



KIDS-BBK057-NSP

## Clinical Study Report

# A Clinical Study of 'GLUTANEX Cica Cream' on the Improvement of Skin Barrier by External Stimulation (Chemical Stimulation) and Skin Soothing Effect

Date : January 10, 2023

Requested by : Nexus Pharma Co., Ltd. (Korea)

Performed by : Korea Institute of Dermatological Sciences (Korea)



Korea Institute of  
Dermatological Sciences

# CERTIFICATE FOR RELIABILITY ASSURANCE



Title of the clinical study : A clinical study of 'GLUTANEX Cica Cream' on the improvement of skin barrier by external stimulation (chemical stimulation) and skin soothing effect

Case control No. : KIDS-BBK057-NSP

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.

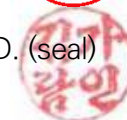
Title of the clinical study	A clinical study of 'GLUTANEX Cica Cream' on the improvement of skin barrier by external stimulation (chemical stimulation) and skin soothing effect				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
December 05, 2022	Study plan	Reporting plan	Approved	December 05, 2022	
December 13, 2022~ December 29, 2022	Performing clinical trial	Reporting implementation	Approved	December 29, 2022	
December 30, 2022~ January 04, 2022	Analyzing data, Confirming the information on test product	Inspecting raw data	Approved	January 04, 2022	
January 05, 2022~ January 09, 2022	Report work	Inspecting draft report	Approved	January 09, 2022	
January 10, 2023	Report final report	Inspecting final report	Approved	January 10, 2023	

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

January 10, 2023

Scientific Director      In Sook An, Ph. D. (seal)

Reliability Assurance      Ka Ram Kim, Ph. D. (seal)



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# SUMMARY OF THE CLINICAL STUDY



Title of the clinical study	A clinical study of 'GLUTANEX Cica Cream' on the improvement of skin barrier by external stimulation (chemical stimulation) and skin soothing effect	
Clinical trial institution	Korea Institute of Dermatological Sciences 6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05836, Republic of Korea	
Sponsor	Nexus Pharma Co., Ltd.	
Chief researcher	In Sook An, Ph.D.	
Researcher	Seungbin Kwon, lil Hong, Yun Kim, Minji Jo, Sujeong Shin, Sugyeong Hong, Hyunkyung Kim, Soyeon Park	
Name of the test material	GLUTANEX Cica Cream	
Trial period	December 5, 2022 (Study initiation) ~ January 10, 2023 (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.	
Trial period (Measurement period)	December 13, 2022 (First date of visit) ~ December 29, 2022 (End date of visit)	
Inclusion criteria	Female volunteers from twenty to sixty five years old with who met the inclusion criteria and were not included in the exclusion criteria were selected for this study.	
The age and number of subjects who completed the final study	Twenty three subjects from twenty eight to sixty (Average 47.35, Standard deviation 8.69) of female	
Methods	Usage of test product	Each subject applied the same amount of test material 'GLUTANEX Cica Cream' evenly on the facial area and left forearm area where the SLS (Sodium Lauryl Sulfate) was treated on both forearm areas and allowed it to be fully absorbed after cleansing twice a day, in the morning and the evening, during the two weeks test period.
Methods	Evaluations	The evaluations were conducted by Standard Operating Procedures of KIDS and all of the procedures were investigated by the person in charge of reliability assurance.  1. Measurements 1) Evaluation of skin barrier by external stimulation (chemical stimulation) improvement

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Methods	Evaluations	<ul style="list-style-type: none"><li>① Inducement of skin irritation using the SLS (Sodium Lauryl Sulfate) solution</li><li>② Evaluation using Vapometer and Video Microscope to assess the skin barrier by external stimulation (chemical stimulation) improvement</li><li>2. Evaluation using SkinColorCatch and VISIA-CA to assess the skin soothing effect</li><li>3. Survey</li></ul>
Results		<p>1. The evaluation results of skin barrier by external stimulation (chemical stimulation) using Vapometer and Video Microscopes The TEWL was decreased 61.86% in the areas where the test material was applied (test group), whereas 47.52% in the areas where the test material was not applied (control group) after two weeks of the test material application respectively in comparison with the pre-application (after SLS treatment) (<math>p &lt; .05</math>).</p> <p>2. The evaluation results of skin soothing effect using SkinColorCatch and VISIA-CA The <math>a^*</math> value indicating skin redness was decreased 6.85% after two weeks of the test material application in comparison with the pre-application (<math>p &lt; .001</math>).</p> <p>3. Subjects' abnormal skin responses were not detected during the trial period.</p>
Conclusion		<p>In the study requested by Nexus Pharma Co., Ltd., 'GLUTANEX Cica Cream' was found to be helpful with improving skin barrier by external stimulation (chemical stimulation) and skin soothing effect.</p>

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