KIDS-BDE001-NSP(2-2)

Clinical Study Report

A safety test of 'GLUTANEX Glow Therapy Spicule Shot 15000' after 24 hours patch on human 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 safety test of 'GLUTANEX Glow Therapy Spicule Shot 15000' after 24 hours patch on human skin

☐ Case control No. : KIDS-BDE001-NSP(2-2)

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 safety test of 'GLUTANEX Glow Therapy Spicule Shot 15000' after 24 hours patch on human skin				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
May 17, 2024	Study plan	Reporting plan	Approved	May 17, 2024	
May 27, 2024 ~ May 30, 2024	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	May 30, 2024	
May 31, 2024 ~ June 14, 2024	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	June 14, 2024	
June 17, 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)

SUMMARY OF THE CLINICAL STUDY

Title of the clinical study	A safety test of 'GLUTANEX Glow Therapy Spicule Shot 15000' after 24 hours patch on human 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	Dermatology specialist Kyunggu Lee, M.D., Ph.D. Seungbin Kwon, Yun Kim, Minji Jo, Hyunkyung Kim, Yunjin Hwang, Soyeon Park, Heeyoung Ko, Hyunjung Ahn, Chaelee Park, Miji Kim, Myeongsun Kim
Trial period	May 17, 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)	May 27, 2024 (First date of visit) ~ May 30, 2024 (End date of visit)
Inclusion criteria	Female volunteers over the age of twenty 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	Thirty five subjects from twenty eight to sixty six (Average 53.00, Standard deviation 9.03) of female
Name of the test material	GLUTANEX Glow Therapy Spicule Shot 15000
Methods	Thirty five healthy volunteers participated in the patch test using Finn Chamber on skin. Each Finn Chamber containing 20 μL of a test material was fixed on the upper back of the subjects after cleaning up the test area with 70% ethanol and drying. The test area was assessed at 30 minutes, 24 hours and 48 hours after a single application during 24 hours patch on the subjects. Skin reactions were scored by a dermatology specialist, following the criterion of International Contact Dermatitis Research Group (ICDRG).

Results	Requested by Nexus Pharma Co., Ltd., skin reaction was assessed at 30 minutes, 24 hours and 48 hours after a single application during 24 hours patch of 'GLUTANEX Glow Therapy Spicule Shot 15000' on human skin. According to the criterion of International Contact Dermatitis Research Group (ICDRG), mean score was calculated after categorizing the degree of skin reaction. No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX Glow Therapy Spicule Shot 15000' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant.
Conclusion	Requested by Nexus Pharma Co., Ltd., ' GLUTANEX Glow Therapy Spicule Shot 15000' can be considered as non-irritant according to the results of the safety test.