PATCH TEST OF SUNSCREEN XPENSIVE CARE

ON NORMAL, DRY, OILY AND COMBINATION SKIN TYPES,

UNDER THE VIGILANCE OF DERMATOLOGIST

CRO Lambent Pvt. Ltd.

Confidential Report

Prepared For	Prepared by
Xpensive Care	CRO Lambent Pvt. Ltd. 3rd Floor, B- 52 Sector - 64 Noida - 201301

- Subject Self Evaluation (SSE)
- Under the vigilance of Dermatologist

Guideline: GCP – EC6(R3)
Report No.: LL86/LL26–27-27/TIPL-003, Version: 01 (July 26)

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PATCH TEST OF SUNSCREEN XPENSIVE CARE ON NORMAL, DRY, OILY AND COMBINATION SKIN TYPES, UNDER THE VIGILANCE OF DERMATOLOGIST

TEST PRODUCTS REFERENCES:

Product Name	Batch No.	Mfg. Date	Test	Mfg. By	Mktd. By
SUNSCREEN XPENSIVE CARE	XC-S001-	07/2026	PATCH TEST ON HEALTHY HUMAN BODY WITH NORMAL, DRY, OILY & COMBINATION SKIN	Trassally International Pvt.Ltd.B-35, Sector-57,Noida, G.B. Nagar, U.P-201301	Xpensive Care

Study Sponsor:

Xpensive Care

Study Monitor:

CRO Lambent Pvt. Ltd.
3rd Floor, B - 52
Sector – 64, Noida
U.P-201301

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ARBRO
PHARMACEUTICALS PRIVATE LIMITED
Analytical Division
ISO 9001 : 2015 Certified & Govt. Approved Test House
4/9, Kirti Nagar Industrial Area, New Delhi - 110015 (INDIA)
Phone : +91 11-45754575, Email : arbrolab@arbropharma.com, Website : www.testing-lab.com

TC-7375

ULR - TC73752600001330

Information by Customer

CERTIFICATE OF ANALYSIS

Report No. : 202607130071

Sample : SUNSCREEN XPENSIVE CARE
Mfg. By : TRASSALLY INTERNATIONAL PVT LTD
Supplied By : CRO LAMBENT PRIVATE LIMITED
Mfg lic. No. : NS
Submitted By : CRO LAMBENT PRIVATE LIMITED
Ref. No. : NS,DATE:11/07/2026
Address : B-52, 3rd Floor, Sector 64, Noida, UTTAR PRADESH- 201301 INDIA

Batch No	Mfg. Date	Expiry Date	Batch Size	Sample Quantity
XC-S001-	07/2026	06/2029	NS	50 gm

Sample ID : 202607130071 **Received On :** 13/07/2026
Date of start of analysis : 13/07/2026 **Date of completion of analysis :** 18/07/2026
MARKETED BY :- XPENSIVE CARE

Description :- Off white soft mass

-

<Parameters>	<Results>	<Unit>	<Req.>	<Claim>	<LLOQ>	<Lower limit>	<Upper limit>	<Method>
Total fatty substance content	: 14.12	% w/w	-		-	-	-	IS 6608:2004
E.Coli	: Absent	per g	-		-	-	-	IS 14648:2011
Total viable count	: Less than 10	cfu/g	-		-	-	-	IS 14648:2011

Report : CUSTOMER ASKED FOR THE ABOVE TESTS ONLY

Vaibhav Tyagi
(OFFICER-TECHNICAL(BIOLOGICAL))

Authorized Signatory Biological

Padam Garg (Assistant Manager)

Authorized Signatory Chemical

Date of Issue : Saturday,Jul 18, 2026

End of Report

To verify Report Scan this Code.

***Terms & Conditions:**
(1) Total liability of this laboratory is limited to the invoice amount.
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ARBRO PHARMACEUTICALS PRIVATE LIMITED
Analytical Division
ISO 9001 : 2015 Certified & Govt. Approved Test House
4/9, Kirti Nagar Industrial Area, New Delhi - 110015 (INDIA)
Phone : +91 11-45754575, Email : arbrolab@arbropharma.com, Website : www.testing-lab.com

Information by Customer

CERTIFICATE OF ANALYSIS

Report No. : A202607130071

Sample : SUNSCREEN XPENSIVE CARE
Mfg. By : TRASSALLY INTERNATIONAL PVT LTD
Supplied By : CRO LAMBENT PRIVATE LIMITED
Mfg lic. No. : NS
Submitted By : CRO LAMBENT PRIVATE LIMITED
Ref. No. : NS,DATE:11/07/2026
Address : B-52, 3rd Floor, Sector 64, Noida, UTTAR PRADESH- 201301 INDIA

Batch No	Mfg. Date	Expiry Date	Batch Size	Sample Quantity
XC-S001-	07/2026	06/2029	NS	50 gm

Sample ID : 202607130071 **Received On :** 13/07/2026
Date of start of analysis : 13/07/2026 **Date of completion of analysis :** 18/07/2026
MARKETED BY :- XPENSIVE CARE

- <Parameters>	<Results>	<Unit>	<Req.>	<Claim>	<LLOQ>	<Lower limit>	<Upper limit>	<Method>
pH	: 5.44	-	-		-	-	-	IS 6608:2004 ,Annex B

Report : CUSTOMER ASKED FOR THE ABOVE TESTS ONLY

Vaibhav Tyagi
(OFFICER-TECHNICAL(BIOLOGICAL))
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EXPERIMENTATION SITES

Site / Facility	Details / Address	Region
URSA Skin & Aesthetics	193, Hamilton Court Road, Sector-27, Gurugram	Delhi-NCR
Arbro Pharmaceuticals Pvt. Ltd.	4/9, Kirti Nagar Industrial Area, New Delhi – 110015	Delhi-NCR

1. ABSTRACT

Dermatological Safety Assessment of a Sunscreen Xpensive Care Following a 24-Hour Occlusive Patch Test in Human Volunteers

Objective:

The objective of this clinical investigation was to determine the cutaneous safety profile, irritation potential, and dermal tolerance **of the investigational a Sunscreen Xpensive Care, when applied under 24-hour** occlusive patch conditions **on healthy human skin. The study aimed to establish the** absence of primary skin irritation or sensitization **under exaggerated exposure conditions as per** dermatological evaluation standards**.**

Study Design and Methodology:

This was a **single-centre, prospective, controlled, non-invasive clinical study** conducted in accordance with the principles of **Good Clinical Practice (GCP)** and **ethical guidelines for biomedical research on human subjects.**

A total of **34 healthy adult volunteers** (18 male and 16 female), aged 20**–55 years,** with all skin types (Oily, combination, Dry & Normal), were enrolled following written informed consent and medical screening. Approximately **0.2 g of the test formulation** was applied to a **2.5 × 2.5 cm hypoallergenic absorbent patch** and affixed to the **interscapular region of the upper back** under **occlusion for 24 ± 2 hours**. Upon removal, the application sites were evaluated at **30 minutes, 5 hours, and 15 hours, 20 hours and 24 hrs. post-decision** by a qualified **dermatologist** for **erythema, oedema, dryness, population, vesiculation, or any visible reaction**.

A **positive control (1% sodium lauryl sulfate solution)** and an **untreated negative control** were incorporated to validate test sensitivity and internal assay integrity.

Results:

A total of 34 subjects were enrolled in the study. Of these, 30 subjects successfully completed the study as per the protocol, while 4 subjects discontinued participation due to personal reasons unrelated to the test product or study procedures. No clinically significant adverse dermal events were reported during the study. No evidence of erythema, oedema, vesiculation, or cutaneous irritation was noted at the test product site at any observation point among the subjects who completed the study.

The **mean cumulative irritation score** was **0.00 ± 0.00**, denoting **"No Visible Reaction"** according to the **Draize Classification Scale**. Expected mild, transient erythema was observed at the positive control site, thereby confirming **methodological validity and reactivity of subjects' skin**.

Conclusion:

Based on the results of the occlusive patch test conducted under controlled conditions, Sunscreen Xpensive Care demonstrated excellent dermatological tolerance. The product was classified as Non-Irritant to Human Skin according to the Draize scoring criteria. These findings confirm that the Sunscreen is dermally safe and well-tolerated, supporting its suitability for cosmetic use, including application on normal, dry, oily, and combination skin.

Keywords:

Sunscreen Xpensive Care, Occlusive Patch Test, Dermatological Safety, Draize Scoring, Skin Irritation Index, Non-Irritant, Human Volunteer Study, Clinical Evaluation.

2. INTRODUCTION

Sunscreen Xpensive Care

Sunscreen Xpensive Care is an advanced sunscreen formulation designed to provide broad-spectrum protection against harmful UVA and UVB rays while helping maintain healthy-looking, hydrated, and protected skin. It is suitable for all skin types, including normal, oily, combination, dry, and sensitive.

This sunscreen helps protect the skin from sunburn, tanning, and the damaging effects of daily UV exposure that may contribute to premature skin aging. Its lightweight formula spreads evenly across the skin to form a protective barrier without leaving a heavy or greasy feel. Regular use helps defend the skin against environmental stressors while supporting an even-toned and well-protected complexion.

Its non-greasy, fast-absorbing formula blends effortlessly into the skin without leaving a sticky residue or white cast, making it comfortable for everyday wear. Suitable for daily use, it layers well under makeup and can be reapplied as needed throughout the day. With regular use, Sunscreen Xpensive Care helps keep the skin protected, comfortable, and healthy-looking while maintaining a smooth and refreshed appearance.

Key Benefits

- **Broad-Spectrum Sun Protection** — Helps protect the skin against harmful UVA and UVB rays that can cause sunburn and tanning.
- **Helps Prevent Sun-Induced Damage** — Supports protection against the visible effects of daily sun exposure, including pigmentation and uneven skin tone.
- **Hydrates & Nourishes Skin** — Helps maintain the skin's natural moisture balance, leaving it feeling soft and comfortable.
- **Lightweight & Non-Greasy Formula** — Absorbs quickly without leaving a sticky residue or heavy feel on the skin.
- **Suitable for Daily Use** — Provides comfortable everyday sun protection and can be worn alone or under makeup.
- **Promotes Healthy-Looking Skin** — Regular use helps maintain protected, smooth, and healthy-looking skin with a natural finish.

Suitable For:

- Normal, dry, oily & combination skin

3. SUMMARY OF THE STUDY

3.1 OBJECTIVE

The objective of this study was to evaluate subjects that have normal, dry, oily and combination skin for reaction on the skin in terms of rashes or itching or irritation.

The evaluation was performed using:

- Subject Self Evaluation (SSE)
- Under the vigilance of a dermatologist

3.2 POPULATION

Subjects (34 Indian male & Female) having normal, dry, oily and combination skin were selected for this study. Of these, 30 subjects successfully completed the study, while 4 subjects discontinued due to personal reasons. The subjects selected for this study were healthy male & female, subjects aged between 20 and 55 years. These subjects were selected according to the inclusion/exclusion criteria listed in paragraph.

3.3 STUDY DURATION

Duration: The study lasted 24 hours following first application of the products.

Scheduled Procedures:

	T0	T1	T2	T3	T4	T5	T6
Protocol Briefing	•						
Habits Questionnaire	•						
History Questionnaire	•						
Subject Self Evaluation		•	•	•	•	•	•
Product Application on site	•						
QM Monitoring	•	•	•	•	•	•	•
							END OF RESULT

3.4 STUDY SCHEDULE:

Screening	T0 - Before application T1 - Immediately T2 - 30 minutes after product application T3 - After 5 hours T4 - After 15 hours T5 - After 20 hours T6 - After 24 hours	T+24 hours after product application

4. THE PRODUCT

4.1 Presentation of the products

The test products were supplied free of charge by the study sponsor.

Reference for the Product	Batch number	Mfg. Date	Exp. Date	Constituent form	Packaging
Sunscreen Xpensive Care	XC-S001-	07/26	06/29	Cream	Jar

The study sponsor oversaw product marketing with the valid details of manufacturing and packaging. He /She was responsible for product identification, purity determination, composition, innocuousness, and any other characteristics of each product to be tested prior to the beginning of the study. For this study, the study sponsor agreed to supply:

The appropriate quantity of the product is required to treat all the subjects; Enough 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. Products were stored in an ambient temperature away from light. On the other hand, the investigator proceeds to eliminate the remaining products according to the method of their choice described in their procedures.

4.2 Product Application

The application was carried out by technical expert at dermatologist clinic:

Products	Application area	Frequency of Application	Conservation
Sunscreen Xpensive Care	Back	Regular	At ambient temperature

4.3 Storage and Disposition:

The test products were stored at the study site in a controlled access room at room temperature 15°C to 30°C. The Investigator or designer maintained an accurate record of the receipt of the Test Products shipped by the Sponsor, including the date and quantity received. On completion of the study, the Investigator or designer would provide the Sponsor with a complete record of test product accountability, upon request. The Sponsor would also be notified of any subsequent changes in Test Products accountability as they occur.

5. Test Products and Control:

i. Negative Control -

Sodium chloride (Isotonic Saline Solution) Injection IP 0.9 % w/v was applied neat. A 0.04 ml of 0.9% w/v solution of Isotonic Saline Solution was placed on the center of an appropriately sized filter paper, which was further placed in the Finn chambers prefixed to a micro pore tape.

ii. Positive Control -

Sodium Lauryl Sulphate**:**1% w/v SLS solution: 1g of SLS was dissolved in distilled water and made up to 100 ml solution using distilled water. A 0.04 ml positive control solution of the sample in distilled water dispensed onto the center of an appropriately sized filter paper placed in the Finn chambers prefixed to a micro pore tape.

6. Test product Application:

The patches were applied on the back region i.e., between the scapula and waist of the participant. The application sites were cleaned up with warm water and wiped with non-abrasive towel prior to 1 hour of patch application. The patch application for all the participants started with the left side of the back. The test product was applied directly onto the test sites. Additionally, 0.04 ml positive control and negative control were put on the Whatman filter paper placed on Finn Chambers held on the adhesive patch. The patch was applied on the application sites of participants.

Code	Batch Number	Name of the Product	Concentration
A	XC-S001-	Sunscreen Xpensive Care	8%w/v sample solution

Along with above 01 test product, 02 additional sites were patched as positive and negative controls as per below:

Code	Control	Identification	Consent ration
AA	Positive Control	Sodium Lauryl Sulphate (SLS) analytical grade 1 % w/v	1 g of SLS in 100 ml of distilled water (1 % w/v)
CC	Negative Control	Sodium chloride (Normal Saline Solution) Injection IP 0.9 % w/v	Neat

All participant's application started with left side of the back (Site#S01 to S07) and then right side of the back for control sites (Site#S08 to S14). 01 patch containing test product was applied on Site#02. Site#12 was used as 1%positive control for the test products & Site#14 was used as Negative Control for the test products.

7. Method of Assigning Participants to Treatment Groups

This was a non-randomized study.

Blinding

This was an evaluator-blind study. The evaluator was blinded to the test product assignment to site and any previous scores. All reasonable attempts were made to ensure that the same individual did all irritation, scoring reactions to the test products during the study.

Prior and Concomitant Therapy

Any medications determined by the Investigator to potentially influence the study outcome were not used during the study, as specified in exclusion criteria. During the study, none of the participants were given any over the counter or prescription medications.

Study End points

Study Measurements Assessed and Flow-chart Skin Irritation Measurements

Irritation scoring was done using Draize Scale on Visit 01, Visit 02, Visit 03, Visit 04. Scoring Method: The reactions namely, erythema, dryness, wrinkles were scored on 0-4-point scale separately for each parameter and oedema on another 0-4-point scale as per the Draize Scale.

Draize Scale for Scoring Application Sites:

Score for Erythema/ Dryness/ wrinkles		Score for Oedema	
Score	**Reactions**	**Score**	**Reactions**
0	No Reaction	0	No reaction
1	Very slight erythema/dryness with shiny Appearance	1	Very light oedema
2	Slight erythema/ dryness/ wrinkles	2	Slight oedema
3	Moderate erythema/ dryness/ wrinkle	3	Moderate oedema
4	Severe erythema/ wrinkle/ scale	4	Severe oedema

Mean Irritation Score (MIS) = Total score (highest score from Erythema, dryness, wrinkles + Oedema) for each test product / Total no. of Participants.

Assessment of mean scores:

Mean Score	Classification
0 to 2.0 out of 8.0	Non-Irritant
Up to 4.0 out of 8.0 i.e. > 2.0 to 4.0	Mild Irritant
Above 4.0 out of 8.0 i.e. > 4.0	Irritant

Safety Assessments

Incidence of undesirable /adverse event: Either self-reported by Participant or assessed by Investigator.

Phase	Screening and Enrollment Visit	Evaluation		Follow up Visit
Details of the Events	**Patch Application + Immediate, Post 30 minutes & 5 hrs. of Patch Removal Irritation scoring**	**Post 15 (± 2) hrs. of Patch Removal Irritation scoring**	**Post 20 (± 2) hrs. of Patch Removal Irritation Scoring**	**Post 24 (± 2) hrs. of Patch Removal Irritation Scoring**
Visit	Visit 01	Visit 02	Visit 03	Visit 04
Day	Day 01	Day 02	Day 02	Day 02
Informed Consent	X			
Demography, Medical History	X			
Inclusion/Exclusion	X			
Urine (Pregnancy Test (if applicable) performed only for a female of childbearing potential	N/A			
Fitzpatrick skin type assessment	X			
Modified Dr. Baumann's skin type Questionnaire (Section 2)[3]	X			
Participant Number Allotment	X			
Acclimatization	X	X	X	X
Examination of skin site prior to patch application	X			
Site Cleaning and Site Marking	X			

Irritation Assessments using Draize Scale by Dermatologist or Dermatologist Validated Scorer		X	X	X
Digital	X	X	X	X
Photographs (As applicable)				
Participant Well-being	X			
Adverse Events Assessment	X	X	X	X
Concomitant Medication	X	X	X	X
Study Instructions and Restrictions	X	X	X	
Patch Application	X			
Patch Removal		X		

Statistical and Analytical Plans

No statistical analysis of the data was carried out.

Data from the individual patch sites are presented in tabular format in the report.

Determination of Sample Size

Based on published Indian Standard guideline, 30 completed participants were required at the end of study.

Changes to Study Conduct or Planned Analyses

Not Applicable

8. STUDY PARTICIPANTS

Disposition of Study Participants

Description	Count (Percent)
Screened participants	34
Screening fails participants	00
Randomized/Enrolled participants	34
No. of participants Screen pass but not enrolled	00
Completed participants	30
Discontinued participants / withdrawal	04
Reason for Discontinued participants /withdrawal	N/A

Protocol Deviations

There were no protocol deviations in this study

9. STUDY EVALUATION

Data Sets Analyzed

A total of 34 participants were enrolled in this study, and 30 participants have completed the study.

The data of all 30 participants who completed the study were analyzed.

Demographic and Other Baseline Characteristics

Summary of Demographic Characteristics		
Variables		(N=30)
Gender n (%)	Female	16 (53.33%)
	Male	14 (46.66%)
Race n (%)	Asian	30 (43.66.00%)
Skin Condition n (%)	Combination	07 (23.33%)
	Dry	08 (26.66%)
	Normal	07 (23.33%)
	Oily	08 (26.66%)
Age (Years)	Total No.	30
	Min, Max	20-55

In this study, there were 14 males and 16 females with Normal, Dry, Oily and Combination skin; age of the participants ranged from 20 to 55 years

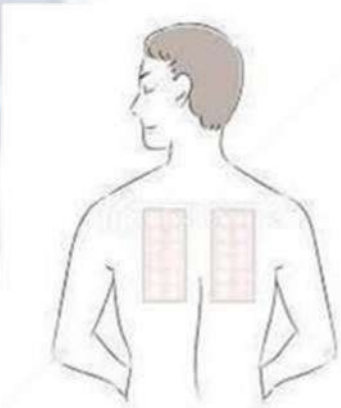


Fig1. Patch Test on Male Body

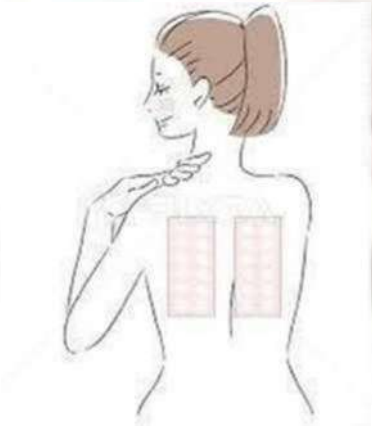


Fig 2. Patch Test on Female Body

10. RESULTS AND TABULATIONS

10.1 Results and Tabulations after patch removal and 5 hrs.+5 min irritation scoring (Visit 01)

Sub Code#	Visit 01: [Patch Removal 5 hrs.+5 mins Irritation Scoring (Day 01)]								
	[Sunscreen Xpensive Care]			[1% Positive Control]			[Negative Control]		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
S – 1	0	0	0	1	1	2	0	0	0
S – 2	0	0	0	1	0	1	0	0	0
S – 3	0	0	0	0	0	0	0	0	0
S – 4	0	0	0	0	1	1	0	0	0
S – 5	0	0	0	1	0	1	0	0	0
S – 6	0	0	0	1	0	1	0	0	0
S – 7	0	0	0	2	1	3	0	0	0
S – 8	0	0	0	1	1	2	0	0	0
S – 9	0	0	0	1	0	1	0	0	0
S - 10	0	0	0	0	0	0	0	0	0
S - 11	0	0	0	0	1	1	0	0	0
S - 12	0	0	0	2	0	2	0	0	0
S - 13	0	0	0	1	1	2	0	0	0
S - 14	0	0	0	1	0	1	0	0	0
S - 15	0	0	0	1	1	2	0	0	0
S - 16	0	0	0	0	0	0	0	0	0
S - 17	0	0	0	1	1	2	0	0	0
S - 18	0	0	0	1	0	1	0	0	0
S - 19	0	0	0	0	0	0	0	0	0
S - 20	0	0	0	2	0	2	0	0	0
S - 21	0	0	0	1	1	2	0	0	0
S - 22	0	0	0	0	0	0	0	0	0
S - 23	0	0	0	1	1	2	0	0	0
S - 24	0	0	0	0	0	0	0	0	0
S - 25	0	0	0	1	1	2	0	0	0

S - 26	0	0	0	1	0	1	0	0	0
S - 27	0	0	0	2	1	3	0	0	0
S - 28	0	0	0	1	0	1	0	0	0
S - 29	0	0	0	0	1	1	0	0	0
S - 30	0	0	0	1	0	1	0	0	0
N	30			30			30		
MIS [Mean Irritation Score]	0.0			1.2			0.0		
Standard Deviation	0.00			0.4			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, up to 4.0/8.0 = Mild Irritant, Above 4.0/8. = Irritant. E/D/W stands for: Erythema/Dryness/Wrinkles score, O stands for : Oedema Score									

10.2 Results and Tabulations after patch removal and 15hrs.+5 min irritation scoring (Visit 02)

Sub Code#	Visit 02: [Patch Removal after 15hrs.+5 mins Irritation Scoring (Day 02)]								
	[Sunscreen Xpensive Care]			[1% Positive Control]			[Negative Control]		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
S - 1	0	0	0	1	0	1	0	0	0
S - 2	0	0	0	1	1	2	0	0	0
S - 3	0	0	0	0	0	0	0	0	0
S - 4	0	0	0	1	0	1	0	0	0
S - 5	0	0	0	1	1	2	0	0	0
S - 6	0	0	0	0	0	0	0	0	0
S - 7	0	0	0	1	0	1	0	0	0
S – 8	0	0	0	0	1	1	0	0	0
S – 9	0	0	0	1	0	1	0	0	0

S – 10	0	0	0	1	0	1	0	0	0
S – 11	0	0	0	2	1	3	0	0	0
S – 12	0	0	0	0	0	0	0	0	0
S – 13	0	0	0	2	0	2	0	0	0
S - 14	0	0	0	1	2	3	0	0	0
S - 15	0	0	0	0	0	0	0	0	0
S - 16	0	0	0	2	0	2	0	0	0
S - 17	0	0	0	0	1	1	0	0	0
S - 18	0	0	0	1	0	1	0	0	0
S - 19	0	0	0	0	0	0	0	0	0
S - 20	0	0	0	1	1	2	0	0	0
S - 21	0	0	0	1	0	1	0	0	0
S - 22	0	0	0	0	0	0	0	0	0
S - 23	0	0	0	1	1	2	0	0	0
S - 24	0	0	0	0	0	0	0	0	0
S - 25	0	0	0	1	0	1	0	0	0
S – 26	0	0	0	2	1	3	0	0	0
S – 27	0	0	0	0	0	0	0	0	0
S – 28	0	0	0	1	0	1	0	0	0
S – 29	0	0	0	0	0	0	0	0	0
S - 30	0	0	0	1	1	2	0	0	0
N	30			30			30		
MIS [Mean Irritation Score]	0.0			1.13			0.0		
Standard Deviation	0.00			0.37			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant		

Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, up to 4.0/8.0 = Mild Irritant, above 4.0/8.0 = Irritant E/D/W stands for: Erythema/Dryness/Wrinkles score, O stands for: Oedema Score

10.3 Results and Tabulations after 20 ± 2 hours of post-patch removal (Visit 03)

Sub Code#	Visit 03: [Irritation scoring at 20±2 hours post-patch removal (Day 02)]								
	[Sunscreen Xpensive Care]			[1% Positive Control]			[Negative Control]		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
S - 1	0	0	0	1	0	1	0	0	0
S - 2	0	0	0	0	0	0	0	0	0
S - 3	0	0	0	2	1	3	0	0	0
S - 4	0	0	0	1	0	1	0	0	0
S - 5	0	0	0	1	0	1	0	0	0
S - 6	0	0	0	0	1	1	0	0	0
S - 7	0	0	0	2	0	2	0	0	0
S - 8	0	0	0	1	1	2	0	0	0
S - 9	0	0	0	1	1	2	0	0	0
S - 10	0	0	0	2	0	2	0	0	0
S - 11	0	0	0	1	0	1	0	0	0
S - 12	0	0	0	0	1	1	0	0	0
S - 13	0	0	0	1	0	1	0	0	0
S - 14	0	0	0	0	0	0	0	0	0
S - 15	0	0	0	1	1	2	0	0	0
S - 16	0	0	0	1	0	1	0	0	0
S - 17	0	0	0	1	0	1	0	0	0
S - 18	0	0	0	0	1	1	0	0	0
S - 19	0	0	0	0	0	0	0	0	0
S - 20	0	0	0	1	1	2	0	0	0
S - 21	0	0	0	1	0	1	0	0	0
S - 22	0	0	0	0	0	0	0	0	0
S - 23	0	0	0	1	0	1	0	0	0
S - 24	0	0	0	1	1	2	0	0	0

S - 25	0	0	0	2	0	2	0	0	0
S - 26	0	0	0	0	1	1	0	0	0
S – 27	0	0	0	0	0	0	0	0	0
S – 28	0	0	0	2	1	3	0	0	0
S – 29	0	0	0	1	1	2	0	0	0
S - 30	0	0	0	1	0	1	0	0	0
N	30			30			30		
MIS [Mean Irritation Score]	0.0			1.26			0.0		
Standard Deviation	0.00			0.42			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, up to 4.0/8.0 = Mild Irritant, above 4.0/8.0 = Irritant E/D/W stands for: Erythema/Dryness/Wrinkles score, O stands for: Oedema Score									

10.4 Result and Tabulations after 24 ± 2 hours of patch removal (Visit 04)

Sub Code#	Visit 04: Follow up visit for reactions if any to confirm recovery [Irritation scoring at 24±2 hours post-patch removal (Day 02)]								
	[Sunscreen Xpensive Care]			[1% Positive Control]			[Negative Control]		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
S - 1	0	0	0	1	0	1	0	0	0
S - 2	0	0	0	1	2	3	0	0	0
S - 3	0	0	0	2	0	2	0	0	0
S - 4	0	0	0	1	0	1	0	0	0
S - 5	0	0	0	1	1	2	0	0	0
S - 6	0	0	0	0	1	1	0	0	0
S - 7	0	0	0	0	0	0	0	0	0
S - 8	0	0	0	1	0	1	0	0	0
S - 9	0	0	0	2	0	2	0	0	0
S - 10	0	0	0	1	0	1	0	0	0
S - 11	0	0	0	0	1	1	0	0	0
S - 12	0	0	0	2	0	2	0	0	0
S - 13	0	0	0	0	1	1	0	0	0
S - 14	0	0	0	1	1	2	0	0	0
S - 15	0	0	0	1	0	1	0	0	0
S - 16	0	0	0	0	1	1	0	0	0
S - 17	0	0	0	1	0	1	0	0	0
S - 18	0	0	0	1	0	1	0	0	0
S - 19	0	0	0	1	1	2	0	0	0
S - 20	0	0	0	1	0	1	0	0	0
S - 21	0	0	0	0	1	1	0	0	0
S - 22	0	0	0	1	0	1	0	0	0
S - 23	0	0	0	1	0	1	0	0	0

S - 24	0	0	0	2	0	2	0	0	0
S - 25	0	0	0	1	1	2	0	0	0
S - 26	0	0	0	0	0	0	0	0	0
S – 27	0	0	0	1	1	2	0	0	0
S – 28	0	0	0	1	0	1	0	0	0
S – 29	0	0	0	1	1	2	0	0	0
S - 30	0	0	0	2	1	3	0	0	0
N	30			30			30		
MIS [Mean Irritation Score]	0.0			1.4			0.0		
Standard Deviation	0.00			0.46			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, up to 4.0/8.0 = Mild Irritant, above 4.0/8.0 = Irritant E/D/W stands for: Erythema/Dryness/Wrinkles score, O stands for: Oedema Score									

11.0 Mean Irritation Score [MIS] for each tested formulation is tabulated below

Code	Product Details	MIS Post patch removal				Irritancy Assessment Post patch Removal			
		5 hr±5 Mins.	15 hr. ± 5 Mins.	20 ± 2 hrs.	24 ± 2 hrs.	5 hr. ± 5 mins.	15 hr. ± 5 mins.	20 ± 2 hrs.	24 ± 2 hrs.
A	Sunscreen Xpensive Care	0.0	0.0	0.0	0.0	Non-Irritant	Non-Irritant	Non-Irritant	Non-Irritant
AA	1% Positive control	1.2	1.13	1.26	1.4	Non-Irritant but a minor itch sensation	Non-Irritant but a minor itch sensation	Non-Irritant but a minor itch sensation	Non-Irritant but a minor itch sensation
CC	Negative control	0.0	0.0	0.0	0.0	Non-Irritant	Non-Irritant	Non-Irritant	Non-Irritant

11.1 SAFETY EVALUATIONS

ADVERSE EVENTS

There were no adverse events reported during the conduct of the study.

12. DISCUSSION

The objective of this study was to evaluate the dermatological safety of the test products (**Sunscreen Xpensive Care**) through a **24-hour Patch Test under complete occlusion** on healthy human participants with normal, dry, oily, and combination skin. This was a **single-centre, evaluator-blind study** conducted on healthy adult participants.

A **single 24-hour application** of the sponsor-provided test products, along with positive and negative controls, was applied under occlusion for at least **24 hours (±2 hours)**. The **upper back region** of each participant (between the scapula and waist) was designated as the application site.

The application sites were assessed for irritation scoring at 5 hr. ± 5 mins, 15 ± 5 hrs., 20 ± 2 hrs. and 24 ± 2 hrs**.** after patch removal. Since no signs of erythema, dryness, oedema, or wrinkling were observed, the participants' involvement was considered complete, and they were compensated appropriately.

A total of **thirty (30) participants** with normal, dry, oily, and combination skin types completed the study. All participants were applied with the test products along with a **positive control (1% Sodium Lauryl Sulphate; AA)** and a **negative control (CC)**. The test products were classified as **non-irritant**, thereby qualifying as dermatological safe.

Occluded patches (Finn Chambers measuring approximately **1 cm in diameter**) were used in this study. A **1 cm diameter filter paper** was placed on each Finn Chamber disc, and the test product was applied onto the filter paper. Only the area directly beneath the patch was considered for irritation evaluation, and any signs of irritation due to adhesive tape were excluded from assessment. No tape-related irritation was observed in this study.

No reactions were observed during the final visit (Visit 04); hence, participants' participation was deemed complete, and compensation was provided accordingly.

13. CONCLUSION

The **Test Product A (Sunscreen Xpensive Care)** qualifies for **dermatological safety** and is classified as **non-irritant** based on the results of a **24-hour Patch Test under occlusion** conducted on healthy human participants with **normal, dry, oily, and combination skin types**.

The study was performed in accordance with the principles of **Good Clinical Practice (EC6). The test product** was evaluated against standard controls:

- **Positive Control:** 1% Sodium Lauryl Sulphate (SLS) – confirmed as **mild irritant** upon evaluation at 30 minutes and 24 hours post patch removal.
- **Negative Control:** Sodium Chloride IP 0.9% – confirmed as **non-irritant** upon evaluation at 30 minutes, 12 hours, and 24 hours post patch removal.

No signs of erythema, dryness, oedema, or wrinkling were observed on any participant's application site following the test product application.

Based on the dermatological assessment conducted by a qualified dermatologist, the **Sunscreen Xpensive Care** was found to be **safe and non-irritant** for use on **normal, dry, oily, and combination skin types**, as per the 24-hour occlusive patch test conducted on **30 healthy adult participants**, where no signs of irritation or adverse reactions were observed.

14. RESULTS & THE STUDY

- **Product A (Sunscreen Xpensive Care)**

i. Concerning the **product safety**, Product A was found to be safe and non-irritant at T0 –Before application, T1 – Immediate after product application, T2 – After 30 minutes, T3 – After 5 hours, T4 – After 15 hours, T5– After 20 hours, T6 – After 24 hours after product application with 95% to 99% agreement.

ii. Concerning the **product efficacy,** test Product A is well appreciated (from 95% to 99% agreement) from T1 – Immediate after product application, T2 – After 30 minutes, T3 – After 5 hours, T4 – After 15 hours, T5– After 20 hours, T6 – After 24 hours of Product application

iii. Concerning **product acceptability**, test Product A (Sunscreen Xpensive Care) is well appreciated for not causing itching, stinging and burning sensation to the skin (with 99 % agreement) at all given times.

15. DISCUSSION & CONCLUSION

Product Name	Batch No.	Mfg. Date	Exp. Date
Sunscreen Xpensive Care	XC-S001-	07/26	06/29

The on-site application of the product on back sides by a panel of 30 Indian subjects, male and female with Normal, dry, oily or combination skin led to the following results after 24 hours of testing:

Subject Self-Evaluation:

On the basis of subject self-evaluation validates all claims related to product safety, product efficacy, and product acceptability are significantly validated by the panel at **T0 –Before application, T1 – Immediate after product application, T2 – After 30 minutes, T3 – After 5 hours, T4 – After 15 hours, T5 – After 20 hours, T6 - After 24 hours after** product application for Product A.

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

Dermatologist Observation & Evaluation:

- √ All study procedures were conducted under the **close supervision of a qualified dermatologist**. As per the dermatologist's clinical observations and evaluations, the **skin of all participants remained free from erythema, rashes, oedema, or any signs of irritation** throughout the 24-hour observation period following patch removal.
- √ Immediately after application, the **test product (Sunscreen Xpensive Care)** rated a **favourable sensory response,** with participants reporting **softer, smoother, and well-moisturized skin**.
- √ No instances of **itching, dryness, or adverse cutaneous reactions** were observed in any subject during or after the study period.
- √ Based on the **dermatologist's expert assessment** and the absence of any adverse dermatological findings, **Product A (Sunscreen Xpensive Care) can be considered safe and well-tolerated for human skin under normal conditions of use**.

Under the experimental conditions, the test product "A" (Sunscreen Xpensive Care) demonstrated excellent dermatological safety and tolerance, with no signs of irritation or adverse reactions observed after 24 hours of occlusive application. The product was classified as non-irritant and exhibited beneficial dermal properties. The product is suitable for normal, dry, oily, and combination skin types.

DR. URVI PANCHAL
M.B.B.S M.D (DERMATOLOGY)
Fellowship in Laser & Aesthetic Medicine (NSC Singapore)
Fellowship in Hair Transplant
Registration Number HN012496

URSA
SKIN & AESTHETICS

DATE: __ / __ / __

NAME _____ AGE _____ SEX _____

CONCERN _____

℞

Product Evaluated: Sunscreen Xpensive Care

Batch No.: XC-S001

Manufacturing Date: 07/26

Study Duration: 24-Hour Occlusive Patch Test

Participant Profile: 30 Healthy Human Volunteers with Normal, Dry, Oily and Combination Skin

Company Name: XPENSIVE CARE

Study Designer & Data Analyst: CRO Lambent Private Limited

Product Code	Product Name
Product A	Sunscreen Xpensive Care

This certificate confirms that **Product A – "Sunscreen Xpensive Care"** was assessed for its **dermatological compatibility and skin irritation potential** by means of a **24-hour occlusive Patch Test** performed under controlled conditions on healthy human volunteers with different skin types.

The product was clinically evaluated following the test application, and **no visible signs of skin irritation, including erythema, oedema, or other adverse reactions, were observed** among the study participants.

Based on the dermatological evaluation and clinical observations, **Sunscreen Xpensive Care** was found to be **well tolerated by the skin** and is classified as **"Non-Irritant"** under the conditions of this study.

Dr Urvi Panchal

NEXT VISIT: __ __ __

TREATMENT ADVISED _____

Clinic 1: 193, Hamilton Court Road,
Sector 27, Gurugram
+91-7447467557

Clinic 2: A- 15, Ground Floor,
Town Square, Vatika India Next,
Sector- 82A, Gurugram
+91-9625659478

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www.ursaskin.com