

At T+30 minutes (± 5mins) after product application:

- Subject Self Evaluation
- Ophthalmological Evaluation: Safety
- Adverse Event/ Serious Adverse Event Monitoring

At T+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
- Ophthalmological Evaluation: Safety
- Weighing of Product
- Adverse Event/ Serious Adverse Event Monitoring

At T+3 days:

- Acclimatization at RH 50 ±10% and temperature 20°C to 25°C for 20 mins.
- Proscriptions and Restrictions
- Concomitant Medication
- Subject Self Evaluation
- Ophthalmological Evaluation: Safety
- Retrieval of the test product and product instruction and 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

Data Analysis was done by mean score calculation.

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 was done using Sigma Stat 3.5 and PAST 4.03

4. ETHICAL AND LEGAL CONSIDERATIONS

4.1 STUDY PERSONNEL

The investigator assures that the study incharge 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.

4.1 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	24/05/2023
2.	Audit of the CRF's	02/06/2023
3.	Audit report of the Trial Master File	02/06/2023
4.	Audit of the Raw Data & Results	13/06/2023
5.	Audit of the Study Report	16/06/2023

4.8 REGULATIONS

This study was carried out in conformity with the most recent recommendations of the World Medical Association (Declaration of Helsinki 1964, amended in Fortaleza, Brazil, 2013).

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

4.9 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. APPENDICES

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+30 minutes	T + 1 day	T + 3 days
Subject Self Evaluation	N/AP	33	33	33
Ophthalmological Evaluation (Safety)	33	33	33	33

5.3 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of **33 Healthy Indian female subjects,** aged between 18 and 40 years old, mean age: 29.9 years old: SD: 7.4 years old; Median: 32 years old, **having normal eye conditions.**

5.4 RESULTS OF THESUBJECT'S SELF ASSESSMENT QUESTIONNAIRE

5.4.1 Table of results: Product A

The table below summarises the agreement percentages recorded for each suggested item for **Product A** after, T+30 minutes, T+1 day and T+3 days of product application as well as their statistical significance evaluated using Chi-squared test at 5%.

		T+30 minutes after product application		T+1 Day		T+3 Days	
	Number of subjects	*33*		*33*		*33*	
		% agreement	*Significant ? (5%)*	*% agreement*	*Significant ? (5%)*	*% agreement*	*Significant ? (5%)*
1	The test product is easy to apply	100%	Yes	-	-	-	-
2	The test product does not cause irritation to eyes & under eye area	100%	Yes	100%	Yes	100%	Yes
3	The test product does not cause itching to eyes & under eye area	100%	Yes	100%	Yes	100%	Yes
4	The test product does not cause watering of eyes	100%	Yes	100%	Yes	100%	Yes
5	The test product does not cause Redness to eyes & under eye area	100%	Yes	100%	Yes	100%	Yes
6	The test product does not cause dryness of eyes & under eye area	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

- **Observed results**

All the items related to the safety of the product are significantly recognised by the panel at all the given time points, with 100% agreement.

Concerning the **Product Characteristics, the panel agreed that the test product A** is easy to apply with 100 % agreement at T+30 Minutes of product application.

Concerning the **Product Safety, the panel agreed that the test product A** does not cause "*irritation*", *"itching," "watering", "redness"* and "*dryness"* of both the eye with 100 % agreement after 3 days of product application.

5.5 OPTHALMOLOGICAL EVALUATION : SAFETY

The studied parameters were:

1. Redness
2. Watery eyes
3. Dryness
4. Itching
5. Irritation
6. Burning of eyes.

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

- **Observed results**

On the basis of Ophthalmological Evaluation: Safety, it has been observed that there is no occurrence of Redness, Watery eyes, Dryness, Itching, Irritation and Burning of both eyes at any given time point for test Product A.

6. DISCUSSION AND CONCLUSION

Once a day application of the test product coded ***Mineral Sunscreen SPF 50 (sport) (1219): Product A*** on the whole face by the panel of 33 exploited Indian female subjects for Product aged between **18 and 40 years old, having normal eye conditions** leads to the following results after 3 days of test.

✓ **Subject's Self Evaluation:**

On the basis of Subject's Self Evaluation, all the claims related to product characteristics and safety are significantly validated by the panel after repeated application of test product A for a period of 3 days of test.

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

✓ **Ophthalmological Evaluation: Safety**

On the basis of Ophthalmological Evaluation for Safety, in average on the whole panel it has been observed that there is no occurrence of clinical signs i.e., Redness, Watery eyes, Dryness, Itching, Irritation and Burning eyes was observed after repeated application of test product A for a period of 3 days of test.

To conclude, for 3 days of test, for assessing Ophthalmological safety of Skin care formulation in the experimental conditions of the study for test product A,

-Ophthalmological evaluation for Safety on an average shows no aggravation of the clinical signs after repeated application of test product A.

- Appreciation from the panel was obtained for product A through subject self evaluation, especially in terms of test product safety.

5. APPENDICES

APPENDIX 1:

QUALITY ASSURANCE STATEMENT

Quality Assurance Statement

This study XXX-6F01-EV-MY23 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-6F01-EV-MY23 -AU01	24/05/2023
2.	Audit of the CRF's	XXX-6F01-EV-MY23 -AU02	02/06/2023
3.	Audit report of the Trial Master File	XXX-6F01-EV-MY23 -AU03	02/06/2023
4.	Audit of the Raw Data & Results	XXX-6F01-EV-MY23 -AU04	13/06/2023
5.	Audit of the Study Report	XXX-6F01-EV-MY23 -AU05	16/06/2023

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: 16/06/2023
Auditor(s)

Signature: N/AP
Auditor(s)

Signature: 16/06/2023
Quality Assurance Manager

APPENDIX 2:

COPY OF THE STUDY PROTOCOL

MASCOT SPINCONTROL
clinical research centre

STUDY SUMMARY: XXX-6F01-EV-MY23

Test Products: Mineral Sunscreen SPF 50 (sport) (1219): Product A

DESCRIPTION OF THE STUDY:

EVALUATION OF THE OF OPHTHALMOLOGICAL SAFETY OF SKIN CARE FORMULATIONS THROUGH:

- **Subject Self Evaluation (SSE)**
- **Ophthalmological Evaluation: Safety**

NATURE OF THE TESTED PRODUCT AND METHODOLOGY:

Product's reference	*Mineral Sunscreen SPF 50 (sport) (1219): Product A*
Study design	*It was a single blinded, non-comparative study, Subjects served as their own reference.*
Total duration of the study	*4 days*
Kinetic	*T0, T+30 minutes, T+1 day and T+3 days*
Product application	*Once a day for the period of 3 days*
Number of volunteers	*33 exploited Indian female subjects*
Special selection criteria	*Having normal eye conditions*

RESULTS AND CONCLUSION

Once a day application of the test product coded ***Mineral Sunscreen SPF 50 (sport) (1219): Product A*** on the panel of 33 exploited Indian female subjects for Product A aged between **18 and 40 years for Product A** having normal eye conditions leads to the following results after 3 days of test.

✓ **Subject's Self Evaluation:**

On the basis of Subject's Self Evaluation, all the claims related to product characteristics and safety are significantly validated by the panel after repeated application of test product A for a period of 3 days of test.

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

✓ **Ophthalmological Evaluation: Safety**

On the basis of Ophthalmological Evaluation for Safety, in average on the whole panel it has been observed that there is no occurrence of clinical signs i.e., Redness, Watery eyes, Dryness, Itching, Irritation and Burning eyes was observed after repeated application of test product A for a period of 3 days of test.

To conclude, for 3 days of test, for assessing Ophthalmological safety of Skin care formulation in the experimental conditions of the study for test product A,

-Ophthalmological evaluation for Safety on an average shows no aggravation of the clinical signs signs after repeated application of test product A.

- Appreciation from the panel was obtained for product A through subject self evaluation, especially in terms of test product safety.

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