



KIDS-BCJ001-NSP(2)

Clinical Study Report

A safety test of 'GLUTANEX Glow Therapy Ampoule and five other kinds of cosmetics' after 24 hours patch on human skin

Date : January 5, 2024

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

CERTIFICATE FOR RELIABILITY ASSURANCE



Title of the clinical study : A safety test of 'GLUTANEX Glow Therapy Ampoule and five other kinds of cosmetics' after 24 hours patch on human skin

Case control No. : KIDS-BCJ001-NSP(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 Ampoule and five other kinds of cosmetics' after 24 hours patch on human skin				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
December 08, 2023	Study plan	Reporting plan	Approved	December 08, 2023	
December 18, 2023 ~ December 21, 2023	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	December 21, 2023	
December 22, 2023 ~ December 28, 2023	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	December 28, 2023	
December 29, 2023 ~ January 04, 2024	Report work	Inspecting draft report	Approved	January 04, 2024	
January 05, 2024	Report final report	Inspecting final report	Approved	January 05, 2024	

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

January 5, 2024

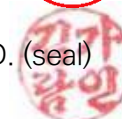
Scientific Director

In Sook An, Ph. D. (seal)



Reliability Assurance

Ka Ram Kim, Ph. D. (seal)



This report is the confidential document and property of the Korea Institute of Dermatological Sciences; its transfer, plagiarism, and disclosure to third parties is prohibited.

SUMMARY OF THE CLINICAL STUDY



Title of the clinical study	A safety test of 'GLUTANEX Glow Therapy Ampoule and five other kinds of cosmetics' 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	December 8, 2023 (study initiation) ~ January 5, 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 18, 2023 (First date of visit) ~ December 21, 2023 (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 four subjects from twenty one to sixty two (Average 47.18, Standard deviation 10.94) of female.
Name of the test materials	GLUTANEX Glow Therapy Ampoule (Test material #1) GLUTANEX UV Glow Balm (Test material #2) GLUTANEX Aloe Booster (Test material #3) GLUTANEX Deo Glow Balm (Test material #4) GLUTANEX Lip Glow Balm_Soft Scarlet (Test material #5) GLUTANEX Lip Glow Balm (Test material #6)
Methods	Thirty four healthy volunteers participated in the patch test using Finn Chamber on skin. Each Finn Chamber containing 20 μ L 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).

This report is the confidential document and property of the Korea Institute of Dermatological Sciences; its transfer, plagiarism, and disclosure to third parties is prohibited.



Results	<p>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 Ampoule and five other kinds of cosmetics' 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.</p> <p>1) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX Glow Therapy Ampoule' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant.</p> <p>2) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX UV Glow Balm' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant.</p> <p>3) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX Aloe Booster' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant.</p> <p>4) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX Deo Glow Balm' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant.</p> <p>5) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX Lip Glow Balm_Soft Scarlet' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant.</p> <p>6) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX Lip Glow Balm' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant.</p>
Conclusion	<p>Requested by Nexus Pharma Co., Ltd., 'GLUTANEX Glow Therapy Ampoule and five other kinds of cosmetics' can be considered as non-irritant according to the results of the safety test.</p>

This report is the confidential document and property of the Korea Institute of Dermatological Sciences; its transfer, plagiarism, and disclosure to third parties is prohibited.