KIDS-BTB016-DMF

Clinical Study Report

# A Clinical Study for the Effects of '3X CROSS-LINK AMPOULE + MEDI NANOPEN-PRO' on Improving T-zone (Right and Left Buccal Regions, Forehead) Pore and Maintaining Skin Elasticity for 24 Hours

Date : April 3, 2020

Requested by : Dermafirm INC. (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 for the effects of '3X CROSS-LINK AMPOULE + MEDI NANOPEN-PRO' on improving T-zone (right and left buccal regions, forehead) pore and maintaining skin elasticity for 24 hours

▫ Case control No. : KIDS-BTB016-DMF

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 for the effects of '3X CROSS-LINK AMPOULE + MEDI NANOPEN-PRO' on improving T-zone (right and left buccal regions, forehead) pore and maintaining skin elasticity for 24 hours | | | | |
|---|---|---|---|---|---|
| Date | Step | RA inspection categories | RA inspection result | Approval date | Note |
| February 17, 2020 | Study plan | Reporting plan | Approved | February 17, 2020 | |
| February 25, 2020 ~ March 18, 2020 | Performing clinical trial | Reporting implementation | Approved | March 18, 2020 | |
| March 19, 2020 ~ March 25, 2020 | Analyzing data, Confirming the information on test products | Inspecting raw data | Approved | March 25, 2020 | |
| March 26, 2020 ~ April 02, 2020 | Report work | Inspecting draft report | Approved | April 02, 2020 | |
| April 03, 2020 | Report final report | Inspecting final report | Approved | April 03, 2020 | |

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

April 3, 2020

Scientific Director In Sook An, Ph.D. (seal)

Reliability Assurance Jinhyuk Jung, Ph.D. (seal)

# SUMMARY OF THE CLINICAL STUDY

| | | |
|---|---|---|
| Title of the clinical study | A clinical study for the effects of '3X CROSS-LINK AMPOULE + MEDI NANOPEN-PRO' on improving T-zone (right and left buccal regions, forehead) pore and maintaining skin elasticity for 24 hours | |
| Clinical trial institution | Korea Institute of Dermatological Sciences<br>6th Floor, Tower A, 25, Beobwon-ro 11-gil, Songpa-gu, Seoul, 05836, Republic of Korea | |
| Sponsor | Dermafirm INC. | |
| Chief researcher | In Sook An, Ph.D. | |
| Researcher | Research Director Seung Bin Kwon, Ph.D.<br>Research Engineer Yujeong Kwon<br>Associate Research Engineer Seulki Yoon · Min Ji Jo · Sujeong Shin<br>Yoonmi Choi · Dasom shin · Songhee Han | |
| Name of the test products | 3X CROSS-LINK AMPOULE (Test product A)<br>MEDI NANOPEN-PRO (Test product B) | |
| Trial period | February 17, 2020 (study initiation) ~ April 3, 2020 (study termination)<br>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. | |
| Subjects | Twenty-three subjects of either sex from forty to sixty years old who met the inclusion criteria and were not included in the exclusion criteria were selected for this study. | |
| Methods | Usage of test products | After washing face twice a day, in the morning and in the evening, during the three weeks test period, each subject applied the same amount of test product A '3X CROSS-LINK AMPOULE' evenly to face area, and only once a week, additionally applied test product B 'MEDI NANOPEN-PRO' for 10 minutes along the entire surface of the skin. |
| | 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.<br>1. Measurements<br>1) Evaluation using VISIA-CA to assess the T-zone (right and left buccal regions, forehead) pore improvement |

# SUMMARY OF THE CLINICAL STUDY

| | | |
|---|---|---|
| Methods | Evaluations | 2) Evaluation using Ballistometer to assess the maintaining skin elasticity for 24 hours<br>2. Evaluation of abnormal skin response<br>3. Survey |
| Results | 1. The evaluation results of T-zone (right and left buccal regions, forehead) pore using VISIA-CA<br>The number of pores was decreased 9.37% after three weeks of the test products application in comparison with the pre-application ($p<.05$).<br><br>2. The evaluation results of maintaining skin elasticity for 24 hours using Ballistometer<br>The CoR value indicating skin elasticity was increased 3.26% and 2.34% after three weeks of the test products application and 24 hours after stop using the test products respectively in comparison with the pre-application ($p<.001$).<br><br>3. Subjects' abnormal skin responses were not detected during the trial period. | |
| Conclusion | In the study requested by Dermafirm INC., '3X CROSS-LINK AMPOULE + MEDI NANOPEN-PRO' were found to improve T-zone (right and left buccal regions, forehead) pore and maintaining skin elasticity for 24 hours. | |