KIDS-BCC011-NSP

Clinical Study Report

A Clinical Study of 'GLUTANEX Aqua Booster' on the Mitigation of Freckles and Pigmentation

Date : April 18, 2023

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



Korea Institute of Dermatological Sciences

□ Title of the clinical study : A clinical study of 'GLUTANEX Aqua Booster' on the mitigation of freckles and pigmentation

□ Case control No. : KIDS-BCC011-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' on the mitigation of freckles and pigmentation					
Date	Step	RA inspection categories	RA inspection result	Approval date	Note	
March 20, 2023	Study plan	Reporting plan	Approved	March 20, 2023		
March 28, 2023 ~ April 11, 2023	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	April 11, 2023		
April 12, 2023 ~ April 13, 2023	Analyzing data, Confirming the information on test product	Inspecting raw data	Approved	April 13, 2023		
April 14, 2023 ~ April 17, 2023	Report work	Inspecting draft report	Approved	April 17, 2023		
April 18, 2023	Report final report	Inspecting final report	Approved	April 18, 2023		

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

April 18, 2023

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' on the mitigation of freckles and pigmentation			
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, II Hong, Yun Kim, Minji Jo, Sugyeong Hong, Hyunkyung Kim, Soyeon Park			
Name of the test material	GLUTANEX Aqua Booster			
Trial period	March 20, 2023 (Study initiation) ~ April 18, 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)	March 28, 2023 (First date of visit) ~ April 11, 2023 (End date of visit)			
Inclusion criteria	Female volunteers from thirty to sixty years old 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 six to fifty five (Average 46.76, Standard deviation 5.93) of female			
	Usage of test material	Each subject applied the same amount of test material 'GLUTANEX Aqua Booster' evenly on the facial area 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 using ANTERA 3D to assess the mitigation of freckles and pigmentation 2. Evaluation of abnormal skin response 3. Survey		

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Results	 The evaluation results of mitigation of freckles and pigmentation using ANTERA 3D The melanin value indicating freckles and pigmentation was decreased 1.08% after two weeks of the test material application in comparison with the pre-application (p(.01). Subjects' abnormal skin responses were not detected during the trial period. 	
Conclusion	In the study requested by Nexus Pharma Co., Ltd., 'GLUTANEX Aqua Booster' w found to be helpful with relieving freckles and pigmentation.	

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