



CONFIDENTIAL

REPORT FOR

Evaluation of Dermatological Safety of Test Articles by Primary Irritation Patch Test on Healthy Adult Human Subjects (Single 24-hour Application).

PROTOCOL NO. C3B01631

REPORT NO. C3B01631-RAV-A

Final Report (01)

16 May 22

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2. SUMMARY

The objective of this study was to determine the potential of the test articles to cause cutaneous irritation in adult human subjects after single 24-hour occluded patch application. This was a single center, evaluator-blinded study in healthy adult human subjects.

For C3B01631-RAV-A, single 24-hour application test articles along with positive and negative controls were kept in contact with the skin of subjects under occlusion for at least 24 hours (+2 hours). Subject's back region i.e. between the scapula and waist of the subject was utilized as application sites. Application sites were evaluated for scoring after 30+5 minutes of patch removal, 24±2 hours and subjects were contacted telephonically for any signs of irritation at patch application site after one week, if there were no signs like erythema, dryness, oedema or wrinkles then subject's participation was considered completed and they were compensated appropriately.

For C3B01631-RAV-A, twenty five (25) subjects completed the study. All subjects received test articles along with positive controls (1% SLS: AA) and negative control (CC).

Occluded patches were used in study (i.e. Finn Chambers measuring about 1 cm diameter). 1 cm diameter filter paper was placed on Finn chamber disc then test article was applied on the filter paper. Only area beneath the patch was considered for the irritation observation and any sign of irritation due to tape was not considered as patch irritation. There was no tape irritation that was observed in this study.

Subjects were contacted telephonically on Day 08 for any signs of irritation at patch application site, there were no complaints from subjects on signs like erythema, dryness, oedema or wrinkles so subject's participation was considered complete and they were compensated appropriately.

Cliantha Code	Batch No.	Product Description
A	AM001	Coffee and Almond Face Scrub
B	AM002	Tea Tree Cleanser Face Wash
C	AM003	Day and Night Care Advance lotion
D	AM004	Vitamin C Cleanser Face Wash
E	AM005	Refreshing Toner with Moringa Oliefera Seed Oil
F	AM006	Retinol Facial Serum
G	AM007	Hyaluronic Facial Serum with Vitamin C
H	AM008	Nourishing and Brightening Moisturizer Face Cream
I	AM009	Ultra-Light UV Cream Daily Protection SPF 50 PA +++

Cliantha Code	Batch No.	Product Description
J	AM010	Refreshing Aqua Foaming cleanser 2 in 1 cleanser and scrub
K	AM011	Vitamin C Facial Serum
L	AM012	Vitamin C Foaming Face Wash
M	AM013	Tea Tree Foaming Face Wash
N	AM014	Exfoliating Facial Serum
O	AM015	Niacinamide Facial Serum

Overall Conclusion:

Test articles A to O qualifies the dermatological safety as per their classification into non-irritant category by 24hrs patch application test under occlusion.

The scoring method and mean score calculation used in this test are as per the Clause 4.3.1.3 in BIS 4011:2018 Methods of test for safety evaluation of cosmetics, Third revision (ICS 71.100.40).

Test articles were tested against 1% as Positive control and Sodium chloride Injection IP 0.9 % as a Negative Control, as per the standard (BIS) method 4011:2018 and 13424:2001. Positive control 1% Sodium lauryl sulfate was confirmed as Mild-Irritant when observed at 30 minutes and 24h post patch removal. Negative control Sodium chloride Injection IP 0.9 % was confirmed as Non-Irritant when observed at 30 minutes and 24h post patch removal.

The results imply that the test articles were tested by Dermatologist and found safe for all skin types as per the test conducted on 26 healthy subjects.

Note: Subjects with sensitive skin were not included in the study.

3. LIST OF ABBREVIATIONS

AE	:	Adverse Event
BIS	:	Bureau of Indian Standards
CRF	:	Case Report Form
CSR	:	Clinical Study Report
°C	:	Degree Celsius
COVID-19	:	Corona Virus Disease-2019
GCP	:	Good Clinical Practice
ICD	:	Informed Consent Document
ICH	:	International Council on Harmonization of Technical Requirements for Pharmaceuticals for Human Use
ICMR	:	Indian council of Medical Research
IEC	:	Institutional Ethics Committee
MIS	:	Mean Irritation Score
mL	:	Milliliter
SLS	:	Sodium Lauryl Sulphate
SOP	:	Standard Operating Procedure

16.3. Efficacy Results and Tabulations

Table 16.3.1 Analysis of Irritation Score after 30+5 min of patch removal (Visit 2)

Sub#	VISIT 02 [Irritation Assessment after 30 + 5 min. of patch removal]											
	Site#01 [Scrub] Coffee and Almond Face Scrub			Site#02 [Tea tree face wash] Tea Tree Cleanser Face Wash			Site#03 [Body lotion] Day and Night Care Advance lotion			Site#04 [Vitamin-C face wash] Vitamin C Cleanser Face Wash		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	1	0	1	0	0	0	1	0	1
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
n	26			26			26			26		
MIS [Mean Irritation Score]	0.0			0.0			0.0			0.0		
Standard Deviation	0.00			0.20			0.00			0.20		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, Upto 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												

Sub#	VISIT 02 [Irritation Assessment after 30 + 5 min. of patch removal]											
	Site#05 [Face toner] Refreshing Toner with Moringa Oliefera Seed Oil			Site#06 [Retinol face serum] Retinol Facial Serum			Site#07 [Hyaluronic acid Serum] Hyaluronic Facial Serum with Vitamin C			Site#08 [Moisturizer] Nourishing and Brightening Moisturizer Face Cream		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
n	26			26			26			26		
MIS [Mean Irritation Score]	0.0			0.0			0.0			0.0		
Standard Deviation	0.00			0.00			0.00			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, Upto 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												

Sub#	VISIT 02 [Irritation Assessment after 30 + 5 min. of patch removal]											
	Site#09 [Sunscreen SPF-60] Ultra-Light UV CreamDaily Protection SPF 50 PA +++			Site#10 [Aqua scrub face wash] Refreshing Aqua Foaming cleanser 2 in 1 cleanser and scrub			Site#11 [Vitamin-c face serum] Vitamin C Facial Serum			Site#12 [Vitamin-c foaming face wash]		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
n	26			26			26			26		
MIS [Mean Irritation Score]	0.0			0.0			0.0			0.0		
Standard Deviation	0.00			0.00			0.00			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, Upto 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												

Table 16.3.2: Analysis of Irritation Score after 24±2 hours of patch removal (Visit 3)

Sub#	VISIT 03 [Irritation Assessment after 24± 2 hours of patch removal]											
	Site#01 [Scrub] Coffee and Almond Face Scrub			Site#02 [Tea tree face wash] Tea Tree Cleanser Face Wash			Site#03 [Body lotion] Day and Night Care Advance lotion			Site#04 [Vitamin-C face wash] Vitamin C Cleanser Face Wash		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
n	25			25			25			25		
MIS [Mean Irritation Score]	0.0			0.0			0.0			0.0		
Standard Deviation	0.00			0.00			0.00			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, Upto 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												

Sub#	VISIT 03 [Irritation Assessment after 24± 2 hours of patch removal]											
	Site#05 [Face toner] Refreshing Toner with Moringa Oliefera Seed Oil			Site#06 [Retinol face serum] Retinol Facial Serum			Site#07 [Hyaluronic acid Serum] Hyaluronic Facial Serum with Vitamin C			Site#08 [Moisturizer] Nourishing and Brightening Moisturizer Face Cream		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
n	25			25			25			25		
MIS [Mean Irritation Score]	0.0			0.0			0.0			0.0		
Standard Deviation	0.00			0.00			0.00			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, Upto 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												

Sub#	VISIT 03 [Irritation Assessment after 24± 2 hours of patch removal]											
	Site#09 [Sunscreen SPF-60] Ultra-Light UV Cream Daily Protection SPF 50 PA +++			Site#10 [Aqua scrub face wash] Refreshing Aqua Foaming cleanser 2 in 1 cleanser and scrub			Site#11 [Vitamin-c face serum] Vitamin C Facial Serum			Site#12 [Vitamin-c foaming face wash]		
	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total	E/D/W	O	Total
1	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0
16	1	0	1	1	0	1	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	1	0	1	0	0	0	0	0	0
23	0	0	0	1	0	1	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	0	0	0	0
25	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0
n	25			25			25			25		
MIS [Mean Irritation Score]	0.0			0.1			0.0			0.0		
Standard Deviation	0.20			0.33			0.00			0.00		
Interpretation	Non-Irritant			Non-Irritant			Non-Irritant			Non-Irritant		
Mean Score Classification: 0 to 2.0/8.0 = Non-Irritant, Upto 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												