18 HERBS ORGANICS - STRESS RELIEF OIL – ASUVAGENTHI BALALAKSHATHI THAILAM

I. STUDY REPORT SUMMARY

Protocol Title	"Dermatological safety evaluation of **18 Herbs Organics** JOINT **PAIN OIL** by Primary Irritation Patch test within 24 hours application on all types of healthy human skin."
Protocol ID	TG/CLI/063d
Principal Investigator	Dr. Sandeep K Alva
Company/Organization	Buy happy Marketing LLP
Sponsor's study team	Mr. Radhakrishnan (Chairman & Managing Director)
Sponsor's Study Coordinator	Sahila Joe
Study Site/CRO	TrialGuna Private Limited
Compliance Statement	The study was conducted as per the protocol, Good Clinical Practice (GCP), International Council for Harmonization (ICH) and the study sponsor accept the responsibility for the scientific correctness of the study and validity of the data produced in this report.
Study Duration	8 days for each subject (+1 window period).
Study Commencement Date	23-Aug-2022
Study Completion Date	29-Aug-2022
Report Number	01
Date Of Report Issue	01-Sep-2022
Test Product Name & Code	18 Herbs Organics Joint Pain oil & 30030000
Control	Positive control: 1% Sodium Lauryl Sulphate Negative Control: 0.9% Normal Saline
Study Schedule	Date of receipt of IEC approval: 04-Aug-2022

Subjects	Date of patch application	Date of patch removal and 0-hou observation	Date of observation 24-hours post patch removal	Date of observation 7 days post patch removal
01001 to 01024	23-Aug-2022	24-Aug-2022	25-Aug-2022	29-Aug-2022

II. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

BIS	Bureau of Indian Standards
ICH	International Council for Harmonization
IEC	Independent Ethics Committee
PI	Principal Investigator
PIPT	Primary Irritation Patch Test
SLS	Sodium Lauryl Sulphate

III. GENERAL INFORMATION

Objective	The objective of this study is to evaluate the dermatological safety of the test products on healthy human subjects.
Method Reference	Study method is based on the Bureau of Indian Standards (BIS) method 4011:2018- third Revision modified in terms of site of application & Test method described in IS 4011:2018 Irritation scoring system is as per the clause 4.3.1.3, 4.3.2.6 on Draize scale for scoring treatment sites.
Test Product Name & Code	18 Herbs Organics Joint Pain oil & 30030000
Control description	Positive control: 1% Sodium Lauryl Sulphate solutions in distilled water. Negative Control: 0.9 % Normal saline

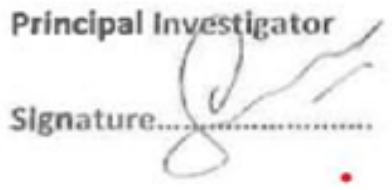
Study in brief	Study was conducted over a period of 08 days for each subject. Product was evaluated through single application closed patch test under occlusion for 24 hours. After patch removal, skin was observed for irritation reactions, at 0-hour patch removal for immediate reactions, at 24 hours. Post patch removal and 7days post patch removal for delayed reactions.
Evaluation method	BIS 4011:2018 Methods of test for safety evaluation of cosmetics, Third revision (ICS71.100.40). Methods of test for safety evaluation of cosmetics, reaffirmed (2004), Edition 3.2 (2007-11), second revision (ICS 71.100.40), clause 4.3.1, 4.3.1.2 BIS 2008. Clause 4.3.1, Skin Irritation Test.

IV. STATEMENT OF COMPLIANCE

Study Protocol No.: TG/CLI/06d version 1.0 dated 11-Jul-2022

Study Title: "Dermatological safety evaluation of 18 Herbs Organics **JOINT PAIN OIL** by Primary
Irritation Patch test within 24 hours application on all types of healthy human skin."

We hereby attest to the authenticity of the study and guarantee that the data is accurate to the best of our knowledge. We also attest that the study was conducted in full compliance with BIS Specification, IS 4011:2018 Methods of test for safety evaluation of cosmetics, reaffirmed (2004), Edition 3.2 (2007-11), second revision (ICS 7 1.1 00.40), clause 4.3.1, 4.3.1.2 BIS 2008. Skin Irritation Test On human subjects, guidelines, and regulations of the Independent Scientific and Ethics Committee for the Purpose of control and supervision of experiments and on getting approval of the sponsor. The study was conducted as per the protocol, Good Clinical Practice (GCP), International Council for Harmonization (ICH).



Date: 9.9.2022

V. SPONSOR SIGNATURE PAGE

The undersigned confirm that the interpretation and presentation of data in this clinical study report are consistent with the results obtained.

For

Buy happy Marketing LLP

Mr. Radhakrishnan
(Chairman & Managing Director) Date Buy happy Marketing LLP
Prince info perk, No. 81 B, 2nd floor, Tower B, 2nd Main, Sai Nagar, Ambattur Industrial estate, Chennai, Tamil Nadu
Study Coordinator: Sahila Joe Phone: +91-7338836092
Email: ceo@buyhappy.co.in.

ACE Independent Ethics Committee

DCGI Reg. No. ECR/141/Indt/KA/2013/RR-19

NABH Certificate No. EC-CT-2018-0029

1	Study Protocol (Composite protocol)	1.0	11-Jul-2022
2	Protocol-A	1.0	11-Jul-2022
3	Protocol-B	1.0	11-Jul-2022
4	Protocol-C	1.0	11-Jul-2022
5	Protocol-D	1.0	11-Jul-2022
6	Protocol Signature Page (Composite protocol)	1.0	25-Jul-2022
7	Protocol Signature Page- Protocol-A	1.0	25-Jul-2022
8	Protocol Signature Page- Protocol-B	1.0	25-Jul-2022
9	Protocol Signature Page- Protocol-C	1.0	25-Jul-2022
10	Protocol Signature Page- Protocol-D	1.0	25-Jul-2022
11	Informed Consent Form-English	1.0	11-Jul-2022
12	CV & MRC of PI	NA	25-Jul-2022
13	IU	NA	25-Jul-2022
14	Case Report Form	1.0	11-Jul-2022

The following members of the ethics committee were present at the meeting held on 26-Jul-2022 and 02-Aug-2022 at 15:00 hrs. The discussions and decision-making process were facilitated through conference call with all quorum members over the Skype.

Sr.No.	Name of Members	Gender	Role	Qualification
1	Dr. Ambrish C.	Male	Chairperson & Basic Medical Scientist	MD Pharmacology
2	Mrs. Rutuja Joshi	Female	Member Secretary	B.Sc. & P.G. Diploma in Dietetics & Clinical Nutrition
3	Dr. Shivaraja Shetty	Male	Basic Medical Scientist	MBBS, MD Biochemistry
4	Dr. Aruna N.	Female	Clinician	M.B.B.S & P.G. Diploma (Diabetology)

Office Address: Top Floor B Portion, Nandanam Building, No. 1, B Channasandra, OMBR 5th Main Road, Bangalore-560043, Karnataka, India. Email ID: aceiec13@gmail.com.

ACE Independent Ethics Committee
DCGI Reg. No. ECR/141/Indt/KA/2013/RR-19
NABH Certificate No. EC-CT-2018-0029

To
Dr. Sandeep K Alwa.,
Principle Investigator
Trial Guna Private Limited
#467,1st Main, 4th Cross, Royal County Layout,
JP Nagar 8th Phase, 2nd block, Bangalore-560083

Dear Dr. Sandeep K Alwa.,

The ACE Independent Ethics Committee, Bangalore reviewed and discussed your application to conduct the clinical trial entitled;

Protocol No: TG/CLI/063.

Protocol Title: "Dermatological safety evaluation of VIP test products-VIP Hair colour Shampoo, VIP Snore care oil, 18 herbs organics Stress relief oil and 18 herbs organics Joint pain oil by Primary Irritation Patch test within 24 h application on all types of healthy human skin".

Dermatological safety evaluation of VIP HAIR COLOUR SHAMPOO by Primary Irritation Patch test within 24 hours application on all types of healthy human skin.

Dermatological safety evaluation of VIP SNORE CARE OIL by Primary Irritation Patch test within 24 hours application on all types of healthy human skin.

Dermatological safety evaluation of 18 Herbs Organics STRESS RELIEF OIL by Primary Irritation Patch test within 24 hours application on all types of healthy human skin.

Dermatological safety evaluation of 18 Herbs Organics JOINT PAIN OIL by Primary Irritation Patch test within 24 hours application on all types of healthy human skin.

The following documents were reviewed;

Sl.no.	Documents	Version	Date

Office Address: Top Floor B Portion, Nandanam Building, No. 1, B Channasandra, OMBR 5th Main Road, Bangalore-560043, Karnataka, India. Email ID: aceiec13@gmail.com.

ACE Independent Ethics Committee

DCGI Reg. No. ECR/141/Indt/KA/2013/RR-19

NABH Certificate No. EC-CT-2018-0029

5	Dr. Pooja Dharman	Female	Clinician	MBBS, MD (Physiology), Certificate course in Diabetology
6	Mr. Sumithra	Female	Social Scientist	BSc, MSW, PGCHRM
7	Mrs. Deepti Ayathan	Female	Legal Expert	B.A., LLB
8	Mrs. Sandhya S.	Female	Lay Person	P.U.C

ACE IEC is functioning in accordance with ICH GCP guideline, Ethical guideline for biomedical research in human subjects by ICMR New Delhi and as per the requirements Laid down in the Indian GCP and in accordance to The New Drugs and Clinical Trial Rules 2019.

We hereby confirm that members of ACE IEC who have participated in decision making process don't have any Conflict of interest in the study and voted unanimously. EC is situated within 50km from study site. We approve the study to be conducted in its presented form.

ACE Independent Ethics Committee expects to be informed about the progress of the study, any SAE and SAE management occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

RUTUJA ANIRUDDHA JOSHI
Digitally signed by RUTUJA ANIRUDDHA JOSHI
Date: 2022.08.04 17:07:12 +05'30'

Yours sincerely,

Member Secretary

1. **Dermatological Safety of Test Product:** The study was designed to test the safety of the test product on healthy human subjects. The test products were deemed to be non-irritant and dermatologically safe for the study population when compared to the positive control.

2. **Executive Summary:** The study was designed to test the safety of topical products on healthy human subjects. 24 subjects were enrolled in the study; all 24 subjects completed the study. Average mean skin irritation score for tested formulation along with positive and negative control is tabulated below:

Sr. No.:	Test Product	Mean Irritation Score 0 Hour	Irritancy assessment	Mean Irritation Score 24 Hours	Irritancy assessment	Mean Irritation Score 7 days	Irritancy assessment
1	30030000	0.08	Non-irritant	0.0	Non-irritant	0.0	Non-irritant
2	0.9 % Normal Saline (Negative Control)	0.08	Non-irritant	0.0	Non-irritant	0.0	Non-irritant
3	Positive Control (1%SLS)	2.62	Irritant	2.04	Irritant	0.0	Non-irritant

- As per Draize scale for scoring irritation, test product emerged as non-irritant products when observed at 0 hour, 24 hours and at 7 days post patch removal.
- Test product was deemed to be dermatologically safe on the test population of healthy human subjects; as per their classification into non-irritant category at all time points of evaluation by 24 hours. Occlusive patch test methods (reference BIS Test method described in IS 4011:2018 Methods of test for safety evaluation of cosmetics, Third revision (ICS71.100.40).
- Positive control (Sodium lauryl sulfate) – 1% was confirmed as irritant, when observed at 0 hour. and at 24 hours and non-irritant when observed at 7 days post patch removal.

3. Study Design:

Number of subjects	24 healthy human subjects
Gender	Male and female
Age group	35 to 60 years
Test site	Back of subjects between the scapulae and waist of the subjects
Duration of study	8 days for each subject (+1 window period)
Control	Positive control: 1%, Sodium Lauryl Sulphate Negative Control: 0.9 % Normal Saline

4. Study Population Description and Methodology: A total 24 healthy male (12) and female (12) subjects of skin types (Normal, Dry, Oily and Combination) in the age group of 18 to 65 years were screened and enrolled in the study.

- **Inclusion criteria**

  - Healthy Men and women volunteers are chosen in ratio of 1:1 aged > 35 and < 60years.10% of the sample size, are chosen having grey hair.
  - Subjects who are willing to participate in the study and sign the informed consent document and comply with the trial procedure.
  - Having healthy skin on test area as assessed by dermatological examination and don't have history
  - of allergy.
  - Subjects who are compliant with the study.
  - Subjects with a wide spectrum of skin types like normal, dry, oily and combination skin
  - Subjects' willingness to avoid intense UV exposure on test site (sun or artificial UV), during the study.
  - Willingness to avoid excessive water contact (for example swimming) or activity which causes excessive sweating (that is exercise, sauna ….), during the study.

- Volunteers evaluated with Fitzpatrick skin type 3 to 5 as per the Fitzpatrick scale (Appendix IV).

- **Exclusion criteria**

  - Pregnant/nursing mothers.
  - Scars, excessive terminal hair, or tattoo on the studied area.
  - Dermatological infection/pathology on level of studied area.
  - Hypersensitivity, allergy antecedent (to any cosmetic product, raw material)
  - Any clinically significant systemic or cutaneous disease, which may interfere with study treatment orprocedures.
  - Chronic illness which may influence the outcome of the study.
  - Subjects on any medical treatment either systemic or topical which may interfere with the performance of the study treatment (presently or in the past 1 month).
  - Subject in an exclusion period or participating in another food, cosmetic, or therapeutic trial.
  - Volunteers evaluated with Fitzpatrick skin type 1,2 and 6 as per the Fitzpatrick scale (Appendix IV).

5. **Screening:** Subjects were screened by the Investigator. Only subjects who meets all the inclusion & no exclusion criteria and are willing to sign an informed consent form were enrolled into the study.

6. **Principle of patch for Irritation:** Irritants are substances that provoke immediate response in the skin perceived as a superficial skin reaction in terms of erythema, oedema and/or papules. The severity of irritation depends upon the nature, concentration, and duration of exposure. Irritation is manifested as inflammatory responses such as erythema (redness), oedema (swelling), and vesiculation and finally, to an intense supportive reaction without the involvement of the immune system. In this test the irritation potential of a substance was assessed by a single application of patch under complete occlusion for 24 hour**s.**

7. **Test site:** Subjects' back between the scapulae and waist of the subjects. The test site should be free of pigmentation, pimple, hair, mole, or any dermatological conditions that can interfere with the reading.

8. **Patch application:** The loaded patch system was applied at the test site of study subjects starting with the lower edge of the patch system and slowly pressing upwards till the top edge to squeeze out the air.

9. **Duration patch:** The patch was kept for approximately 24 hours (+1 hour- window period).

   - Screening visit (visit 1) and patch application visit (visit 2) was performed on the same day.
   - Visit 3: 0-hour reading (+1-hour window) post patch removal.
   - Visit 4: 24-hours post patch removal (+1-hour window).
   - Visit 5: Day 7 post patch removal (+1-hour window).

10. Patch methodology

- Dermatologist examined the test site for baseline skin condition before patch application.
- Subjects' feedback on skin condition at each test site was collected at baseline.
- All the test products including the positive control and negative control were applied. Patches of test formulations were applied onto designated test sites and retained till 24 hours.
- The patch was removed after 24 hours. The test sites were wiped with a clean tissue to remove any residue prior to evaluation.
- Subjects were acclimatized at room temperature for 20 to 30 minutes (at 18°C to 25°C, 50% ± 10% Relative humidity) on all the visits before starting the study procedure.
- Dermatologist visually assessed the skin condition of each test site at the following frequencies: post patch removal reading for 0-hour reading, 24 hours, and 168 hours (7 days) as per Draize scoring system.
- Subjects were given feedback on the skin condition of each test site at the following frequencies: at baseline, post patch removal (0-hour reading), 24 hours and 168 hours (7 days) as per investigator's interview of the subject.

11. **Dermatologist visual assessment:** Test sites were assessed for erythema / dryness/ wrinkles and oedema as per the Draize scale for scoring at the treatment site.

Table 1: Draize Scale for Irritation Scoring

Score for Erythema (Including wrinkles and dryness)	Reaction	Score for Oedema	Reaction
0	No reaction	0	No Oedema
1	ght 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

$$\textbf{Mean score for irritation} = \frac{\text{Total score (Erythematic + Oedema) for each sample}}{\text{Total number of Subjects}}$$

12. **Subjects' self-assessment on skin irritation:** Subjects' feedback on skin irritation sensations like burning, itching, stinging, tingling and others was recorded at baseline (before patch application) 0-hour, 24 hours and 7 days post patch removal. Subject's self-feedback was filled by investigator based on Subject's interview.

    None = 0, Mild = 1, Moderate = 2, and Severe = 3.

13. **Schedule of assessments:**

Table 2: Schedule of Assessments

Sr No.	Parameters	Visit 1 (Screening visit)	Visit-2 (Patch application)	Visit-3 (Patch removal – 0 hour)	Visit- 4 (24 hours)	Visit-5 (168 hours/ 7 Day)
1	Briefing subjects for study	X	-	-	-	-
2	Obtaining consent	X	-	-	-	-
3	Medical History	X	-	-	-	-
4	General Physical examination	X	-	-	-	-
5	Urine Pregnancy Test*	X	-	-	-	-
6	Dermatological Examination	X	-	-	-	-
7	Inclusion criteria/Exclusion criteria	X	-	-	-	-
8	Concomitant Medications	X	X	X	X	X
9	Fitzpatrick scale		X	X	X	X
10	Dermatologist's Assessment (Draize scale) with digital images before & after patchtest at specified	-	X	X	X	X

	site					
11	Subject's Self-Assessment on skin irritation	X	X	X	X	X
12	Patch Application	-	X	-	-	-
13	Patch Removal	-	-	X		
14	BIS Mean Scoring method 4011:2018 of test for safety evaluation of cosmetics	-	-	X	X	X
15	Adverse Event/ Serious Adverse Event Monitoring	X	X	X	X	X

VI. TREATMENTS

1. Test product and controls

Table 3: Test product and controls

Product/Batch No.	PIPT analysis to be done
30030000/39	No dilution
0.9 % Normal Saline (Negative Control)	No dilution
Positive Control (SLS)	1% w/w in distilled water

2. **Sample preparation method Test product:** 40µl of test product was pipetted out on the pre-cut filter paper placed inside the allotted Derma proof aluminum Finn chamber prefixed to a scan pore tape.

3. **Positive control:** 40µl of positive control (Sodium Lauryl Sulphate, diluted to a concentration of 1% w/w for test products tested as per BIS 4011: 2018) was pipetted out on the pre-cut filter paper placed inside the allotted Derma proof aluminum Finn chamber prefixed to a scamper tape.

4. **Negative control:** 40µl of 0.9 % Normal Saline was pipetted out on the pre-cut filter

paper placed inside the allotted Derma proof® aluminum Finn chamber prefixed to a scan pore tape.

VII. RESULTS

1. **Subject disposition and demographic characteristics:** A total 24 subjects (12 male and 12 female) were enrolled in the study. All 24 subjects completed the study.

Table 4: Demographic Data of Subjects who participated in the Study

Subject No.	Age (yrs.)	Gender
01001	55	Female
01002	49	Female
01003	37	Male
01004	36	Female
01005	41	Female
01006	40	Female
01007	49	Male
01008	49	Male
01009	55	Female
01010	39	Female
01011	41	Male
01012	36	Male
01013	50	Male
01014	41	Female
01015	39	Female
01016	37	Female
01017	46	Female
01018	42	Female
01019	37	Male
01020	53	Male
01021	37	Male
01022	49	Male
01023	42	Male
01024	37	Male

2. **Subject Distribution Based on Skin type:** A total 06 (03 male and 03 female) normal skin type, 08 subjects (02 male and 06 female) Dry skin type, 06 (05 male and 01 female) oily skin type and 04 subjects (02 male & 02 female) combination skin type subjects were enrolled in the study.

Table 5: Subjects based on skin type

Skin Type	Male	Female	Total
Normal	03	03	06
Dry	02	06	08
Oily	05	01	06
Combination skin type	02	02	04

3. **Protocol deviations:** There were no protocol deviations recorded in the study.

4. **Dermatologist's visual assessment**

- **Test product:** The individual Dermatologist's visual assessment and mean score irritation of erythema (including wrinkles and dryness) and Oedema was presented in table 6 and table 7 respectively.

Based on assessments 30030000 (18 Herbs Organics Joint Pain oil) was non-irritant when observed at 0-hour, 24 hours and 7 days post removal.

Table 6: Dermatologist's visual assessment for individual subjects – 30030000

Subject Number	0-hour post patch removal		24-hours post patch removal		7 days post patch removal	
	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
01001	0	0	0	0	0	0
01002	0	0	0	0	0	0
01003	0	0	0	0	0	0
01004	0	0	0	0	0	0
01005	0	0	0	0	0	0
01006	0	0	0	0	0	0
01007	0	0	0	0	0	0
01008	0	0	0	0	0	0
01009	0	0	0	0	0	0
01010	0	0	0	0	0	0
01011	0	0	0	0	0	0
01012	0	0	0	0	0	0
01013	0	0	0	0	0	0

Subject Number	0-hour post patch removal		24-hours post patch removal		7 days post patch removal	
	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
01014	0	0	0	0	0	0
01015	1	0	0	0	0	0
01016	0	0	0	0	0	0
01017	1	0	0	0	0	0
01018	0	0	0	0	0	0
01019	0	0	0	0	0	0
01020	0	0	0	0	0	0
01021	0	0	0	0	0	0
01022	0	0	0	0	0	0
01023	0	0	0	0	0	0
01024	0	0	0	0	0	0

Table 7: Mean irritation score – 30030000 (18 HERBS ORGANICS Joint Pain oil)

	0-hour post patch removal	24-hours post patch removal	7 days post patch removal
Mean irritation Score	0.08	0.00	0.0

5. **Negative Control: 0.9 % Normal Saline:** The individual Dermatologist's visual assessment and mean score irritation of erythema (including wrinkles and dryness) and Oedema was presented in table 8 and table 9 respectively. Based on assessments, Negative Control was non- irritant when observed at 0-hour, 24 hour and 7 days post removal.

Table 8: Dermatologist's visual assessment for individual subjects - Negative Control

Subject Number	0-hour post patch removal		24-hours post patch removal		7 days post patch removal	
	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
01001	0	0	0	0	0	0
01002	0	0	0	0	0	0
01003	0	0	0	0	0	0
01004	0	0	0	0	0	0
01005	0	0	0	0	0	0
01006	0	0	0	0	0	0
01007	0	0	0	0	0	0
01008	0	0	0	0	0	0
01009	0	0	0	0	0	0

Subject Number	0-hour post patch removal		24-hours post patch removal		7 days post patch removal	
	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
01010	0	0	0	0	0	0
01011	0	0	0	0	0	0
01012	0	0	0	0	0	0
01013	0	0	0	0	0	0
01014	0	0	0	0	0	0
01015	1	0	0	0	0	0
01016	0	0	0	0	0	0
01017	0	0	0	0	0	0
01018	1	0	0	0	0	0
01019	0	0	0	0	0	0
01020	0	0	0	0	0	0
01021	0	0	0	0	0	0
01022	0	0	0	0	0	0
01023	0	0	0	0	0	0
01024	0	0	0	0	0	0

Table 9: Mean irritation score - Negative Control

Mean irritation Score	0-hour post patch removal	24-hour post patch removal	7 days post patch removal
	0.08	0.0	0.0

6. **Positive control: 1%, Sodium Lauryl Sulphate:** The individual Dermatologist's visual assessment and mean score irritation of erythema (including wrinkles and dryness) and Oedema was presented in table 10 and table 11 respectively.

Mean irritation score for Positive Control was 1.2 and 1.0 at 0-hour, 24 hours respectively. Mean irritation score was 0.0 at 7 days post removal.

Table 10: Dermatologist's visual assessment for individual subjects - Positive control

Subject Number	0-hour post patch removal		24-hours post patch removal		7 days post patch removal	
	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
01001	1	2	1	1	0	0

01002	1	1	1	2	0	0
01003	1	2	1	1	0	0

Subject Number	**0-hour post patch removal**		**24-hours post patch removal**		**7 days post patch removal**	
	Erythema	**Oedema**	**Erythema**	**Oedema**	**Erythema**	**Oedema**
01004	2	1	1	1	0	0
01005	1	2	1	1	0	0
01006	1	2	1	1	0	0
01007	2	2	1	1	0	0
01008	1	1	1	1	0	0
01009	2	2	1	1	0	0
01010	2	1	1	1	0	0
01011	2	1	1	1	0	0
01012	1	1	1	1	0	0
01013	0	2	0	2	0	0
01014	1	1	1	1	0	0
01015	1	1	1	1	0	0
01016	1	1	1	1	0	0
01017	1	1	1	1	0	0
01018	1	2	1	1	0	0
01019	1	2	1	1	0	0
01020	1	2	1	1	0	0
01021	2	1	1	1	0	0
01022	1	1	1	1	0	0
01023	1	1	1	1	0	0
01024	1	1	1	1	0	0

Table 11: Mean irritation score - Positive control

Mean irritation Score	**0-hour post patch removal**	**24-hours post patch removal**	**7 days post patch removal**
	2.62	2.04	0.0

7. **Subject's Self-Assessment on Skin Irritation:** Overall subject's self-assessment on skin irritation sensations like burning, itching, stinging, and, tingling for test product, negative control and positive control were presented in table 12, table 13 and table 14 respectively.

   Based on assessment test product was nonirritant.

Table 12: Overall Self-Assessment on skin irritation sensations like burning, itching, stinging, and tingling – Test product

Assessments	Baseline (Before patch application)	Baseline (After patch application)	0-hour post patch removal	24-hours post patch removal	7 days post patch removal
Burning	0	0	0	0	0
Itching	0	0	0	0	0
Stinging	0	0	0	0	0
Tingling	0	0	0	0	0

Table 13: Overall Self-Assessment on skin irritation sensations like burning, itching, stinging, and tingling – Negative control

Assessments	Baseline (Before patch application)	Baseline (After patch application)	0-hour post patch removal	24-hours post patch removal	7 days post patch removal
Burning	0	0	0	0	0
Itching	0	0	0	0	0
Stinging	0	0	0	0	0
Tingling	0	0	0	0	0

Table 14: Overall Self-Assessment on skin irritation sensations like burning, itching, stinging, and tingling – Positive control

Assessments	Baseline Before patch application)	Baseline (After patch application)	0-hour post patch removal	24-hour post patch removal	7 days post patch removal
Burning	0	0	0	0	0
Itching	0	0	0	0	0
Stinging	0	0	0	0	0
Tingling	0	0	0	0	0

8. Adverse events: There were no adverse events or serious adverse events recorded in the study.

VIII. CONCLUSION

The objective of this study was to evaluate the dermatological safety of the test products on healthy human subjects. Dermatologist visually assessed erythema (including dryness and wrinkles) and oedema as per the Draize scale for scoring at the treatment site and subjects' self-assessments on skin irritation sensations like burning, itching, stinging, and tingling at baseline (before patch application),0-hour, 24 hour and 7 days' post patch removal was found to be nonirritant.

The test product 30030000 (18 HERBS ORGANICS Joint Pain oil) qualifies the dermatological safety as per their classification into non-irritant category by 24 hours. patch application test under occlusion.

The results imply that the test product was safe for all skin type as per the test conducted on 24 healthy subjects.

This test product can be claimed to be dermatologically tested/ Clinically tested on the study population.

Test product was tested against 1% SLS as Positive control as per the standard (BIS) method 4011:2018. Positive control 1% Sodium lauryl sulfate was confirmed as irritant when observed at 0 h and irritant at 24h post patch removal and as non-irritant at day 7 post patch removal.

