# CONFIDENTIAL REPORT

**Ref: XXX-2F06-EV-NR23**

**Version: 01**

**Dated: 01/02/2024**

## EVALUATION OF THE SAFETY OF SKIN CARE FORMULATION

**THROUGH:**

- **Subject Self Evaluation (SSE)**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Ophthalmological Evaluation: Safety**

**TEST PRODUCT REFERENCE:**

- **Ultra Matte Oil-free Fluid SPF 50+ : 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:
**MASCOT SPINCONTROL INDIA PVT. LTD**
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Lower Parel,
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**FEBRUARY 2024**

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# 1. EXPERIMENTATION SITE, PARTICIPANTS

## 1.1 EXPERIMENTATION SITE

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**SPONSOR**

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## 1.3 STUDY MONITOR

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## 1.4 STUDY DIRECTOR

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Signature:

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## 1.5 PRINCIPAL INVESTIGATOR

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### 1.6 OPHTHALMOLOGIST

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### 1.7 QUALITY ASSURANCE MANAGER

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MASCOT-SPINCONTROL
Telephone: +91-22-43349191 / 192 Date:
E-mail: shraddhajadhav@mascotspincontrol.in

# 2. SUMMARY OF THE STUDY

## 2.1 OBJECTIVE

The objective of this study was to evaluate the in-vivo safety of the skin care formulation on healthy human subjects for product coded:

- **Ultra Matte Oil-free Fluid SPF 50+ : Product A**

The evaluation was performed using:

- **Subject Self Evaluation (SSE)**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Ophthalmological Evaluation: Safety**

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

## 2.2 POPULATION

**36 (18 males + 18 females) subjects were selected for the study.**

**The subjects selected for this study were healthy males and females, aged between 18 and 30 years, presenting oily or mixed oily skin on the face (visual assessment by dermatologist).**

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+14 days | T+28 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** | | | ■ | ■ |
| **Dermatological Evaluation: Cosmetic Acceptability** | | ■ | ■ | ■ |
| **Ophthalmological Evaluation: Safety** | | ■ | ■ | ■ |
| **Product Weighing** | | ■ | | |
| **Distribution of Product and Product Instruction & Diary Sheet** | | ■ | | |
| **Product Application on site** | | ■ | | |
| **Product Retrieval** | | | | ■ |
| **Adverse Event/ Serious Adverse Event Monitoring** | | ■ | ■ | ■ |
| | | | | **End of the study** |

**Study Schedule:**

| Screening & T0 | T+14 Days | T+28 Days |
|---|---|---|
| 11/12/2023 | 26/12/2023 | 08/01/2024 |

### 2.4 STUDY DESIGN

- Single 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 Organization 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, Gujarati and/or English language: i.e. only Hindi, Marathi, Gujarati and/or English speaking subjects capable of reading the consent documents and able to accept the participation conditions.
- No individual sentenced to imprisonment by a court decision or by an administrative decision, or hospitalized without consent, or admitted in a medical or social establishment.
- No minor as well as individual of age benefiting from a legal protection measure or enable to express her/his consent.

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

A selection of 36 (18 males + 18 females) subjects were made for this study.

Subject's Self Evaluation, Dermatological Evaluation: Cosmetic Acceptability and Ophthalmological Evaluation: Safety was done on all the 36 (male and female) 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 and 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 30 years of age.
- Skin is healthy on the studied anatomic unit (free of eczema, wounds, inflammatory scar….)

**Specific criteria**

- Having oily or mixed oily skin on the face (visual assessment by dermatologist).

### 3.1.2 Non-inclusion criteria

**Standard criteria**

- For female, being pregnant or breastfeeding or having stopped to breastfeed in the past three months.
- Having refused to give 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)
- Having a chronic dermatosis liable to modify the cutaneous reactivity on the tested area (except for specific studies on a determined dermatosis)
- Having non stabilized thyroid problems (requirement of a stabilized treatment for at least 6 months)
- 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 (the only medication permitted is paracetamol)
- Having cutaneous 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 her 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 the first day of the study (only face cleaned with water is accepted)
- Having applied hair oil during the entire duration of the study

**Refusing to follow the restrictions below during the study:**

- For female: Do not take part in any family planning activities leading to pregnancy and breastfeeding.
- Do not take part in another study liable to interfere with this study.
- Do not take medicinal treatment comprising any of the following products: aspirin-based products, anti-inflammatories, anti-histamines, corticotherapy, taken by general or local routes (the only medication permitted is paracetamol)**.**
- Do not change 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 product to the studied areas (only the usual cleanser and make-up for the lips and eyes are accepted)
- During the study: Do not use hair oil.
- The day of the measurements: No test product must be used (only face cleaned with water is accepted)

**Specific criteria**

**In the 6 previous months**

- 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

**In the previous month**

- 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.

**In the 2 previous weeks**

- Having applied cosmetic products with anti-seborrheic aims or cosmetics for oily skin
- Having had oral or local antibiotic treatment for acne

**In the previous week**

- 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.

**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 sunbathe (activities outside which do not last too much time are authorized).

## 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 | Mfg. Date | Expiry Date | Constituent form | Packaging | Capacity |
|---|---|---|---|---|---|---|---|
| **Ultra Matte Oil-free Fluid SPF 50+** | **A** | **1793** | **31-10-2023** | **N/AV** | **Lotion** | **Bottle** | **40ml** |
| | | **1751** | **19.10.2023** | | | | |
| | | **1863** | **23.11.2023** | | | | |

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 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 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; except the first application of test product was carried out at Mascot Spincontrol under the guidance of the CRA:

| Product | Product Code | Application area | Frequency of application | Application duration | Conservation |
|---|---|---|---|---|---|
| **Ultra Matte Oil-free Fluid SPF 50+(1793)** | A | Whole Face | Once a day | 28 days | At ambient temperature |

**Modalities of application:**

Approximately 0.5 gm of given test product was taken on tip of index finger. Applied dot wise on the whole face; then the test product was gently spread using only fingers in outward direction. **Ensured that the product was not rubbed into skin.** Applied the product once a day in morning on the whole face for the period of 28 days**.**

***Note:***
***Wash the face only with water on study visits i.e., T+14 days and T+28 days in morning.***
***Don't apply the test product on study visits i.e., T+14 days and T+28 days in morning.***
***Apply the test product after going home on T+14 days visit.***

### 3.3 STUDY DESIGN

- This study was carried out as a "single blind test", the subjects participating was not aware of the type of product being applied.
- This was a non-comparative study.
- The subjects served as their own references.

### 3.4 RANDOMISATION

There was no randomization in the study.

## 3.5 STUDY PROCEDURES

### 3.5.1 Subject Self Evaluation

#### *3.5.1.1. Acquisition of source data*

- Principle

The subjects were asked to answer self-evaluation questionnaire at T+14 days and T+28 days in order to evaluate the overall opinion and their attitude towards the safety and efficacy of the product and at T+14 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 was carried out in accordance with the promoter as follows:

**Product Efficacy**

1. The test product does not produce comedons/ acne/ pimples on the face after application.
2. The test product does not make my skin oily.

**Product Characteristics at T+14 days**

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

**Product Acceptability**

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

For each Item, the possible answers were:

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

#### *3.5.1.2. Treatment of Raw Data*

Questionnaires was filled out manually in paper version and all the captured data was treated and analyzed with Microsoft Excel.

### 3.5.2 Dermatological Evaluation (Cosmetic Acceptability)

#### *3.5.2.2 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+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

#### *3.5.2.2 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 dermatologist.
All the shutters of the room was 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 reports the grade in the CRF.

#### *3.5.2.3 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 Ophthalmological Evaluation (Safety)

#### *3.5.3.1 Acquisition of source data*

- Principle

The evaluation of the ocular acceptability carried out by the ophthalmologist at T0, T+14 days and T+28 days, was 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 was performed using the following scale:

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

#### *3.5.3.2 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 ophthalmologist.
The subject was positioned just below a lamp of ceiling. All the shutters of the room was closed and the only light was provided by the lamp of the ceiling.

- Studied areas: Both Eyes.
- Measures

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

#### *3.5.3.3 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 products was evaluated over a 28-days period. The scheduled measurement procedures was 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
- Dermatological Evaluation: Cosmetic Acceptability
- 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.
- 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
- Ophthalmological Evaluation: Safety
- 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

- Ophthalmological Evaluation: Safety
- Weighing of Product
- 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

### 3.10.1 Data analysis of technical data (not for dermatological evaluation for cosmetic acceptability)

To be carried out at Mascot Spincontrol
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 (Only for dermatological evaluation for efficacy).
- Numbers and percentages of subjects presenting an improvement.

*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%.

### 3.10.2 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 93000036230500000001).

## 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.

| Sr. No. | Audit Report | Date of Auditing |
|---|---|---|
| 1. | Audit of study protocol | 06/12/2023 |
| 2. | Audit of the CRF's | 08/12/2023 |
| 3. | Audit of the Raw Data & Results | 10/01/2023 |
| 4. | Audit report of the Trial Master File | 11/01/2024 |
| 5. | Audit of the Study Report | 22/01/2024,<br>01/02/2024 |

### 4.9 REGULATIONS

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

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

### 4.10 PRACTICAL CONSIDERATIONS

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

# 5. RESULTS

## 5.1 DEVIATIONS FROM THE STUDY PROTOCOL

The protocol has been respected as a whole.

## 5.2 ABSENCES

- **Subject no. 012, GALS3 & Subject no. 028, JA175** did not report on T+14 Days visit.

***The data of the subject is not exploited in the global study results.***

## 5.3 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS

**At T0, 36 subjects were recruited,**

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

| Techniques / Times | T0 | T+14 Days | T+28 Days |
|---|---|---|---|
| **Subject Self Evaluation** | **N/AP** | **34** | **34** |
| **Dermatological Evaluation (Cosmetic Acceptability)** | **36** | **34** | **34** |
| **Ophthalmological Evaluation: Safety** | **36** | **34** | **34** |

## 5.4 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of **34** (16 females & 18 males) healthy Indian subjects, aged between **18 and 30** years old, (Mean age: 21.3 years old: SD: 3.4 years old; Median: 20 years old) presenting oily or mixed oily skin on the face.

## 5.5 RESULTS OF THE SUBJECT'S SELF ASSESSMENT QUESTIONNAIRE

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

**Product A**

**SUBJECT SELF-EVALUATION QUESTIONNAIRE**

| | | T+14 Days | | T+28 Days | |
|---|---|---|---|---|---|
| | *Number of subjects* | *34* | | *34* | |
| | | *% agreement* | *Significant ? (5%)* | *% agreement* | *Significant ? (5%)* |
| 1 | The test product does not produce comedons/ acne/ pimples on the face after applicatio | 100% | Yes | 100% | Yes |
| 2 | The test product does not make my skin oily. | 97% | Yes | 100% | Yes |
| 3 | The test product is non greasy. | 97% | Yes | - | - |
| 4 | The texture of the test product is appealing. | 97% | Yes | - | - |
| 5 | The test product spreads properly on the face. | 100% | Yes | - | - |
| 6 | The test product gets absorbed quickly in the skin. | 100% | Yes | - | - |
| 7 | The test product does not cause itching. | 100% | Yes | 100% | Yes |
| 8 | The test product does not cause irritation. | 100% | Yes | 100% | Yes |
| 9 | The test product does not give burning sensation. | 100% | Yes | 100% | Yes |

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

### 5.5.1 Observed results

For Product A**, all the suggested items are significantly and highly recognized by the panel,** with 97% to 100% agreement for all the items.

- Concerning the **product efficacy**, test product A is well appreciated for not producing comedons/ acne/pimples on face with 100% agreement and for not making the skin oily with 97% to 100 % agreement respectively at T+14 days & T+28 days of product application.
- Concerning the **physical characteristics**, test product A is well appreciated for non greasy & appealing texture of the test product with 97% agreement & proper spreadability on face & quickly absorption with 100% agreement after T+14 days of product application.
- Concerning the **product acceptability**, test product A is well appreciated for not causing itching, irritation & burning sensation to the skin with 100 % agreement at all given time point.

## 5.6 DERMATOLOGICAL EVALUATION: COSMETIC ACCEPTABILITY

**The studied parameters were:**

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 for Product A:

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 OPHTHALMOLOGICAL 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)

### 5.7.1. Observed results for Product A:

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

# 6. DISCUSSION AND CONCLUSION

Once a day application of test product coded **Ultra Matte Oil-free Fluid SPF 50+(1793): Product A** on whole face by the panel of 34 Indian (18 male & 16 female) subjects, aged between **18 and 30 years old**, **presenting oily or mixed oily skin on the face** leads to the following results **after 28 days of test**;

✓**Subject's Self Evaluation:**

On the basis of Subject's Self Evaluation, all the claims are significantly validated by the panel for the test product A in terms of efficacy, product characteristics & product acceptability after 28 days of product application.

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

✓ **Dermatological Evaluation for Cosmetic Acceptability:**

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

✓ **Ophthalmological Evaluation for Safety:**

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

**To conclude, in the experimental conditions of the study, after 28 days of application of the test product coded: Ultra Matte Oil-free Fluid SPF 50+(1793): Product A, the following points have been demonstrated;**

**- 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 is obtained for test product through subject self-evaluation for product efficacy, product characteristics and product safety till 28 days of product application.**

**- Through Dermatological Evaluation for cosmetic acceptability, it is evaluated that Product A showed no significant difference of clinical and functional signs upto 28 days of product application.**

# 7. APPENDICES

# APPENDIX 1:

# QUALITY ASSURANCE STATEMENT

## Quality Assurance Statement

This study (XXX-2F06-EV-NR23) 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-2F06-EV-NR23-AU01 | 06/12/2023 |
| 2. | Audit of the CRF's | XXX-2F06-EV-NR23-AU02 | 08/12/2023 |
| 3. | Audit report of the Trial Master File | XXX-2F06-EV-NR23-AU03 | 10/01/2023 |
| 4. | Audit of the Raw Data & Results | XXX-2F06-EV-NR23-AU04 | 11/01/2024 |
| 5. | Audit of the Study Report | XXX-2F06-EV-NR23-AU05 | 22/01/2024, 01/02/2024. |

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

Signature: _____
Auditor(s)

Signature: _____
Auditor(s)

Signature: _____
Quality Assurance Manager

# APPENDIX 2:

# COPY OF PROTOCOL

***STUDY SUMMARY: XXX-2F06-EV-NR23***
***Test Product: Ultra Matte Oil-free Fluid SPF 50+(1793):Product A***

**DESCRIPTION OF THE STUDY:**

**EVALUATION OF THE SAFETY OF SKIN CARE FORMULATION THROUGH:**

- **Subject Self Evaluation**
- **Dermatological Evaluation: Cosmetic Acceptability**
- **Ophthalmological Evaluation: Safety**

**NATURE OF THE TESTED PRODUCT AND METHODOLOGY:**

| | |
|---|---|
| Product reference | *Ultra Matte Oil-free Fluid SPF 50+(1793):Product A* |
| Study design | *It was a single blinded non-comparative study. Subjects served as their own reference.* |
| Total duration of the study | *28 days following the first application of product.* |
| Kinetic | *T0, T+14 days & T+28days.* |
| Product application | *Once a day* |
| Number of volunteers | *34 Indian (18 male & 16 Female) healthy human subjects.* |
| Special selection criteria | *Having mixed oily or oily skin on the face.* |

**RESULTS AND CONCLUSION**

Once a day application of test product coded **Ultra Matte Oil-free Fluid SPF 50+(1793): Product A** on whole face by the panel of 34 Indian (18 male & 16 female) subjects, aged between **18 and 30 years old**, **presenting oily or mixed oily skin on the face** leads to the following results **after 28 days of test**;

✓ **Subject's Self Evaluation:**

On the basis of Subject's Self Evaluation, all the claims are significantly validated by the panel for the test product A in terms of efficacy, product characteristics & product acceptability after 28 days of product application.

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

✓ **Dermatological Evaluation for Cosmetic Acceptability:**

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

✓ **Ophthalmological Evaluation for Safety:**

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

**To conclude, in the experimental conditions of the study, after 28 days of application of the test product coded: Ultra Matte Oil-free Fluid SPF 50+(1793): Product A, the following points have been demonstrated;**

**- 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 is obtained for test product through subject self-evaluation for product efficacy, product characteristics and product safety till 28 days of product application.**

**- Through Dermatological Evaluation for cosmetic acceptability, it is evaluated that Product A showed no significant difference of clinical and functional signs upto 28 days of product application.**