



KIDS-BBF023-NSP

Clinical Study Report

A Clinical Study of 'GLUTANEX Aqua Booster' in Skin Irritation Soothing Effect by Heat (Infrared Light)

Date : July 7, 2022

Requested by : Nexus Pharma Co., Ltd. (Korea)
Performed by : Korea Institute of Dermatological Sciences (Korea)

CERTIFICATE FOR RELIABILITY ASSURANCE



Title of the clinical study : A clinical study of 'GLUTANEX Aqua Booster' in skin irritation soothing effect by heat (infrared light)

Case control No. : KIDS-BBF023-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 Aqua Booster' in skin irritation soothing effect by heat (infrared light)				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
June 14, 2022	Study plan	Reporting plan	Approved	June 14, 2022	
June 23, 2022	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	June 23, 2022	
June 24, 2022~ June 29, 2022	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	June 29, 2022	
June 30, 2022~ July 06, 2022	Report work	Inspecting draft report	Approved	July 06, 2022	
July 07, 2022	Report final report	Inspecting final report	Approved	July 07, 2022	

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

July 7, 2022

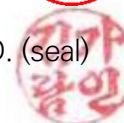
Scientific Director

In Sook An, Ph. D.



Reliability Assurance

Ka Ram Kim, Ph. D.



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SUMMARY OF THE CLINICAL STUDY



Title of the clinical study	A clinical study of 'GLUTANEX Aqua Booster in skin irritation soothing effect by heat (infrared light)	
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, Yujeong Kwon, Yoon Kim Minji Jo, Sujeong Shin, Heemin Kwon, Jiyeon Kang, Sugyeong Hong, Hyunkyung Kim, Soyeon Park	
Name of the test material	GLUTANEX Aqua Booster	
Trial period	June 14, 2022 (study initiation) ~ July 7, 2022 (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)	June 23, 2022 (First and 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 one subjects from thirty seven to sixty (Average 50.81, Standard deviation 6.10) of female	
Methods	Usage of test material	The same investigator applied the same amount of test material 'GLUTANEX Aqua Booster' on all the subjects' left side of the facial area and allowed it to be fully absorbed.
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 irritation soothing effect by heat (infrared light) ① Increase in the skin temperature induced by an infrared radiator

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Methods	Evaluations	② Evaluation using JANUS-1 and Image Analyzing Program to assess the skin irritation soothing effect by heat (infrared light) ③ Evaluation using Thermal Imaging Camera to assess the skin irritation soothing effect by heat (infrared light) 2. Evaluation of abnormal skin response 3. Survey
Results	1. The evaluation results of skin irritation soothing effect by heat (infrared light) using JANUS-1, Image Analyzing Program and Thermal Imaging Camera 1) The evaluation results of skin irritation soothing effect by heat (infrared light) using JANUS-1 and Image Analyzing Program The Δa^* value indicating skin redness was decreased 87.67% in the areas where the test material was applied (test group), whereas 37.63% in the areas where the test material was not applied (control group) after one-time use of the test material respectively in comparison with after heating (after 20 minutes). And the evaluation result of a test group was statistically significant ($p < .01$) in comparison with a control group. 2) The evaluation results of skin irritation soothing effect by heat (infrared light) using Thermal Imaging Camera The skin temperature was decreased 161.44% in the areas where the test material was applied (test group), whereas 58.75% in the areas where the test material was not applied (control group) after one-time use of the test material respectively in comparison with after heating (after 20 minutes). And the evaluation result of a test group was statistically significant ($p < .001$) in comparison with a control group. 2. Subjects' abnormal skin responses were not detected during the trial period.	
Conclusion	In the study requested by Nexus Pharma Co., Ltd., 'GLUTANEX Aqua Booster' was found to be helpful with skin irritation soothing effect by heat (infrared light).	

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