KIDS-BCK061-NSP

**Clinical Study Report** 

## A Clinical Study of 'GLUTANEX UV Glow Balm' on the Mitigation of Melasma and Pigmentation and Improvement of Skin Elasticity

Date : January 12, 2024

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



Corea Institute of Dermatological Sciences

## **CERTIFICATE FOR RELIABILITY ASSURANCE**

□ Title of the clinical study : A clinical study of 'GLUTANEX UV Glow Balm' on the mitigation of melasma and pigmentation and improvement of skin elasticity

□ Case control No. : KIDS-BCK061-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 UV Glow Balm' on the mitigation of melasma and pigmentation and improvement of skin elasticity |                            |                            |                   |      |
|--|--|----------------------------|----------------------------|-------------------|------|
| Date                                     | Step   | RA inspection categories   | RA<br>inspection<br>result | Approval date     | Note |
| December 01, 2023                        | Study plan   | Reporting plan             | Approved                   | December 01, 2023 |      |
| December 11, 2023 ~<br>December 26, 2023 | Performing clinical trial<br>(Measurement progress)  | Reporting implementation   | Approved                   | December 26, 2023 |      |
| December 27, 2023 ~<br>January 04, 2024  | Analyzing data,<br>Confirming the information<br>on test product   | Inspecting<br>raw data     | Approved                   | January 04, 2024  |      |
| January 05, 2024 ~<br>January 11, 2024   | Report work  | Inspecting<br>draft report | Approved                   | January 11, 2024  |      |
| January 12, 2024                         | Report final report  | Inspecting<br>final report | Approved                   | January 12, 2024  |      |

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

January 12, 2023

Scientific Director

In Sook An, Ph. D.

Reliability Assurance

Ka Ram Kim, Ph. D.

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## SUMMARY OF THE CLINICAL STUDY

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| Title of the clinical study  | A clinical study of 'GLUTANEX UV Glow Balm' on the mitigation of melasma and pigmentation and improvement of skin elasticity   |   |  |
|--|--|---|--|
| Clinical trial<br>institution  | Korea Institute of Dermatological Sciences<br>6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05836, Republic of Korea  |   |  |
| Sponsor  | Nexus Pharma Co., Ltd.   |   |  |
| Chief<br>researcher  | In Sook An, Ph.D.  |   |  |
| Researcher   | Seungbin Kwon, Yun Kim, Minji Jo, Hyunkyung Kim,<br>Yunjin Hwang, Soyeon Park, Heeyoung Ko, Hyunjung Ahn,<br>Chaelee Park, Miji Kim, Myeongsun Kim   |   |  |
| Name of the test material  | GLUTANEX UV Glow Balm  |   |  |
| Trial period   | December 1, 2023 (Study initiation) ~ January 12, 2024 (Study termination)<br>For the study initiation, the person in charge of the study signed the clinical study proposal; for the study termination,<br>the person in charge of the study signed the final report. |   |  |
| Trial period<br>(Measurement<br>period)                                  | December 11, 2023 (First date of visit) ~ December 26, 2023 (End date of measurement)  |   |  |
| Inclusion criteria   | Male and female volunteers over thirty years old who met the inclusion criteria and were not included in the exclusion criteria were selected for this study.  |   |  |
| The age and<br>number of<br>subjects who<br>completed the<br>final study | Twenty one subjects from thirty one to sixty three (Average 49.76, Standard deviation 9.78) of either sex  |   |  |
|  | Usage of<br>test material  | Each subject applied the same amount of test material 'GLUTANEX<br>UV Glow Balm' evenly on the right facial area and allowed it to be fully<br>absorbed after cleansing twice a day, in the morning and the evening,<br>during the two weeks test period. |  |
| Methods  | Evaluations  | The evaluations were conducted by Standard Operating Procedures<br>of KIDS and all of the procedures were investigated by the person in<br>charge of reliability assurance.   |  |
|  |  | <ol> <li>Measurements</li> <li>Evaluation using ANTERA 3D to assess the mitigation of melasma<br/>and pigmentation</li> <li>Evaluation using Ballistometer to assess the skin elasticity</li> </ol>   |  |

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| Methods    | Evaluations  | <ol> <li>Evaluation of abnormal skin response</li> <li>Survey</li> </ol> |               |  |
|------------|--|--|---------------|--|
|            | 1. The evaluation results of mitigation of melasma and pigmentation using ANTERA<br>3D   |  |               |  |
|            |  |  | After 2 weeks |  |
|            | Improvement rate (%)   |  | 1.12          |  |
| Results    | 2. The evaluat   | The evaluation results of skin elasticity using Ballistometer            |               |  |
|            |  |  | After 2 weeks |  |
|            | Imp  | provement rate (%)   | 1.56          |  |
|            | 3. Subjects' abnormal skin responses were not detected during the trial period.  |  |               |  |
| Conclusion | In the study requested by Nexus Pharma Co., Ltd., 'GLUTANEX UV Glow Balm' was found to be helpful with relieving melasma and pigmentation and improving skin elasticity. |  |               |  |

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