KIDS-BCC001-NSP

**Clinical Study Report** 

## A safety test of 'GLUTANEX RETINOL EYE CREAM and three other kinds of cosmetics' after 24 hours patch on human skin

Date : March 22, 2023

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



Korea Institute of Dermatological Sciences □ Title of the clinical study : A safety test of 'GLUTANEX RETINOL EYE CREAM and three other kinds of cosmetics' after 24 hours patch on human skin

□ Case control No. : KIDS-BCC001-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 safety test of 'GLUTANEX RETINOL EYE CREAM and three other kinds of cosmetics' after 24 hours patch on human skin				
Date	Step	RA inspection categories	RA inspection result	Approval date	Note
February 24, 2023	Study plan	Reporting plan	Approved	February 24, 2023	
March 06, 2023 ~ March 09, 2023	Performing clinical trial (Measurement progress)	Reporting implementation	Approved	April 09, 2023	
March 10, 2023 ~ March 15, 2023	Analyzing data, Confirming the information on test material	Inspecting raw data	Approved	April 15, 2023	
March 16, 2023 ~ March 21, 2023	Report work	Inspecting draft report	Approved	April 21, 2023	
March 22, 2023	Report final report	Inspecting final report	Approved	March 22, 2023	

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

March 22, 2023

Scientific Director

Reliability Assurance



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## SUMMARY OF THE CLINICAL STUDY

Title of the clinical study	A safety test of 'GLUTANEX RETINOL EYE CREAM and three 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 Wonwoong Shin, M.D., Ph.D. Seungbin Kwon, II Hong, Yun Kim Minji Jo, Sugyeong Hong, Hyunkyung Kim, Yunjin Hwang, Soyeon Park		
Trial period	February 24, 2023 (study initiation) ~ March 22, 2023 (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)	March 6, 2023 (First date of visit) ~ March 9, 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 three subjects from twenty four to sixty six (Average 48.33, Standard deviation 8.56) of female.		
Name of the test materials	GLUTANEX RETINOL EYE CREAM (Test material #1) GLUTANEX WHITENING IN-SHOWER BODY CREAM (Test material #2) GLUTANEX SUN STICK (Test material #3) GLUTANEX AHA BHA LHA MICRO-FOAMING PORE CLEANSER (Test material #4)		
Methods	Methods Thirty three healthy volunteers participated in the patch test using Finn Char ber on skin. Each Finn Chamber containing 20 $\mu$ L of a test material was fix on the upper back of the subjects after cleaning up the test area with 70 ethanol and drying. In the case of test material #4, 20 $\mu$ L of a test material was dropped into a filter paper disc placed on 8 mm Finn Chamber. The test material #4 was applied after dilution with sterile distilled water at a conce tration of 1%. The test area was assessed at 30 minutes, 24 hours at 48 hours after a single application during 24 hours patch on the subject Skin reactions were scored by a dermatology specialist, following the criteri of International Contact Dermatitis Research Group (ICDRG).		

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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 RETINOL EYE CREAM and three 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. 1) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX RETINOL EYE CREAM' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant. 2) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX WHITENING IN-SHOWER BODY CREAM' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant. 3) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX WHITENING IN-SHOWER BODY CREAM' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant. 4) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX SUN STICK' on the test area and the mean score obtained was 0.00. Thus, the test material can be considered as non-irritant. 4) No skin reaction was noticed at 30 minutes, 24 hours and 48 hours after removing patch of 'GLUTANEX AHA BHA LHA MICRO-FOAMING PORE CLEANSER' 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 RETINOL EYE CREAM and three other kinds of cosmetics' can be considered as non-irritant according to the results of the safety test.

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