TESTED
By Mascot Spincontrol

MASCOT SPINCONTROL
clinical research centre

SPINCONTROL®
au coeur de la peau...

CONFIDENTIAL REPORT

Ref: D01-6Q09-ZS-MH26

Version: 01

Dated: 20-04-2026

EVALUATION OF THE IRRITATION POTENTIAL OF

SKIN CARE FORMULATION

THROUGH:

■ **Dermatological Evaluation –Single Application Patch Test Method**

TEST PRODUCT REFERENCE:

- **Heyglow Mediclear Daily Face Wash (371 S12 08/25) : Product A**

Study Sponsor:

Zymo Cosmetics

Block No. – 115, Santej Vadsar Road,
Village – Santej, Tal-Kalol, Dist-Gandhinagar,
Gujarat-382721, India

Investigator:

MASCOT SPINCONTROL INDIA PVT. LTD.

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

APRIL-2026

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK

20/04/2026

CONTENTS

1. EXPERIMENTATION SITE, PARTICIPANTS 4
1.1. EXPERIMENTATION SITE 4
1.2. STUDY SPONSOR 4
1.3. STUDY MONITOR 4
1.4. STUDY DIRECTOR 4
1.5. PRINCIPAL INVESTIGATOR 4
1.6. QUALITY ASSURANCE MANAGER 5
2. SUMMARY OF THE STUDY 6
2.1. OBJECTIVE 6
2.2. POPULATION 6
2.3. STUDY DURATION 6
2.4. STUDY DESIGN 8
3. STUDY PROTOCOL 9
3.1. SUBJECT SELECTION 9
3.2. THE PRODUCT 12
3.3. STUDY DESIGN 14
3.4. STUDY PROCEDURE 15
3.5. EXAMINATION SCHEDULE 17
3.6. DATA ANALYSIS AND STATISTICS OF TECHNICAL DATA 18
4. ETHICAL AND LEGAL CONSIDERATIONS 19
4.1 STUDY PERSONNEL 19
4.2 DATA ARCHIVING 19
4.3 ANONYMITY OF THE SUBJECTS 19
4.4 CONSENT TO PARTICIPATE IN THE STUDY 19
4.5 USE OF IMAGE 19
4.6 CONFIDENTIALITY 19
4.7 QUALITY ASSURANCE 20
4.8 REGULATIONS 20
4.9 PRACTICAL CONSIDERATIONS 20
5. RESULTS: 21
5.1 PROTOCOL DEVIATIONS 21

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK

5.2 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS 21
5.3 DESCRIPTION OF THE EXPLOITED PANEL 21
5.4 DERMATOLOGICAL EVALUATION 21
5.4.1 Observed results at T2 days (24 Hours after the Patch Removal) 22
5.4.2 Analysis 22
6. DISCUSSION AND CONCLUSION 23
7. APPENDICES : 23
APPENDIX 1:
CHARACTERISTICS OF THE PANEL
APPENDIX 2:
RESULT OF THE STUDY
APPENDIX 3:
QUALITY ASSUARANCE STATEMENT
APPENDIX 4:
COPY OF STUDY PROTOCOL

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK

1. EXPERIMENTATION SITE, PARTICIPANTS

1.1. EXPERIMENTATION SITE

MASCOT SPINCONTROL INDIA PVT. LTD.
Sea Breeze Building, 9th Floor, AppaSaheb
Marathe Marg, Century Bazaar, Prabhadevi,
Mumbai, Maharashtra 400025.
Telephone: +91-22-43349191/192
E-mail: info@mascotspincontrol.in

STUDY SPONSOR

1.2. STUDY SPONSOR

Zymo Cosmetics
Block No. – 115, Santej Vadsar Road,
Village – Santej, Tal-Kalol, Dist-Gandhinagar,
Gujarat-382721, India

1.3. STUDY MONITOR

Ms Shreya
Zymo Cosmetics
Block No. – 115, Santej Vadsar Road,
Village – Santej, Tal-Kalol,
Dist-Gandhinagar, Gujarat-382721, India
Telephone: + 91 9016825280

MASCOT SPINCONTROL

1.4. STUDY DIRECTOR

Mr. Mohit Lalvani
MD
MASCOT SPINCONTROL
Telephone: +91-22-43349191/ 92
E-mail: mohit@mascotspincontrol.in

Signature: 
Date: 20/04/2026

1.5. PRINCIPAL INVESTIGATOR

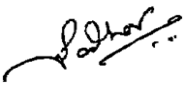
Dr. Nihaarika Salian
Dermatologist
Reg. No. 2011/05/1530
MASCOT SPINCONTROL
Telephone: +91-22-43349191/ 92

Signature: 
Date: 20/04/2026



1.6. QUALITY ASSURANCE MANAGER

Ms. Shraddha Jadhav
General Manager - Quality Assurance
MASCOT SPINCONTROL
Telephone: +91-22-43349191/ 92
E-mail: shraddhajadhav@mascotspincontrol.in

Signature: 

Date: 20/04/2026

2. SUMMARY OF THE STUDY

2.1. OBJECTIVE

The objective of this study was to evaluate the irritation potential on healthy human subjects having varied skin of Skin Care Formulation.

The evaluation was performed using:

- **Dermatological Evaluation: Single Application Patch Test Method***
  (*Primary irritation patch test method)

2.2. POPULATION

Twenty-six (26) subjects were selected for the study.

The subjects selected for this study were healthy females and males **with Varied skin types,** aged between **18 and 56** years old. In which **13 were female and 13 were male subjects.**

The distribution of volunteers as per skin type was as follows:

Oily skin – 3 Females + 3 Males

Normal skin – 4 Females + 4 Males

Dry skin – 3 Females + 3 Males

Combination skin – 3 Females + 3 Males

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

2.3. STUDY DURATION

Duration: 8 days [3days and T8 (T+1 week after 0 hour of patch removal) visit was scheduled to monitor follow up reactions].

Scheduled Procedures:

	Screening	T0 (before patch application)	T1 day (0 hour after the patch removal)	T2 days (24 hours after the patch removal)	T8 days (T+1 week after 0 hour of patch removal)
		Patch Application Day	Patch Removal Day		
Registration	■				
Protocol Briefing	■				
Consent	■				
ICF		■			
Inclusion and Non-Inclusion criteria by the Dermatologist	■	■			
History Questionnaire	■				
Routine Check up	■				
Clinical Observation	■				
Site Identification		■			
Proscriptions and Restrictions			■	■	■
Concomitant Medication		■	■	■	■
Patch Application		■			
Patch Removal			■		
Dermatological Evaluation reading of patch tests				■	■
AE/SAE Monitoring		■	■	■	■
					End of the study

Study Schedule:

Screening & T0 (before patch application)	T1 (0 hour after the patch removal)	T2 (24 hours after the patch removal)	T8 (T+1 week after 0 hour of patch removal)
08-04-2026	**09-04-2026**	**10-04-2026**	**16-04-2026**

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK

2.4. STUDY DESIGN

- Single application, closed, occlusive patch test.
- Non comparative, single center 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 Principal investigator for subjects, prior to the study that provides details of their medical history, possible allergies, skin-care, hair-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 which is read and filled in freely and intentionally, 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 Principal Investigator/Co-Investigator.

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

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

The subjects selected for the study was chosen under the supervision of the Principal Investigator and co-investigator, on the basis of the inclusion/non-inclusion criteria listed below.
A selection of 26 subjects was made for this study.
The results given included all of the present and assessable subjects at each examination.

3.1.1. Inclusion criteria

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

Standard criteria

- Asian Indian male and female subjects.
- Healthy human 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 check-up)
- Between **18 and 65** of age.
- Skin is healthy on the studied anatomic unit (free of eczema, wounds, inflammatory scar….)

Specific criteria

- Subjects representing varied skin types (ideally equal representation of all 4 skin types – Oily, Normal, Dry and Combination).

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 his/her assent by not signing the consent form
- Taking part in another study liable to interfere with this study
- Being diabetic.
- Being asthmatic.
- 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 (except in the case of studies with evaluation of sensitive skin).
- Having a diagnosed or highly probable allergy to one or several compounds of the cosmetic products.
- Having undergone a surgery requiring a general anaesthesia of more than one hour in the past 6 months.
- Having changed his/her cosmetic habits in the 14 days preceding the start of the study on the studied anatomic unit.
- The day of the patch application: no cosmetic product must be used (test site clean with water only).
- Refusing to follow the restrictions below during the study:

- For female: Do not become pregnant nor breastfeed.
- 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, and anti-histamines, corticotherapy, taken by general or local routes (the only medication permitted is paracetamol).
- Do not change his/her cosmetic habits apart from the particular conditions mentioned in the protocol, on the studied anatomic unit.

Specific criteria

- Having eczema, psoriasis, lichen plan, vitiligo whatever the considered area
- Having disorder of the healing (whatever the considered area)
- Having a rhinitis, allergic conjunctivitis or rhino sinusitis
- Having an allergy to perfumes and/or preservatives in cosmetic products
- Having an allergy to plaster
- Having a food allergy
- Having a cardiovascular pathology (taking a beta blocker treatment)
- Having immunosuppressive drugs, such as cyclophosphamide, methotrexate, azathioprine, etc.
- Taking a retinoid-based treatment by general or oral route
- Taking specific treatment on the back.
- Having taken an anti-histaminic treatment in the last 2 weeks preceding the start of the study
- Having miliaria (prickly heat) on the back.
- Presenting too many naevus on the back
- Having high pilosity on the back.
- Refusing to follow the restrictions below during the study:

- During the first 24 hours (after patch application), neither cosmetic products nor water must be applied on the back.
- Till the follow up period of until T8 days, only water is accepted from the first reading i.e., T2 days (24 hours after the patch removal).
- Do not practice an intensive sport activity during the first 24 hours (until the removal of the patches)
- Do not expose the back to the sun.

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	Code	Batch/ LT	Constituent form	Mfg. Date	Expiry Date	Packaging	Capacity
Heyglow Mediclear Daily Face Wash (371 S12 08/25)	A	371 S12 08/25	Emulsion	26-03-2026	N/AV	Bottle	N/AV

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

For this study, the study sponsor agrees to supply:

The appropriate quantity of the products required to treat all of the subjects; A sufficient quantity of the products for any additional subjects participating in the study;

One products per reference and per batch was retained in the sample cabinet of MASCOT SPINCONTROL.

Products are stored in an ambient temperature away from light.

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

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

The cost of the products destruction by the investigator are charged to the sponsor

3.2.2 Patch Preparation

The patches were prepared in the morning of the application, one hour before the visit i.e., at T0 in acclimatized room 20°C -25°C.

The product was stored in IP storage room (T°C between 20°C -25°C., Humidity between 40 RH and 60 RH).

Product	Codes	Patch No.	Application area	Frequency of application	Application duration	Conservation
Test Product A	**A**	1	Between scapulae and waist	Once	24 hours	At an ambient temperature
Negative Control (0.9% Isotonic saline solution)	**-**	2	Between scapulae and waist	Once	24 hours	At an ambient temperature
Positive Control (1% w/w SLS)	**-**	3	Between scapulae and waist	Once	24 hours	At an ambient temperature

3.2.2.1 Patch Preparation for Test Product

a. Procedure for Patch Preparation of Test Product A as per BIS Standard clause 4.3.1.2.2, IS 4011:2018,3rd Revision:

- 8% w/w solution of the investigational product will be prepared by weighing 2g of the product and dissolving it in distilled water and making up the final weight to 25g.
- 0.04 ml or 40 µl of the prepared samples will be transferred on previously numbered Aluminium Finn Chamber with an appropriately sized disc of Whatman no. 3 filter paper with the help of micropipette.
- The Finn chambers with the sample loaded filter paper discs will then be taped onto the back of subjects.

b. Patch preparation for Negative control as per BIS Standard clause 4.3.1.2.4, IS 4011:2018, 3rd Revision :

- 0.04 ml (40 µl) of 0.9% Isotonic Saline Solution was transferred to previously numbered Aluminium Finn Chamber with an appropriately sized disc of Whatman no. 3 filter paper with the help of Micropipette.
- The Finn chamber with the loaded 0.9% Isotonic Saline solution was then taped onto the back of subjects.

c. Patch preparation for Positive control as per BIS Standard clause 4.3.1.2.4, IS 4011:2018, 3rd Revision :

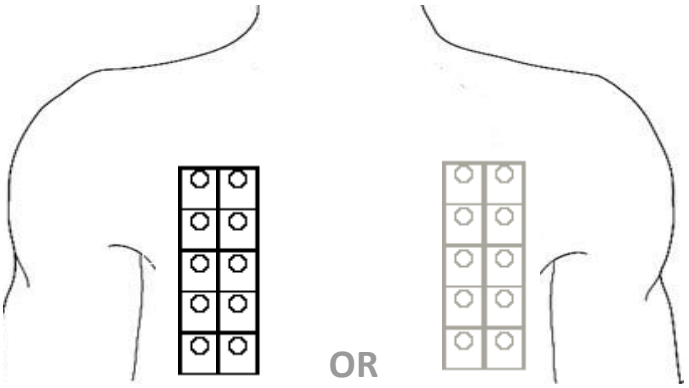
- Sodium Lauryl Sulphate solution: 1% w/w solution of SLS in distilled water was prepared.
- 0.04 ml (40 µl) of the SLS solution was loaded onto a Whatman no. 3 filter paper disc, placed in clean Aluminium Finn Chamber.
- The Finn chamber with the loaded 1% w/w SLS solution was then taped onto the back of subjects.

Patch application

The patch application was carried out by the CRA:

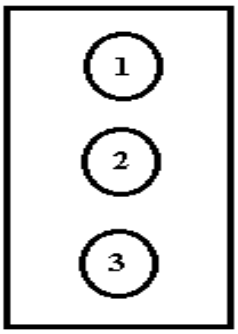
For subject:

- The Dermatologist determined the site that poses to be the most appropriate, based on moles, body hair; freckles of the selected area was sound, without excessive hair growth.
- Patches were not applied on a nevus.
- Location of application: Between scapula and waist.
- The application of the patches was made as follows:



For CRA

- Hands were washed with disinfectant.
- Began application of the strip by the bottom, the rooms were pressed up to release the air.
- When the tape was fully in place, each patch was gently pressed containing a test product or Control, to ensure an even distribution of the substance.
- Pressure was applied to the tape and especially its edges to ensure good fixation. The person being tested avoided sudden movements.
- The application of patches was strengthened by applying micropore tape on all the four sides of patch.



3.3. STUDY DESIGN

- This was a single application closed, occlusive patch test.
- Non comparative, single center study.
- Subjects served as their own references.

3.4. STUDY PROCEDURE

3.4.1. Dermatological Evaluation

➢ **Principle**

The patch test under occlusion was a method used to check safety in terms of irritation potential of any cosmetic or cosmeceutical formulation which is to be applied topically on healthy human subjects.

Irritants are the substances that may damage the skin. The damage will depend upon the nature, concentration and duration of exposure. Irritation is manifested as inflammatory responses such as erythema (redness) and oedema (swelling), vesiculation and finally to an intense suppurate reaction without the involvement of immune system

The evaluation of the different products were compared with 1% (w/w) sodium lauryl sulphate as positive control & 0.9% isotonic saline solution as negative control.

The kinetic of the evaluation is as follows:

T0 = (before patch application)	Patch application
T1 day = (0hour after the patch removal)	Patch removal
T2 days = (24 hours after patch removal)	Patch reading by the Dermatologist
T8* days = (T+1 week after 0 hour of patch removal)	Checking of the evolution of the positive cases

➢ **Methodology of patch application**

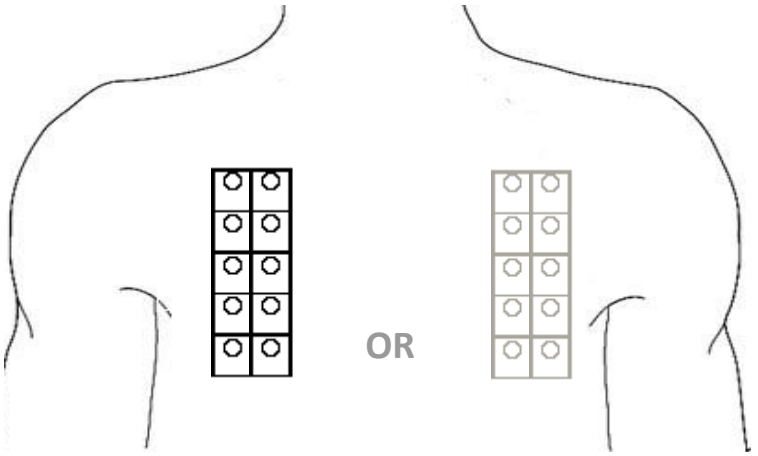
The patch application is carried out at T0 visit by the CRA.

- Hands were washed with disinfectant.
- Began application of the strip by the bottom, the rooms were pressed up to release the air.
- When the tape was fully in place, each patch was gently pressed containing a test product or Control, to ensure an even distribution of the substance.
- Pressure was applied to the tape and especially its edges to ensure good fixation. The person being tested avoided sudden movements.
- The application of patches were strengthened by applying micropore tape on all the four sides of patch.
    - Studied areas and location

The patches were applied on the top of the back near the shoulder blade.

The dermatologist determines the best area to apply the patch, depending on the naevi, the pilosity and the freckles. The selected area was healthy, without an excessive pilosity. Patches were not applied on a naevi.

The patches were applied on the right &/or left part of the back: the side was mentioned in the CRF by the dermatologist.



- Position of the subject

It was recommended that the subject sat with the back slightly bent forward.

➢ **Methodology of patch removal**

The CRA removed the patch from the bottom to the top. The area was gently wiped off with a soft tissue paper.

➢ **Methodology of patch reading by the Dermatologist**

The skin reaction was assessed under a constant artificial daylight source.

The Dermatologist scores the reactions namely erythema (including dryness, scaliness and wrinkles) on a 0–4-point scale and oedema on another 0 - 4-point scale as per Draize Scale (Clause 4.3.1.3 Observation and scoring for Skin Irritation Test, Draize scale for scoring the treatment sites- IS 4011:2018 Methods of test for safety evaluation of cosmetics – 3rd Revision).

Score for Erythema/ dryness/ wrinkles	Reaction	Score for Oedema	Reaction
0	No reaction	0	No reaction
1	Very slight erythema/dryness with shiny appearance	1	Very slight Oedema
2	Slight erythema/ dryness/wrinkles	2	Slight Oedema
3	Moderate erythema/ dryness/wrinkles	3	Moderate Oedema
4	Severe erythema/ wrinkles/scales	4	Severe Oedema

In case of positive reaction, a photograph of the patches were captured on T2 days. Another photograph at T+8 days was enabled to evaluate the evolution of the sign.

3.5. EXAMINATION SCHEDULE

The effect of the product was evaluated over a 3 - day's period and follow up visit at T8 (T+1 week after 0 hour of patch removal). The scheduled measurement procedures were as follows:

Screening

- Registration
- Protocol Briefing
- Reading and signature of the consent form
- History Questionnaire
- Routine Check up
- Clinical Observations
- Checking of the inclusion/non-inclusion criteria by the Dermatologist

***At T0* (before patch application)**

- Acclimatization at temperature 20°C - 25°C for 20 mins.
- Acknowledgement, reading and signature of the ICF
- Concomitant Medication
- Checking of the inclusion/non-inclusion criteria by the Dermatologist
- Site Identification by Dermatologist
- Patch Application by CRA.
- AE/SAE Monitoring

***At T1* (0 hour after the patch removal)**

- Acclimatization at temperature 20°C - 25°C for 20 mins
- Proscriptions and restrictions
- Concomitant Medication
- Patch Removal by CRA.
- AE/SAE Monitoring

***At T2* (24 hours after the patch removal)**

- Acclimatization at temperature 20°C - 25°C for 20 mins
- Proscriptions and restrictions
- Concomitant Medication
- Dermatological Evaluation: patch test reading
- AE/SAE Monitoring

***At T8* (T+1 week after 0 hour of patch removal)**

- Acclimatization at temperature 20°C - 25°C for 20 mins
- Proscriptions and restrictions
- Concomitant Medication
- Dermatological Evaluation: patch test reading
- AE/SAE Monitoring
- Filling of Study completion form by the Dermatologist

3.6. DATA ANALYSIS AND STATISTICS OF TECHNICAL DATA

- Carried out by Study In charge at Mascot Spincontrol India.

The assessment was only based on the mean score obtained 24 hours after the patch removal (T2) for the technique dermatological evaluation.

Mean Score for Irritation = $\frac{\text{Total score (Erythema+ Oedema) for each sample}}{\text{Total no. of Subjects}}$

To calculate the mean score of observations made for assessing the investigational site for Skin Irritation as presented in Mean Score for Irritation:(Clause 4.3.1.3 Observation and scoring for Skin Irritation Test, Draize scale for scoring the treatment sites (IS 4011:2018 Methods of test for safety evaluation of cosmetics – 3rd Revision)

Mean Score	Classification
2.0 / 8.0	Non- Irritant
Up to 4.0 / 8.0	Mild Irritant
Above 4.0 / 8.0	Irritant

Average score produced by each of the test sample will be compared with that produced by the positive control & negative control.

Note: Positive control must give combined mean score of greater than 2.
Negative control must give combined mean score of less than 2.

If positive control gives a combined mean score less than 2.0 and/or negative control gives a combined mean score of greater than 2.0, then the test need to be repeated on another group of newly recruited volunteers.

4. ETHICAL AND LEGAL CONSIDERATIONS

4.1 STUDY PERSONNEL

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

4.2 DATA ARCHIVING

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

4.3 ANONYMITY OF THE SUBJECTS

The subjects are identified for the study sponsor using a five-character alphanumeric code and a number. The investigator makes a commitment not to raise the anonymity of the subjects.
The study sponsor cannot have access to the confidential data relative to the subjects registered in the data base of Mascot Spincontrol.

4.4 CONSENT TO PARTICIPATE IN THE STUDY

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

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

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

4.5 USE OF IMAGE

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

4.6 CONFIDENTIALITY

All the information, data, results and audio-visual recordings of informed consent process 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.

ETHICS COMMITTEE

The ETHOS Institutional Ethics Committee reviews & gives approval for the clinical trial.
Approval of Date: 08/04/2026

4.7 QUALITY ASSURANCE

Our quality system has been developed to meet guidelines relevant to our type of activity for ingredients and cosmetic product efficiency and tolerance testing.
As such, our Quality System is in full compliance with ICH-E6 -Good Clinical Practice (GCP) guidelines in our test companies: Mascot Spincontrol (India) and Spincontrol 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	10/03/2026
2.	Audit of the CRF's	08/04/2026
3.	Audit report of the Trial Master File	17/04/2026
4.	Audit of the Raw Data & Results	17/04/2026
5.	Audit of the Study Report	20/04/2026

4.8 REGULATIONS

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

4.9 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. RESULTS:

This report is based on the exploitation of the results regarding the irritation potential of having varied skin types of Skin Care Formulation by Primary Irritation Patch Test Method.

5.1 PROTOCOL DEVIATIONS

The protocol has been respected as a whole.

5.2 POPULATION CONSIDERED IN THE EXPRESSION OF THE RESULTS

At T0, 26 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, presented in the following table:

Technique	T0 (before patch application)	T1 day (0 hour after the patch removal)	T2 days (24 hours after the patch removal)	T8 (T+1 week after 0 hour of patch removal)
Dermatological Evaluation	26	26	26	26

From above techniques and time points data for T2 visit (24 hrs. of patch removal) – Dermatological evaluation was considered for the mean score calculation of patch test.

5.3 DESCRIPTION OF THE EXPLOITED PANEL

The exploited panel consisted of 26 healthy females and males' subjects aged between 18 and 56 years old (Mean age in years: 29.92 Standard deviation in years: 11.27 and median age in years: 27 of Asian (Indian) skin type.

5.4 DERMATOLOGICAL EVALUATION

The detailed results of the dermatological evaluation are presented in Appendix 2.
The studied parameters are:

1. Erythema
2. Oedema

5.4.1 Observed results at T2 days (24 Hours after the Patch Removal)

The following table summarizes the total and mean scores obtained on the exploited panel, for the erythema and oedema parameters, as well as the conclusion concerning the irritation potential of each tested material (if applicable), 24 hours after the patch removal, on the back.

	Results For T2 Days (24 Hours After The Patch Removal) Visit For Dermatological Evaluation				
Test material	**Total Score for Erythema**	**Total Score for Oedema**	**Total Score for Erythema + Oedema**	**Mean Score (Irritation)**	**Conclusion on the Irritation Assessment**
Test Product A	21.0	2.0	23.0	0.9	Non-Irritant
Negative Control (0.9% Isotonic saline solution)	0.0	0.0	0.0	0.0	-
Positive Control (1% w/w SLS)	44.0	32.0	76.0	2.9	-

5.4.2 Analysis

At T2 days (24 hours after patch removal) visit mean score of erythema and oedema by dermatologist is found as follows:

- **0.9** Score for **Heyglow Mediclear Daily Face Wash (371 S12 08/25) Product: A** show that product is **Non-Irritant.**
- No irritative type response at T2 day (24 hours after patch removal) was observed by dermatologist.
- No reaction was observed for the negative control (i.e. 0.9% Isotonic Saline Solution).
- The Mean Score for positive control 1% w/w SLS solution is **2.9.**

6. DISCUSSION AND CONCLUSION

In our experimental conditions, based on the incident of the response and comparison of the mean scores with positive and negative control of erythema and oedema observed for the Single application closed, occlusive patch study patch for 24 hours of the having varied skin type of the Skin Care formulation for Product coded **Test Product A** according to the Primary irritation patch test method on panel of 26 healthy human subjects (13 males + 13 females) Having a Varied Skin type,, aged between 18 and 56 years old, leads to the following results through dermatological evaluation at 24 hours after the patch removal.

Test Product A was **dermatologically tested for safety** & are **Non-Irritant to skin**.

7. APPENDICES :

APPENDIX 1:

CHARACTERISTICS OF THE PANEL

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK

CHARACTERISTICS OF THE PANEL

Subject_No	Subject_Code	Age	Sex	SkinType
001	NANKO	32	Male	Combination
002	VARO1	23	Male	Normal
003	MOR27	25	Male	Combination
004	KARR1	42	Male	Dry
005	SHAAK	46	Male	Dry
006	NISS6	18	Male	Oily
007	LANK1	19	Male	Normal
008	SAW66	20	Male	Normal
009	MANA6	25	Male	Combination
010	MANG1	19	Male	Oily
011	GAWAV	19	Male	Oily
012	KHAKU	19	Male	Normal
013	KAM2	56	Male	Dry
014	KODAN	41	Female	Dry
015	KEWSU	42	Female	Dry
016	SHAWA	43	Female	Dry
017	SARJY	41	Female	Combination
018	SHAT8	39	Female	Combination
019	DHADI	29	Female	Normal
020	SURS6	18	Female	Oily
021	SURS5	40	Female	Normal
022	MASSA	35	Female	Combination
023	KAM84	30	Female	Normal
024	CH173	20	Female	Normal
025	KAM75	19	Female	Oily
026	KA101	18	Female	Oily
Mean		**29.92**	**Males: 13**	
Minimum		**18**	**Females: 13**	
Maximum		**56**		
Standard Deviation		**11.27**		
Median		**27**		
Total Subjects		**26**		

APPENDIX 2:

RESULT OF THE STUDY

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK

RESULT OF THE STUDY

Product_Name	Total_Erythema	Total_Oedema	Total_Score	Mean_Score	Conclusion
Heyglow Mediclear Daily Face Wash (371 S12 08/25)	21.0	2.0	23.0	0.9	Non-Irritant
Negative Control (0.9% Isotonic saline solution)	0.0	0.0	0.0	0.0	-
Positive Control (1% w/w SLS)	44.0	32.0	76.0	2.9	-

APPENDIX 3:

QUALITY ASSURANCE STATEMENT

QUALITY ASSURANCE STATEMENT

This study D01-6Q09-ZS-MH26 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	D01-6Q09-ZS-MH26-AU01	10/03/2026
2.	Audit of the CRF's	D01-6Q09-ZS-MH26-AU02	08/04/2026
3.	Audit report of the Trial Master File	D01-6Q09-ZS-MH26-AU03	17/04/2026
4.	Audit of the Raw Data & Results	D01-6Q09-ZS-MH26-AU04	17/04/2026
5.	Audit of the Study Report	D01-6Q09-ZS-MH26-AU05	20/04/2026

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

Signature: 20/04/2026
Auditor(s)

Signature: **N/AP**
Auditor(s)

Signature: 20/04/2026
Quality Assurance Manager

APPENDIX 4:

COPY OF STUDY PROTOCOL

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK

MASCOT SPINCONTROL
clinical research centre

SUMMARY: D01-6Q09-ZS-MH26

TEST PRODUCT: Product A

DESCRIPTION OF THE STUDY:

EVALUATION OF THE IRRITATION POTENTIAL OF SKIN CARE FORMULATION THROUGH:

- **Dermatological Evaluation –Single Application Patch Test Method**

NATURE OF THE TESTED PRODUCT AND METHODOLOGY:

Product Reference	Test Product A
Study design	Single application, closed, occlusive patch test, non-comparative, single center study, Subjects served as their own references.
Total duration of the study	8 days [3 days and T8 (T+1 week after 0 hour of patch removal) visit was scheduled to monitor follow up reactions].
Kinetics	T0 (before patch application), T1 day (0 hour after the patch removal), T2 days (24 hours after the patch removal) and T8 (T+1 week after 0 hours of patch removal).
Product application	Single application of test product, Positive control (1% w/w SLS) & Negative control (0.9% Isotonic Saline Solution), on the back, under occlusion for 24 hours.
Number of volunteers	26 (13 females and 13 males) Healthy Human Subjects having Varied skin type.
Special selection criteria	Subjects representing varied skin types (ideally equal representation of all 4 skin types – Oily, Normal, Dry and Combination).

RESULTS AND CONCLUSION

In our experimental conditions, based on the incident of the response and comparison of the mean scores with positive and negative control of erythema and oedema observed for the Single application closed, occlusive patch study patch for 24 hours of the having varied skin type of the **Skin Care Formulation** for Product coded **Test Product A** according to the Primary irritation patch test method on panel of 26 healthy human subjects (13 males + 13 females) Having a Varied Skin type, aged between 18 and 56 years old, leads to the following results through dermatological evaluation at 24 hours after the patch removal.

Test Product coded **Heyglow Mediclear Daily Face Wash (371 S12 08/25) Product: A** was **dermatologically tested for safety** & is **Non-Irritant to skin**.

MASCOT SPINCONTROL INDIA PVT. LTD. QA CHECK
20/04/2026

Note: Based on result & conclusion client can only claim Non-irritant & Dermatologically tested for safety.