KIDS-BTB015-DMF

Clinical Study Report

A Clinical Study for the Effects of '3X CROSS-LINK AMPOULE' on the Improvement of T-zone (Right and Left Buccal Regions, Forehead) Pore, Mitigation in Area of Melasma and Pigmentation, Skin Tone (Clarity), Eye Wrinkles, Cheek Lifting (Temporary Volume), Nasolabial Folds Lifting (Temporary Volume), Orbital Region Lifting (Temporary Volume), Saggy Forehead Lifting, Saggy Submental Fat Lifting, Lips Lifting (Temporary Volume), Skin Elasticity, and Skin Hydration

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' on the improvement of T-zone (right and left buccal regions, forehead) pore, mitigation in area of melasma and pigmentation, skin tone (clarity), eye wrinkles, cheek lifting (temporary volume), nasolabial folds lifting (temporary volume), orbital region lifting (temporary volume), saggy forehead lifting, saggy submental fat lifting, lips lifting (temporary volume), skin elasticity, and skin hydration

▫ Case control No. : KIDS-BTB015-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.

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Date	Step	RA inspection categories	RA inspection result	Approval date	Note
February 17, 2020	Study plan	Reporting plan	Approved	February 17, 2020	
February 26, 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 material	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' on the improvement of T-zone (right and left buccal regions, forehead) pore, mitigation in area of melasma and pigmentation, skin tone (clarity), eye wrinkles, cheek lifting (temporary volume), nasolabial folds lifting (temporary volume), orbital region lifting (temporary volume), saggy forehead lifting, saggy submental fat lifting, lips lifting (temporary volume), skin elasticity, and skin hydration	
Clinical trial institution	Korea Institute of Dermatological Sciences 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. Research Engineer Yujeong Kwon Associate Research Engineer Seulki Yoon · Min Ji Jo · Sujeong Shin Yoonmi Choi · Dasom shin · Songhee Han	
Name of the test material	3X CROSS-LINK AMPOULE	
Trial period	February 17, 2020 (study initiation) ~ April 3, 2020 (study termination) 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-one 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 material	Each subject applied the same amount of test material '3X CROSS-LINK AMPOULE' evenly to the face area including submental and lips and allowed it to be fully absorbed after cleansing twice a day, in the morning and in the evening, during the three weeks test period.
	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. 1. Measurements 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 ANTERA 3D to assess the mitigation in area of melasma and pigmentation 3) Evaluation using SkinColorCatch and VISIA-CA to assess the skin tone (clarity) improvement 4) Evaluation using ANTERA 3D to assess the eye wrinkles improvement 5) Evaluation using ANTERA 3D to assess the cheek lifting (temporary volume) improvement 6) Evaluation using ANTERA 3D to assess the nasolabial folds lifting (temporary volume) improvement 7) Evaluation using ANTERA 3D to assess the orbital region lifting (temporary volume) improvement 8) Evaluation using ANTERA 3D to assess the saggy forehead lifting improvement 9) Evaluation using PRIMOS Face & Body SCAN 3D to assess the saggy submental fat lifting improvement 10) Evaluation using ANTERA 3D to assess the lips lifting (temporary volume) improvement 11) Evaluation using Ballistometer to assess the skin elasticity improvement 12) Evaluation using Epsilon E100 to assess the skin hydration improvement 2. Evaluation of abnormal skin response 3. Survey
Results	1. The evaluation results of T-zone (right and left buccal regions, forehead) pore using VISIA-CA The number of pores was decreased 5.42% and 9.34% after two and three weeks of the test material application respectively in comparison with the pre-application ($p<.05$). 2. The evaluation results of mitigation in area of melasma and pigmentation using ANTERA 3D The Affected area value indicating area of melasma and pigmentation was decreased 11.16% and 10.15% after two and three weeks of the test material application respectively in comparison with the pre-application ($p<.05$).	

Results	3. The evaluation results of skin tone (clarity) using SkinColorCatch and VISIA-CA The L* value indicating skin lightness was increased 0.43% and 0.90% after two and three weeks of the test material application respectively in comparison with the pre-application ($p<.05$). 4. The evaluation results of eye wrinkles using ANTERA 3D The Wrinkles small value indicating skin wrinkles was decreased 6.87% and 7.02% after two and three weeks of the test material application respectively in comparison with the pre-application ($p<.05$). 5. The evaluation results of cheek lifting (temporary volume) using ANTERA 3D The Depressions medium value indicating depressed volume of skin was decreased 12.33% and 14.42% after one-time use and after two weeks of the test material application respectively in comparison with the pre-application ($p<.05$). 6. The evaluation results of nasolabial folds lifting (temporary volume) using ANTERA 3D The Depressions large value indicating depressed volume of skin was decreased 18.63% and 27.00% after one-time use and after two weeks of the test material application respectively in comparison with the pre-application ($p<.001$). 7. The evaluation results of orbital region lifting (temporary volume) using ANTERA 3D The Depressions medium value indicating depressed volume of skin was decreased 9.21% and 13.67% after one-time use and after two weeks of the test material application respectively in comparison with the pre-application ($p<.05$). 8. The evaluation results of saggy forehead lifting using ANTERA 3D The Depressions large value indicating depressed volume of skin was decreased 24.60% and 23.00% after one-time use and after two weeks of the test material application respectively in comparison with the pre-application ($p<.001$). 9. The evaluation results of saggy submental fat lifting using PRIMOS Face & Body SCAN 3D The submental volume was decreased 0.39 mL and 0.31 mL after one-time use and after two weeks of the test material application respectively in comparison with the pre-application ($p<.01$).

Results	10. The evaluation results of lips lifting (temporary volume) using ANTERA 3D The Depressions small value indicating depressed volume of skin was decreased 18.31% and 11.60% after one-time use and after two weeks of the test material application respectively in comparison with the pre-application ($p<.01$). 11. The evaluation results of skin elasticity using Ballistometer The CoR value indicating skin elasticity was increased 2.02% and 3.22% after two and three weeks of the test material application respectively in comparison with the pre-application ($p<.001$). 12. The evaluation results of skin hydration using Epsilon E100 The skin moisture was increased 144.98% and 81.25% after one-time use and after two weeks of the test material application respectively in comparison with the pre-application ($p<.001$). 13. Subjects' abnormal skin responses were not detected during the trial period.
Conclusion	In the study requested by Dermafirm INC., '3X CROSS-LINK AMPOULE' was found to improve T-zone (right and left buccal regions, forehead) pore, mitigate in area of melasma and pigmentation, skin tone (clarity), eye wrinkles, cheek lifting (temporary volume), nasolabial folds lifting (temporary volume), orbital region lifting (temporary volume), saggy forehead lifting, saggy submental fat lifting, lips lifting (temporary volume), skin elasticity, and skin hydration. In addition, the test material was found to be effective on the three parts of the face lifting by improving cheek lifting (temporary volume), nasolabial folds lifting (temporary volume), and saggy submental fat lifting. Also, the test material was found to be effective on the six parts of the face lifting by improving cheek lifting (temporary volume), nasolabial folds lifting (temporary volume), orbital region lifting (temporary volume), saggy forehead lifting, saggy submental fat lifting, and lips lifting (temporary volume).