

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 mm 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, skin gloss, and temporary improvement of skin redness and under-eye skin tone

ver.2.1

December 12, 2022



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 mm 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, skin gloss, and temporary improvement of skin redness 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.2.1

December 12, 2022

Global Institute of Dermatological Sciences



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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 mm 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, skin gloss, and temporary improvement of skin redness 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 15, 2022	Approved	
Initial IRB Review	July 15, 2022	Approved	70094430-2207-HR-037-03
Study Initiation	July 19, 2022	Approved	
Study Completion	July 21, 2022		
Data Analysis and Report Work	July 22, 2022 ~ July 28, 2022	Approved	
Draft Study Report	July 29, 2022	Approved	
IRB Study Closure Report	August 01, 2022	Approved	70094430-2207-HR-037-07
Final Study Report	August 04, 2022	Approved	
Study Report Revision	August 23, 2022	Approved	Revision of the name of study product and evaluations (ver.2.1)
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



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SUMMARY

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 mm 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, skin gloss, and temporary improvement of skin redness and under-eye skin tone	
Study Identification Code	GLB-220719-I1	
Study Institution	Global Institute of Dermatological Sciences 4F, 94, Seokchonhosu-ro, Songpa-gu, Seoul, Republic of Korea	
Sponsoring Institution	APR Corporation 36F, 300, Olympic-ro, Songpa-gu, Seoul, Republic of Korea	
Study Approval Date	July 15, 2022	
Participation Period of Subjects	July 19, 2022 ~ July 21, 2022	
Reporting Date	July 29, 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: 48.364±5.251_22 completion, 0 drop-out)	
Study Products	Study Product A: At-home skincare device (Industrial product) 'MEDICUBE AGE-R BOOSTER-H' Study Product B: Basic skin care products, Essence 'MEDICUBE DEEP VITA C AMPOULE 2.0'	
Methods	Usage of Study Products	<ul style="list-style-type: none"> - Applying study products as a following procedure, once at the first visit after cleansing face: 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. - Applying study product A after removing any jewelry or metals on the body, and avoid applying study product A to the eye area.

	Evaluations	<p>1. Effectiveness evaluations</p> <ol style="list-style-type: none"> 1) Measurement of 2.5 mm dermal hydration: MoistureMeterD Compact 2) Measurement of epidermal hydration: Corneometer 3) Measurement of skin brightness: Mark Vu, Chromameter CR-400 4) Measurement of skin volume: Antera 3D 5) Measurement of skin texture: Antera 3D 6) Measurement of dermal density: DUB SkinScanner 7) Measurement of skin barrier function: VapoMeter 8) Measurement of skin elasticity: Cutometer 9) Measurement of depressed skin volume on five facial area (forehead, glabella, outer corner of eye, nasolabial, mouth corner): Antera 3D 10) Measurement of skin sagging on facial (cheek) area: F-ray, Image PRO 11) Measurement of skin pores volume: Antera 3D 12) Measurement of the number of skin pores: Antera 3D 13) Measurement of skin redness: Mark-Vu, Chromameter CR-400 14) Measurement of skin gloss: Mark-Vu, SkinGlossMeter 15) Measurement of under-eye skin tone: Mark Vu, Chroma meter CR-400 <p>2. Safety evaluation</p> <p>3. Subjective questionnaire evaluation</p>
Results		<p>1. Results of effectiveness evaluation</p> <ol style="list-style-type: none"> 1) The evaluation results for 2.5 mm dermal hydration improvement using MoistureMeterD Compact <p>Significant improvements in 2.5 mm dermal hydration were observed on both application area in comparison to baseline; TDC value, representing water content of dermis, was increased 4.504% ($p<.001$) on A+B application area immediately after once of study products application, and increased 2.491% ($p<.01$) on B application area immediately after once of study product application.</p> <p>In addition, 2.5 mm dermal hydration was further improved when study product A+B were used together; TDC value of A+B application area showed statistically significant ($p<.01$) difference to B application area immediately after once of study products application.</p>

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 16.470% ($p < .001$) on A+B application area immediately after once of study products application, and increased 11.195% ($p < .001$) on B application area immediately after once 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 ($p < .05$) difference to B application area immediately after once of study products application.

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

A significant improvement in skin brightness was observed in comparison to baseline; L^* value, representing skin brightness, was increased 0.339% ($p < .05$) on A+B application area immediately after once of study products 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 immediately after once 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 17.330% ($p < .01$) on A+B application area immediately after once 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 ($p < .05$) difference to B application area immediately after once 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; R_a value, representing average skin roughness, was decreased 4.642% ($p < .001$) on A+B application area immediately after once of study products application, and decreased 1.833% ($p < .05$) on B application area immediately after once 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 ($p < .05$) difference to B application area immediately after once 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 5.740% ($p < .001$) on A+B application area immediately after once of study products application, and increased 1.443% ($p < .05$) on B application area immediately after once 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 ($p < .001$) difference to B application area immediately after once of study products application.

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

Significant improvements in skin barrier function were observed on both application area in comparison to baseline; TEWL (Transepidermal Water Loss) was decreased 9.841% ($p < .001$) on A+B application area immediately after once of study products application, and decreased 5.660% ($p < .001$) on B application area immediately after once of study product 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 immediately after once 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 3.668% ($p < .001$) on A+B application area immediately after once of study products application, and increased 1.078% ($p < .01$) on B application area immediately after once 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 ($p < .001$) difference to B application area immediately after once of study products application.

	<p>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</p> <p>① Depressed skin volume on forehead area: A significant improvement in depressed skin volume on forehead area was observed in comparison to baseline; Indentation Index, representing average depth of skin wrinkles, was decreased 4.066% ($p<.01$) on A+B application area immediately after once of study products application.</p> <p>In addition, Indentation Index of A+B application area showed statistically significant ($p<.05$) difference to B application area immediately after once of study products application.</p> <p>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 3.901% ($p<.01$) on A+B application area immediately after once of study products application.</p> <p>In addition, Indentation Index of A+B application area was not shown statistically significant ($p>.05$) difference to B application area.</p> <p>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 4.903% ($p<.001$) on A+B application area immediately after once of study products application.</p> <p>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 immediately after once of study products application.</p> <p>④ Depressed skin volume on nasolabial area: A significant improvement in depressed skin volume on nasolabial area was observed in comparison to baseline; Indentation Index, representing average depth of skin wrinkles, was decreased 10.122% ($p<.001$) on A+B application area immediately after once of study products application.</p> <p>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 ($p<.01$) difference to B application area immediately after once of study</p>
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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 4.723% ($p < .01$) on A+B application area immediately after once 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 immediately after once of study products application.

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

A significant improvement in skin sagging on facial (cheek) area was observed in comparison to baseline; minor/major axis ratio was increased 3.738% ($p < .001$) on A+B application area immediately after once of study products 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 immediately after once 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 23.934% ($p < .001$) on A+B application area immediately after once of study products application, and decreased 7.331% ($p < .05$) on B application area immediately after once of study product application.

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

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

A significant improvement in the number of skin pores was observed in comparison to baseline; the number of skin pores was decreased 16.836% ($p < .001$) on A+B application area immediately after once of study products 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 immediately after once of study products application.

13) The evaluation results for temporary skin redness improvement using Mark-Vu, Chromameter CR-400

A significant improvement in temporary skin redness was observed in comparison to baseline; a* value, representing skin redness, was decreased 2.838% ($p < .01$) on A+B application area immediately after once of study products application.

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

14) The evaluation results for skin gloss improvement using Mark-Vu, SkinGlossMeter

Significant improvements in skin gloss were observed on both application area in comparison to baseline; skin gloss was increased 57.395% ($p < .001$) on A+B application area immediately after once of study products application, and increased 44.896% ($p < .001$) on B application area immediately after once of study product application.

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

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

A significant improvement in under-eye skin tone was observed in comparison to baseline; L* value, representing skin brightness, was increased 0.315% ($p < .001$) on A+B application area immediately after once of study products application.

In addition, under-eye skin tone was temporarily 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 immediately after once 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

	<p>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.</p> <p>3. Results for subjective questionnaire evaluation</p> <p>Subjective questionnaire was conducted 49 questions: a question about subjects' skin type, 36 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 (%).</p>
Conclusion	<p>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 mm 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, skin gloss, and to temporarily improve of skin redness and under-eye skin tone. In addition, the study products were considered to have skin moisture glow effect by improving 2.5 mm dermal hydration, epidermal hydration, and skin glow.</p>