



KIDS-BDE065-NSP

## Clinical Study Report

# A Clinical Study of 'GLUTANEX Glow Therapy Spicule Shot 15000' on the Mitigation of Melasma and Pigmentation, Improvement of Skin Texture, and Exfoliation (Flaky Skin)

Date : June 28, 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 Spicule Shot 15000' on the mitigation of melasma and pigmentation, improvement of skin texture, and exfoliation (flaky skin)

Case control No. : KIDS-BDE065-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 Spicule Shot 15000' on the mitigation of melasma and pigmentation, improvement of skin texture, and exfoliation (flaky skin)				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
May 27, 2024	Study plan	Reporting plan	Approved	May 27, 2024	
June 03, 2024 ~ June 17, 2024	Performing clinical trial	Reporting implementation	Approved	June 17, 2024	
June 18, 2024 ~ June 24, 2024	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	June 24, 2024	
June 25, 2024 ~ June 27, 2024	Report work	Inspecting draft report	Approved	June 27, 2024	
June 28, 2024	Report final report	Inspecting final report	Approved	June 28, 2024	

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

June 28, 2024

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 Spicule Shot 15000' on the mitigation of melasma and pigmentation, improvement of skin texture, and exfoliation (flaky skin)	
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 Spicule Shot 15000	
Trial period	May 27, 2024 (Study initiation) ~ June 28, 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)	June 3, 2024 (First date of visit) ~ June 17, 2024 (End date of visit)	
Inclusion criteria	Female volunteers over twenty 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 sixty two (Average 49.48, Standard deviation 8.91) of female	
Methods	Usage of test material	Each subject applied the same amount of the test material 'GLUTANEX Glow Therapy Spicule Shot 15000' evenly on the facial area by firmly pressing and allowed it to be fully absorbed after cleansing twice a week, in the evening, during the 2 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

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Methods	Evaluations	2) Evaluation using ANTERA 3D to assess the skin texture improvement 3) Evaluation using Video Microscope and Image Analyzing Program to assess the exfoliation (flaky skin) improvement 2. Evaluation of abnormal skin response 3. Survey												
Results		1. The evaluation results of mitigation of melasma and pigmentation using ANTERA 3D <table border="1"><thead><tr><th></th><th>After 2 weeks</th></tr></thead><tbody><tr><td>Improvement rate (%)</td><td>1.27</td></tr></tbody></table> 2. The evaluation results of skin texture using ANTERA 3D <table border="1"><thead><tr><th></th><th>After 1 time use</th></tr></thead><tbody><tr><td>Improvement rate (%)</td><td>13.63</td></tr></tbody></table> 3. The evaluation results of exfoliation (flaky skin) using Video Microscope and Image Analyzing Program <table border="1"><thead><tr><th></th><th>After 1 time use</th></tr></thead><tbody><tr><td>Improvement rate (%)</td><td>93.94</td></tr></tbody></table> 4. Subjects' abnormal skin responses were not detected during the trial period.		After 2 weeks	Improvement rate (%)	1.27		After 1 time use	Improvement rate (%)	13.63		After 1 time use	Improvement rate (%)	93.94
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Improvement rate (%)	93.94													
Results		In the study requested by Nexus Pharma Co., Ltd., 'GLUTANEX Glow Therapy Spicule Shot 15000' was found to be helpful with mitigating melasma and pigmentation, improvement of skin texture, and exfoliation (flaky skin).												

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