# Study Report

**A study to evaluate the effectiveness of 'MEDICUBE AGE-R BOOSTER-H' and one other cosmetic product in the improvement of 2.5 ㎜ dermal hydration, epidermal hydration, skin brightness, skin volume, skin texture, dermal density, skin barrier function, skin elasticity, depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner), skin sagging on facial (cheek) area, skin pores volume, the number of skin pores, and under-eye skin tone**

**ver.2.0**

**December 12, 2022**

**GLOBAL INSTITUTE OF DERMATOLOGICAL SCIENCES**

# DESCRIPTION FOR SUBMISSION

An Industrial R&D Center of APR Corporation (hereinafter referred to as "Global Institute of Dermatological Sciences") conducted this study to contribute to the research and development process focusing on the safety and effectiveness of cosmetics sponsored by APR Corporation on the human body. A study to evaluate the effectiveness of 'MEDICUBE AGE-R BOOSTER-H' and one other cosmetic product in the improvement of 2.5 ㎜ dermal hydration, epidermal hydration, skin brightness, skin volume, skin texture, dermal density, skin barrier function, skin elasticity, depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner), skin sagging on facial (cheek) area, skin pores volume, the number of skin pores, and under-eye skin tone was conducted according to following related documents: Guidelines to Application Test to a Human Body and Efficacy Test of Cosmetic Product; Guidelines to Test Methods for the Substantiation Labeling and Advertisement of Cosmetic Product; Guideline for Effectiveness Assessment of Functional Cosmetics by Ministry of Food and Drug Safety; Bioethics and Safety Act by Ministry of Health and Welfare; and Standard Operating Procedure (SOPs) of Global Institute of Dermatological Sciences. The results were reported as follows and this study report is an English translation copy of Korean study report.

## ver.2.0

## December 12, 2022

## Global Institute of Dermatological Sciences     (seal)

President of Global Institute of Dermatological Sciences:

Dermatologist   M.D. Myung Sun Choi   (seal)

Principal Investigator of this study:        Dermatologist   M.D. Myung Sun Choi   (seal)

Sub-investigator of this study:                        Dasom Shin   (seal)

# CERTIFICATE OF RELIABILITY ASSURANCE

This study is about the evaluation of the effectiveness of 'MEDICUBE AGE-R BOOSTER-H' and one other cosmetic product in the improvement of 2.5 ㎜ dermal hydration, epidermal hydration, skin brightness, skin volume, skin texture, dermal density, skin barrier function, skin elasticity, depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner), skin sagging on facial (cheek) area, skin pores volume, the number of skin pores, and under-eye skin tone.

This study was appropriately conducted based on the World Medical Association Declaration of Helsinki, and in accordance with following applicable regulatory requirements: 『Bioethics and Safety Act』; 『Cosmetics Act』 of the Republic of Korea; public announcement from Ministry of Food and Drug Safety; Regulation for Designation of Testing Institutes for Drugs, etc., Cosmetics, and Medical Devices; Korea Good Clinical Practice (KGCP) for Drugs; Guidelines to Application Test to a Human Body and Efficacy Test of Cosmetic Product; Guidelines to Test Methods for the Substantiation Labeling and Advertisement of Cosmetic Product; Guideline on Effectiveness Assessment of Functional Cosmetics; and Standard Operating Procedure (SOPs) of Global Institute of Dermatological Sciences. This report guarantees the reliability of following results.

| Monitoring procedures | Date | Result | Note |
|---|---|---|---|
| Study Protocol | July 01, 2022 | Approved | |
| Initial IRB Review | July 01, 2022 | Approved | 70094430-2206-HR-036-03 |
| Study Initiation | July 13, 2022 | Approved | |
| Protocol Amendment | August 10, 2022 | Approved | 70094430-2206-HR-036-05 |
| Study Completion | August 17, 2022 | Approved | |
| Data Analysis and Report Work | August 18, 2022 ~ August 25, 2022 | Approved | |
| Draft Study Report | August 26, 2022 | Approved | |
| IRB Study Closure Report | August 29, 2022 | Approved | 70094430-2206-HR-036-07 |
| Final Study Report | September 01, 2022 | Approved | |
| English Translation Report | November 21, 2022 | Approved | Summary only |
| Final English Translation Report | December 12, 2022 | Approved | |

Director of Reliability Assurance:

Global Institute of Dermatological Sciences      Hyeyoung Kim      (seal)

# SUMMARY

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| Title of Study | A study to evaluate the effectiveness of 'MEDICUBE AGE-R BOOSTER-H' and one other cosmetic product in the improvement of 2.5 ㎜ dermal hydration, epidermal hydration, skin brightness, skin volume, skin texture, dermal density, skin barrier function, skin elasticity, depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner), skin sagging on facial (cheek) area, skin pores volume, the number of skin pores, and under-eye skin tone |
| Study Identification Code | GLB-220713-I1 |
| Study Institution | Global Institute of Dermatological Sciences<br>4F, 94, Seokchonhosu-ro, Songpa-gu, Seoul, Republic of Korea |
| Sponsoring Institution | APR Corporation<br>36F, 300, Olympic-ro, Songpa-gu, Seoul, Republic of Korea |
| Study Approval Date | July 01, 2022 |
| Participation Period of Subjects | July 13, 2022 ~ August 17, 2022 |
| Reporting Date | August 26, 2022 |
| Subjects | 22 Korean adult women aged 20 to 60 who met the inclusion criteria and were not included in the exclusion criteria were enrolled for this study. (Average age: 50.773±3.280_22 completion, 0 drop-out) |
| Study Products | Study Product A: At-home skincare device (Industrial product)<br>        'MEDICUBE AGE-R BOOSTER-H'<br>Study Product B: Basic skin care products, Essence<br>        'MEDICUBE DEEP VITA C AMPOULE 2.0' |
| Methods | Usage of Study Products | - Applying 0.5 g of study product B 'MEDICUBE DEEP VITA C AMPOULE 2.0' to the whole face once in every morning after cleansing face during 4 weeks of study period.<br>- Applying study products as a following procedure, once in every night after cleansing face during 4 weeks of study period: ① Applying 0.5 g of study product B 'MEDICUBE DEEP VITA C AMPOULE 2.0' to the whole face; ② Set study product A 'MEDICUBE AGE-R BOOSTER-H' as Level 5; ③ Apply study product A to the left side of face for 3 minutes.<br>- Applying study product A after removing any jewelry or metals on the body, and avoid applying study product A to |

| | | the eye area. |
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| | | - Applying sunscreen when going-out during 4 weeks of study period. |
| | | - Pre-testing before use when using study product A together with cosmetics which contains retinol, AHA, or BHA. |
| | | - Storing study products out of reach of children and at room temperature (1~30 ℃) to avoid direct sunlight. And avoid over-charging the battery of study product A. |
| | Evaluations | 1. Effectiveness evaluations<br><br>1) Measurement of 2.5 ㎜ dermal hydration: MoistureMeterD Compact<br><br>2) Measurement of epidermal hydration: Corneometer<br><br>3) Measurement of skin brightness: Mark Vu, Chromameter CR-400<br><br>4) Measurement of skin volume: Antera 3D<br><br>5) Measurement of skin texture: Antera 3D<br><br>6) Measurement of dermal density: DUB SkinScanner<br><br>7) Measurement of skin barrier function: VapoMeter<br><br>8) Measurement of skin elasticity: Cutometer<br><br>9) Measurement of depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner): Antera 3D<br><br>10) Measurement of skin sagging on facial (cheek) area: F-ray, Image PRO<br><br>11) Measurement of skin pores volume: Antera 3D<br><br>12) Measurement of the number of skin pores: Antera 3D<br><br>13) Measurement of under-eye skin tone: Mark Vu, Chromameter CR-400<br><br>2. Safety evaluation<br><br>3. Subjective questionnaire evaluation |
| Results | | 1. Results of effectiveness evaluation<br><br>1) The evaluation results for 2.5 ㎜ dermal hydration improvement using MoistureMeterD Compact<br><br>Significant improvements in 2.5 ㎜ dermal hydration were observed on both application area in comparison to baseline; TDC value, representing water content of dermis, was increased 2.868% ($p$<.001) on A+B application area after 4 weeks of study products application, and increased 1.357% ($p$<.05) on B application area after 4 weeks of study product application. |

In addition, 2.5 ㎜ dermal hydration was further improved when study product A+B were used together; TDC value of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

2) The evaluation results for epidermal hydration improvement using Corneometer

Significant improvements in epidermal hydration were observed on both application area in comparison to baseline; capacitance, representing hydration of SC (stratum corneum) of epidermis, was increased 7.553% ($p<.001$) on A+B application area after 4 weeks of study products application, and increased 3.743% ($p<.01$) on B application area after 4 weeks of study product application.

In addition, epidermal hydration was further improved when study product A+B were used together; capacitance of A+B application area showed statistically significant ($p<.01$) difference to B application area after 4 weeks of study products application.

3) The evaluation results for skin brightness improvement Mark-Vu, Chroma meter CR-400

Significant improvements in skin brightness were observed on both application area in comparison to baseline; L* value, representing skin brightness, was increased 0.657% ($p<.001$) on A+B application area after 4 weeks of study products application, and increased 0.272% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, skin brightness was further improved when study product A+B were used together; L* value of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

4) The evaluation results for skin volume improvement using Antera 3D

A significant improvement in skin volume was observed in comparison to baseline; volume value, representing depressed volume of skin, was decreased 31.115% ($p<.001$) on A+B application area after 4 weeks of study products application.

In addition, skin volume was further improved when study product A+B were used together; volume value of A+B application area showed statistically significant ($p<.01$) difference to B application area after 4 weeks of study products application.

5) The evaluation results for skin texture improvement using Antera 3D

Significant improvements in skin texture were observed on both application area in comparison to baseline; Ra value, representing average skin roughness, was decreased 7.137% ($p<.001$) on A+B application area after 4 weeks of study products application, and decreased 2.571% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, skin texture was further improved when study product A+B were used together; Ra value of A+B application area showed statistically significant ($p<.01$) difference to B application area after 4 weeks of study products application.

6) The evaluation results for dermal density improvement using DUB Skin Scanner

Significant improvements in dermal density were observed on both application area in comparison to baseline; dermal density was increased 9.409% ($p<.001$) on A+B application area after 4 weeks of study products application, and increased 3.693% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, dermal density was further improved when study product A+B were used together; dermal density of A+B application area showed statistically significant ($p<.01$) difference to B application area after 4 weeks of study products application.

7) The evaluation results for skin barrier function improvement using VapoMeter

A significant improvement in skin barrier function was observed in comparison to baseline; TEWL (Transepidermal Water Loss) was decreased 10.677% ($p<.001$) on A+B application area after 4 weeks of study products application.

In addition, skin barrier function was further improved when study product A+B were used together; TEWL of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

8) The evaluation results for skin elasticity improvement using Cutometer

Significant improvements in skin elasticity were observed on both application area in comparison to baseline; R2 value, representing overall elasticity of skin, was increased 3.636% ($p<.001$) on A+B application area after 4 weeks of study products application, and increased 1.627% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, skin elasticity was further improved when study product A+B

were used together; R2 value of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

9) The evaluation results for depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner) improvement using Antera 3D

① Depressed skin volume on forehead area: Significant improvements in depressed skin volume on forehead area were observed on both application area in comparison to baseline; Indentation Index, representing average depth of skin wrinkles, was decreased 6.233% ($p<.01$) on A+B application area after 4 weeks of study products application, and decreased 2.919% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, Indentation Index of A+B application area was not shown statistically significant ($p>.05$) difference to B application area.

② Depressed skin volume on glabella area: A significant improvement in depressed skin volume on glabella area was observed in comparison to baseline; Indentation Index, representing average depth of skin wrinkles, was decreased 5.483% ($p<.01$) on A+B application area after 4 weeks of study products application.

In addition, Indentation Index of A+B application area was not shown statistically significant ($p>.05$) difference to B application area.

③ Depressed skin volume on outer corner of eye area: A significant improvement in depressed skin volume on outer corner of eye area was observed in comparison to baseline; Indentation Index, representing average depth of skin wrinkles, was decreased 5.886% ($p<.001$) on A+B application area after 4 weeks of study products application.

In addition, depressed skin volume on outer corner of eye area was further improved when study products A+B were used together; Indentation Index of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

④ Depressed skin volume on nasolabial area: Significant improvements in depressed skin volume on nasolabial area were observed on both application area in comparison to baseline; Indentation Index, representing average depth of skin wrinkles, was decreased 10.592% ($p<.001$) on A+B application area after 4 weeks of study products

application, and decreased 3.700% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, depressed skin volume on nasolabial area was further improved when study products A+B were used together; Indentation Index of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

⑤ Depressed skin volume on mouth corner area: A significant improvement in depressed skin volume on mouth corner area was observed in comparison to baseline; Indentation Index, representing average depth of skin wrinkles, was decreased 9.725% ($p<.01$) on A+B application area after 4 weeks of study products application.

In addition, depressed skin volume on mouth corner area was further improved when study products A+B were used together; Indentation Index of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

10) The evaluation results for skin sagging on facial (cheek) area improvement using F-ray, Image PRO

Significant improvements in skin sagging on facial (cheek) area were observed on both application area in comparison to baseline; minor/major axis ratio was increased 4.625% ($p<.001$) on A+B application area after 4 weeks of study products application, and increased 2.120% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, skin sagging on facial (cheek) area was further improved when study product A+B were used together; minor/major axis ratio of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

11) The evaluation results for skin pores volume improvement using Antera 3D

Significant improvements in skin pores volume were observed on both application area in comparison to baseline; Total Pore Volume value was decreased 28.540% ($p<.001$) on A+B application area after 4 weeks of study products application, and decreased 10.699% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, skin pores volume was further improved when study product A+B were used together; Total Pore Area value of A+B application area showed statistically significant ($p<.05$) difference to B application area

after 4 weeks of study products application.

12) The evaluation results for the number of skin pores improvement using Antera 3D

Significant improvements in the number of skin pores were observed on both application area in comparison to baseline; the number of skin pores was decreased 17.207% ($p<.001$) on A+B application area after 4 weeks of study products application, and decreased 8.284% ($p<.01$) on B application area after 4 weeks of study product application.

In addition, the number of skin pores was further improved when study product A+B were used together; the number of skin pores of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

13) The evaluation results for under-eye skin tone improvement using Mark-Vu, Chromameter CR-400

Significant improvements in under-eye skin tone were observed on both application area in comparison to baseline; L* value, representing skin brightness, was increased 0.640% ($p<.001$) on A+B application area after 4 weeks of study products application, and increased 0.273% ($p<.05$) on B application area after 4 weeks of study product application.

In addition, under-eye skin tone was further improved when study product A+B were used together; L* value of A+B application area showed statistically significant ($p<.05$) difference to B application area after 4 weeks of study products application.

2. Results for safety evaluation

The principal investigator or the sub-investigator entrusted by the principal investigator monitored whether subjects had any of the following skin responses: erythema, edema, scaling, itching, stinging, burning, tightness, and prickling, through asking and assessment for every visit. And the result showed that abnormal skin responses to application area before and after study products application were not detected during the study period.

3. Results for subjective questionnaire evaluation

Subjective questionnaire was conducted 45 questions: a question about subjects' skin type, 32 questions about an extent of skin condition improvement after study products application, and 12 questions about satisfaction about study products. And results for each question were taken statistics as average, standard deviation (SD), and positive answer rate (%).

| Conclusion | The study products 'MEDICUBE AGE-R BOOSTER-H' and one other cosmetic product, requested by the APR Corporation, were considered to be effective to improve 2.5 ㎜ dermal hydration, epidermal hydration, skin brightness, skin volume, skin texture, dermal density, skin barrier function, skin elasticity, depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner), skin sagging on facial (cheek) area, skin pores volume, the number of skin pores, and under-eye skin tone. |
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