



KIDS-BBF025-NSP

Clinical Study Report

A Clinical Study of 'GLUTANEX Spot Cream' on the Mitigation of Melasma (Pigmentation)

Date : July 29, 2022

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

Performed by : Korea Institute of Dermatological Science (Korea)



Korea Institute of
Dermatological Sciences

CERTIFICATE FOR RELIABILITY ASSURANCE



Title of the clinical study : A clinical study of 'GLUTANEX Spot Cream' on the mitigation of melasma (pigmentation)

Case control No. : KIDS-BBF025-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 Spot Cream' on the mitigation of melasma (pigmentation)				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
June 14, 2022	Study plan	Reporting plan	Approved	June 14, 2022	
June 24, 2022 ~ July 15, 2022	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	July 15, 2022	
July 18, 2022 ~ July 22, 2022	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	July 22, 2022	
July 25, 2022 ~ July 28, 2022	Report work	Inspecting draft report	Approved	July 28, 2022	
July 29, 2022	Report final report	Inspecting final report	Approved	July 29, 2022	

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

July 29, 2022

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 Spot Cream' on the mitigation of melasma (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, Il Hong, Yujeong Kwon, Kim Yoon, Minji Jo, Sujeong Shin, Heemin Kwon, Jiyeon Kang, Sugyeong Hong, Hyunkyung Kim, Soyeon Park	
Name of the test material	GLUTANEX Spot Cream	
Trial period	June 14, 2022 (study initiation) ~ July 29, 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 24, 2022 (Date of visit) ~ July 15, 2022 (End date of measurement)	
Inclusion criteria	Female volunteers from thirty to sixty five 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 to sixty two (Average 46.43, Standard deviation 7.19) of female	
Methods	Usage of test material	Each subject applied the same amount of test material 'GLUTANEX Spot Cream' 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 three 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 melasma (pigmentation) 2. Evaluation of abnormal skin response 3. Survey

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Results	<ol style="list-style-type: none">1. The evaluation results of mitigation of melasma (pigmentation) using ANTERA 3D The melanin value indicating melasma (pigmentation) was decreased 1.85% after three weeks of the test material application in comparison with the pre-application ($p < .001$).2. Subjects' abnormal skin responses were not detected during the trial period.
Conclusion	In the study requested by Nexus Pharma Co.,Ltd., 'GLUTANEX Spot Cream' was found to be helpful with mitigating melasma (pigmentation).

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