



KIDS-BTC001-DMF

Clinical Study Report

A safety test of '3X CROSS-LINK AMPOULE' after 24 hours patch on human skin

Date : April 3, 2020

Requested by : Dermafirm INC. (Korea)

Performed by : Korea Institute of Dermatological Sciences (Korea)



**Korea Institute of
Dermatological Sciences**

CERTIFICATE FOR RELIABILITY ASSURANCE



□ Title of the clinical study : A safety test of '3X CROSS-LINK AMPOULE' after 24 hours patch on human skin

□ Case control No. : KIDS-BTC001-DMF

This study was conducted according to the regulations of designation as the test institution for drugs, quasi-drugs, cosmetics, and medical devices; the guidelines of the management standards for clinical drug evaluations; the guidelines of *in vivo* clinical and *in vitro* evaluation studies; the guidelines of the experimental methods for cosmetic display and advertisements; and the guidelines of the validation of functional cosmetics of the Ministry of Food and Drug Safety, Republic of Korea; the laws of the bioethics and safety of the Ministry of Health and Welfare, Republic of Korea; and the standard operation procedure of the Korea Institute of Dermatological Sciences. All procedures were investigated by the person in charge of reliability assurance.

Title of the clinical study	A safety test of '3X CROSS-LINK AMPOULE' after 24 hours patch on human skin				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
February 28, 2020	Study plan	Reporting plan	Approved	February 28, 2020	
March 09, 2020 ~ March 13, 2020	Performing clinical trial	Reporting implementation	Approved	March 13, 2020	
March 16, 2020 ~ March 24, 2020	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	March 24, 2020	
March 25, 2020 ~ April 02, 2020	Report work	Inspecting draft report	Approved	April 02, 2020	
April 03, 2020	Report final report	Inspecting final report	Approved	April 03, 2020	

This report was prepared on the basis of the experiment results and accurately reflects the data.

April 3, 2020

Scientific Director In Sook An, Ph. D.



Reliability Assurance Jinhyuk Jung, Ph. D.



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SUMMARY OF THE CLINICAL STUDY



Title of the clinical study	A safety test of '3X CROSS-LINK AMPOULE' after 24 hours patch on human skin
Clinical trial institution	Korea Institute of Dermatological Sciences 6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05836, Republic of Korea
Trial period	February 28, 2020 (study initiation) ~ April 3, 2020 (study termination) For the study initiation, the person in charge of the study signed the clinical study proposal; for the study termination, the person in charge of the study signed the final report.
Subjects	Thirty-three subjects of either sex who met the inclusion criteria and were not included in the exclusion criteria were selected for this study.
Name of the test material	3X CROSS-LINK AMPOULE
Methods	Thirty-three healthy volunteers participated in the patch test using Finn Chamber on skin. Each of Finn Chambers containing a test material were fixed on the upper back of the subjects after cleaning up the test area with 70% ethanol and drying. 20 µL of a test material was dropped into a filter paper disc placed on 8 mm Finn Chamber. The test area was assessed at 30 minutes, 24 hours and 48 hours after 24 hours patch on the subjects. Skin reactions were scored by a dermatology specialist, following the criterion of International Contact Dermatitis Research Group (ICDRG).
Results	Skin reaction was assessed at 30 minutes, 24 hours and 48 hours after 24 hours patch of '3X CROSS-LINK AMPOULE' sponsored by Dermafirm INC., on human skin. According to the criterion of International Contact Dermatitis Research Group (ICDRG), mean score was calculated after categorizing the degree of skin reaction. No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of '3X CROSS-LINK AMPOULE' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non irritant.
Conclusion	'3X CROSS-LINK AMPOULE' sponsored by Dermafirm INC., can be considered as non irritant according to the results of the safety test.

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