

Study Report

**A study to evaluate the effectiveness of
'MEDICUBE AGE-R BOOSTER-H' and one other cosmetic
product in the improvement of facial swelling and
skin barrier function of irritated skin induced by tape stripping**

ver.2.0

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 facial swelling and skin barrier function of irritated skin induced by tape stripping 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



President of Global Institute of Dermatological Sciences:

Dermatologist M.D. Myung Sun Choi



Principal Investigator of this study:

Dermatologist M.D. Myung Sun Choi



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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 facial swelling and skin barrier function of irritated skin induced by tape stripping.

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	October 17, 2022	Approved	
Initial IRB Review	October 17, 2022	Approved	70094430-2210-HR-056-03
Study Initiation	October 18, 2022	Approved	
Study Completion	October 20, 2022		
Data Analysis and Report Work	October 21, 2022 ~ October 27, 2022	Approved	
IRB Study Closure Report	October 24, 2022	Approved	70094430-2210-HR-056-07
Draft Study Report	October 28, 2022	Approved	
Final Study Report	November 02, 2022	Approved	
English Translation Report	November 14, 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 facial swelling and skin barrier function of irritated skin induced by tape stripping	
Study Identification Code	GLB-221018-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	October 17, 2022	
Participation Period of Subjects	October 18, 2022 ~ October 20, 2022	
Reporting Date	October 28, 2022	
Subjects	21 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: 47.143±8.027_21 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, Cream 'MEDICUBE TRIPLE DEEP ERASING CREAM'	
Methods	Usage of Study Products	- Applying study products as a following procedure, once at the first visit after cleansing face and forearm: ① Apply study product B 'MEDICUBE TRIPLE DEEP ERASING CREAM' 0.5 g to the whole face, 0.1 g each to the designated A+B application area (T) and B application area (C1) on left forearm; 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, to A+B application area (T) on left forearm for 1 minute.
	Evaluations	1. Effectiveness evaluations 1) Measurement of facial swelling: VECTRA H2 2) Measurement of skin barrier function of irritated skin induced by tape stripping: VapoMeter 2. Safety evaluation 3. Subjective questionnaire evaluation

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Results	<p>1. Results of effectiveness evaluation</p> <p>1) The evaluation result for facial swelling improvement using VECTRA H2 A significant ($p<.001$) improvement in facial swelling was observed in comparison to baseline; ΔVolume value, representing skin volume changes, was decreased 0.360 cc on A+B application area immediately after once of study products application; And A+B application area showed statistically significant ($p<.01$) difference to non-application area.</p> <p>2) The evaluation results for skin barrier function of irritated skin induced by tape stripping improvement using VapoMeter Significant improvements in skin barrier function of irritated skin induced by tape stripping were observed on both application area in comparison to baseline (after tape stripping); TEWL (Transepidermal Water Loss) were decreased 51.327% ($p<.001$) on A+B application area, and decreased 42.335% ($p<.001$) on B application area immediately after once of study products application; And both application area showed statistically significant ($p<.001$) differences each to non-application area. In addition, skin barrier function of irritated skin induced by tape stripping 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.</p> <p>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. 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 Subjective questionnaire was conducted 16 questions: 2 questions about subjects' facial and body skin type, 2 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 facial swelling and skin barrier function of irritated skin induced by tape stripping.</p>