



KIDS-BCK060-NSP

Clinical Study Report

A Clinical Study of 'GLUTANEX Glow Therapy Ampoule' on the Mitigation of Melasma and Pigmentation and Improvement of Skin Wrinkles, Skin Elasticity, and Skin Pores

Date : January 12, 2024

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 Glow Therapy Ampoule' on the mitigation of melasma and pigmentation and improvement of skin wrinkles, skin elasticity, and skin pores

Case control No. : KIDS-BCK060-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 Glow Therapy Ampoule' on the mitigation of melasma and pigmentation and improvement of skin wrinkles, skin elasticity, and skin pores				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
December 01, 2023	Study plan	Reporting plan	Approved	December 01, 2023	
December 11, 2023 ~ December 26, 2023	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	December 26, 2023	
December 27, 2023 ~ January 04, 2024	Analyzing data, Confirming the information on test product	Inspecting raw data	Approved	January 04, 2024	
January 05, 2024 ~ January 11, 2024	Report work	Inspecting draft report	Approved	January 11, 2024	
January 12, 2024	Report final report	Inspecting final report	Approved	January 12, 2024	

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

January 12, 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 Glow Therapy Ampoule' on the mitigation of melasma and pigmentation and improvement of skin wrinkles, skin elasticity, and skin pores	
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, Yun Kim, Minji Jo, Hyunkyung Kim, Yunjin Hwang, Soyeon Park, Heeyoung Ko, Hyunjung Ahn, Chaelee Park, Miji Kim, Myeongsun Kim	
Name of the test material	GLUTANEX Glow Therapy Ampoule	
Trial period	December 1, 2023 (Study initiation) ~ January 12, 2024 (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 11, 2023 (First date of visit) ~ December 26, 2023 (End date of measurement)	
Inclusion criteria	Male and female volunteers over thirty 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 one to sixty three (Average 49.76, Standard deviation 9.78) of either sex	
Methods	Usage of test material	Each subject applied the same amount of test material 'GLUTANEX Glow Therapy Ampoule' evenly on the left 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.
	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 melasma and pigmentation 2) Evaluation using ANTERA 3D to assess the skin wrinkles 3) Evaluation using Ballistometer to assess the skin elasticity

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Methods	Evaluations	4) Evaluation using ANTERA 3D to assess the skin pores 2. Evaluation of abnormal skin response 3. Survey
Results	1. The evaluation results of mitigation of melasma and pigmentation using ANTERA 3D	
		After 2 weeks
	Improvement rate (%)	1.48
	2. The evaluation results of skin wrinkles using ANTERA 3D	
		After 2 weeks
Improvement rate (%)	8.52	
3. The evaluation results of skin elasticity using Ballistometer		
	After 2 weeks	
Improvement rate (%)	1.66	
4. The evaluation results of skin pores using ANTERA 3D		
	After 2 weeks	
Improvement rate (%)	28.56	
5. Subjects' abnormal skin responses were not detected during the trial period.		
Conclusion	In the study requested by Nexus Pharma Co., Ltd., 'GLUTANEX Glow Therapy Ampoule' was found to be helpful with relieving melasma and pigmentation and improving skin wrinkles, skin elasticity, and skin pores.	

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