

CLINICAL TRIAL REPORT

PNK-21707-I7RE

**The Safety assessment of NWK A-FV
by Skin Primary Irritation Test**

Requested by : NAEWOIKOREA Co., Ltd.

July 16, 2021



Authentication

P&K Skin Research Center reports test result of “The Safety assessment of NWK A-FV by Skin Primary Irritation Test” requested by NAEWOIKOREA Co., Ltd. This clinical test was conducted in accordance with Regulations for the Evaluation of Functional Cosmetics (Ministry of Food and Drug Safety Notice No.2017-42) and P&K Skin Research Center's SOP.

2021. 07. 16.

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		Researcher	Jeong Ok Lee
		Researcher	Jin Sol Park
		Researcher	Min Kyeong Lee, Da Som Kim, Su Hyun Lee
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		Researcher	Ra Yeon Park, Eun Ju Lee, Set Byul Park
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		Assistant	Ye Jin Park, Ha Young Lee, So Jung Hong
		Assistant	Ji Hye Park, Min Jung Yoon, Na Young Lee
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Final Report

Subject of Study	The Safety assessment of NWK A-FV by Skin Primary Irritation Test		
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Duration of Research	Start Date	June 23, 2021	
	End Date	July 16, 2021	
Duration of Study	July 07, 2021 ~ July 09, 2021		
Date of Report Completion	July 16, 2021		
Requester	Requested Date	June 23, 2021	
	Company Name	NAEWOIKOREA Co., Ltd.	
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	Research President	Hae Kwang Lee (sign)	
	Person in Charge	Da Som Kim	Tel. 02-6925-1501~3

Contents

Conformation of Reliability Assurance-----	5
Summary Report of the Clinical Study -----	7
Research on the Actual Condition of Test Facilities -----	10
1. Object and purpose of the study -----	11
2. Study Purpose-----	12
3. Test Product-----	12
4. Selection of Subjects-----	13
5. Number of Subjects and Calculation basis -----	13
6. Method of Study -----	14
7. Method of evaluation -----	15
8. Regulations and Others -----	17
9. Test results -----	18
10. Conclusion -----	21
Reference -----	22
Appendix 1. Information for Consent form -----	23
Appendix 2. Informed Consent form-----	26
Appendix 3. Subject Information-----	27
Appendix 4. Subject Skin types and characteristics-----	28
Appendix 5. Results of Visual assessment -----	29
Appendix 6. Test product ingredients-----	30
Researcher Profile -----	31
Accomplishment of Chief Researcher -----	43



Conformation of Reliability Assurance

No.	PNK-21707-I7RE	Version No.	Ver. 1.0																													
Study title	The Safety assessment of NWK A-FV by Skin Primary Irritation Test																															
	Duration	June 23, 2021 ~ July 16, 2021																														
<p>1. Following basic documentations stored? (Able to check multiple)</p> <p> <input checked="" type="checkbox"/> Study protocol <input checked="" type="checkbox"/> CRF <input checked="" type="checkbox"/> Informed consent <input checked="" type="checkbox"/> Contract <input checked="" type="checkbox"/> Researcher profile <input type="checkbox"/> Subject ID Number <input checked="" type="checkbox"/> Subject selection record <input checked="" type="checkbox"/> Subject registration record <input checked="" type="checkbox"/> Information for subject informed consent <input type="checkbox"/> Blind release <input checked="" type="checkbox"/> Subject compensation standard <input checked="" type="checkbox"/> Delegation Log <input type="checkbox"/> Report of SEA </p>																																
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<p>4. Has any documents been changed?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>(If 'Yes' : _____)</p>																																
<p>5. Did the study processed according to the Standard of operation procedures?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>																																

6. Following items of subject information reported in Case Report Form (CRF)?

- Subject Initial Date of birth Subject identification number
 Gender Age

7. Did all subjects sign and write date by own in the informed consent form?

- Yes No

8. Any informed consent signed by subject representative?

- Yes No (If yes _____ times)

* Reason for representative agreement

9. Any copy of informed consent provided to subject or subject representative?

- Yes No

10. Any documents such as data and CRF stored separately?

- Yes No

11. Any adverse event or specified changes occurred?

If yes, please summarize and hand in as Appendix.

- Yes No

12. Any case of subject complain?

If yes, please summarize and hand in as Appendix.

- Yes No

<Results>

This clinical test was conducted in accordance with P&K Skin Research Center's SOP.

Also it has been confirmed by the person in quality assurance and submitted to chief researcher.

Date : July 16, 2021

Quality assurance : Jin Hee Shin (sign)

Chief researcher : Beom Joon Kim (sign)

Summary Report of Clinical Study

Title of Study	The Safety assessment of NWK A-FV by Skin Primary Irritation Test		
Research Facility	P&K Skin Research Center Co., Ltd	Test Number	PNK-21707-I7RE
Duration of Study	June 23, 2021 ~ July 16, 2021		
Test Product	NWK A-FV		
Object of Study	This clinical study was conducted to verify the safety by Skin primary irritation test.		
Subjects of Study	Adults aged between 20~55 who are included from Selection Criteria of Subjects and excluded from Exclusion Criteria of Subjects		
Number of Subjects	32 people		
Selection Criteria	<p>Selection criteria are as following:</p> <ol style="list-style-type: none"> Adults aged between 20 and 55. Subjects who do not have any acute or chronic disease including skin ailments Subjects who have signed consent form voluntarily after being informed well of object of study and all related contents Subjects who can be observed and traced for the entire experiment period 		
Exclusion Criteria	<p>Exclusion criteria are any of as following:</p> <ol style="list-style-type: none"> Subjects who do not want to fill out a consent form Subjects who have traumas such as erythema, wound, scars or tattoos on the test site that make evaluation difficult. Subjects who have infectious skin diseases Subjects who have medical history or treatment history related to skin reaction Subjects who have systemic allergies or hypersensitivity to cosmetics, drugs, or sunlight. Subjects who are participating in another clinical center. Females who are pregnant or breast-feeding Any subjects who are considered to be inappropriate to participate in the study by the researcher. 		
Test method	<ol style="list-style-type: none"> Attached area: The part of back that is flat, smooth) where there is no pigmentation of skin damage, excluding the vertebral region Evaluation lists <ol style="list-style-type: none"> Researcher visual assessment <ul style="list-style-type: none"> Skin irritation degree 		

	<p>In accordance with the modification of Frosch & Kligman, CTFA guideline and Using the Draize method, check the range of the skin irritation index to distinguish the skin irritation level.</p> <p>3. Other inquiries</p> <p>1) Demographic information : Sex, date of birth, age before the clinical study.</p> <p>2) Vital sign survey : Visual assessment before the clinical study.</p> <p>3) Medical history : Main symptom, initiation date of disease, test and treatment history.</p> <p>4. Visiting schedule : Visiting 3 times</p> <p>1) Visit 1: Filling out the consent form, inclusion and exclusion of subjects, put the test product patch, and adverse event check</p> <p>2) Visit 2: Remove the patch, visual assessment of test participant regarding the skin reaction for 1 hour after the removal, and adverse event check</p> <p>3) Visit 3: Visual assessment of test participant regarding the skin reaction for 24 hours after the removal, and adverse event check</p>				
Primary outcome measures	Skin irritation degree 1 hour and 24 hours after the removal of the patch				
Safety evaluation	Any adverse event occurred after test product use is evaluated.				
Results of Study	<p>The safety evaluation of "NWK A-FV" was conducted on adults aged 20 to 55.</p> <p>1) All the 32 subjects were female, with an average age of 39.094. The skin types were 13 of dry skin, 6 of dry to normal skin, 11 of normal skin, 1 of normal to oily skin, 1 of oily skin. Selected subjects did not show any adverse or have any medical or drug history that might affect the study.</p> <p>2) Result</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;">Test product</th> <th style="width: 40%;">Irritation degree</th> </tr> </thead> <tbody> <tr> <td>NWK A-FV</td> <td>No(non) irritation</td> </tr> </tbody> </table> <p>3) There was no report about adverse effect by subjects during the application period of test product.</p> <p>The test product "NWK A-FV" was applied to the test site of the subjects for 24 hours, and the researcher visually evaluated the skin reaction of the test site 1</p>	Test product	Irritation degree	NWK A-FV	No(non) irritation
Test product	Irritation degree				
NWK A-FV	No(non) irritation				

	<p>hour and 24 hours after the patch was removed. As the result, “NWK A-FV” has no (none) stimulation.</p>
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Research on the Actual Condition of Test Facilities

Research Center	Name: P&K Skin Research Center Co., Ltd
	Address: 4F, 25 Gukhoe-daero 62-gil, Yeongdeungpo-gu, Seoul, Korea
	President: Hae Kwang Lee (sign)
	Tel :02-6925-1501~3, (Fax) 02-6925-1504
Object of Establishment	This research center was founded for accomplishing clinical study of cosmetics or quasi-drugs such as safety, moisturizing effect, acne improvement, elimination effect of dead skin cell, whitening effect, wrinkle improvement, and sun protection. Through these scientific evaluations, P&K Skin Research Center provides its clinical study reports and all its related technical information to the requester.
Study Item	<p>Efficacy Evaluation & Study of Cosmetics.</p> <p>Safety Test & Study of Cosmetics.</p> <p>Efficacy Evaluation & Study of Functional Cosmetics.</p> <p>Evaluation & Study of quasi-drugs</p>
Chief Researcher	<p>P&K Skin Research Center Co., Ltd</p> <p>Chung-Ang University Hospital Dermatology Department</p> <p>Beom Joon Kim (sign)</p>
Researcher	Jong Ho Park, Myeong Rae Kim, A Reum Kim, Yoon Kim, Jeong Ok Lee, En Hae Lee, Ji Su An, Eun Kyoung Lee. Jin Young Jang, Mi Hye Seo, Ga Bin Ryu, Min Jin Ha, Hye Jin Kim, Jin Sol Park, Da Young Yoon, Min Kyoung Lee, Mi Ae Lee. Hae Na Lee, So Eun Cho, Yeo Jin Hwang, Su Ji Park, Myeong Sun Kim, Do Eun Kim, Jung Min Lee, So Hee Kim, Sung Mi Cho, Min A Park, Dan Bi Lim, Yae Ji Kim, Hyun Ju Kim, Su Ji Lee, Hyun Woo Lee, Da Som Kim, Min Seo Kim, Soo Hyun Lee, Eun Bin Jeon, Da Hae Shin, Jae Won Jeong, Joo Won Shin, Ji Eun Lim, Mi Ji Kim, Hee Jeong Kim, Ye Jin Park, Bo Ram Heo, So Jeong Hong, Ha Young Lee, Ji Hae Park, Min Jung Yoon, Ji Young Kim, You Jeong Lee, Eun Jin Jeong, So Hyun Pack
Main facilities and Equipments	Multi Probe-Adaptor MPA5, MPA5 Data recorder, Cutometer dual MPA580, Sebumeter SM815, Corneometer CM825 probe, Cutometer probe, Skin-pH meter PH905 probe, Skin-Thermometer ST500 probe, Mexameter MX18 probe, Tewameter TM300 probe, Sensor for Room Condition RHT100, Skin Visiometer SV600, Visioscan VC98, Skin Visiometer SV700, Visioscan VC98 USB, Skin Visiometer data recorder, VisioLine VL650, MoistureMap MM100, Visoface Quick, VapoMeter, SkinGlossMeter, MoistureMeterD XS5/S15/M25/L50, MoistureMeterD Compact, Chromameter CR400, Spectrophotometer CM-700d, Multiport Solar Simulator 601-300W, Multiport Solar Simulator 601-300W V2.5, Xenon Lamp Power Supply, Adjustable Multiport Column, Radio meter PMA2100, UVA Detector PMA2113, SUVDetector PMA2103, Whirl pool system, Micropipette, Chemical Balance, Folliscope 4.0, Folliscope 5.0, Scopeman, Thermo-hygrostat STHC-MB, Fomex D400(SS-B), DSLR, SkinScanner-DUB [®] , Epsilon E100, SAMBA Hair, Bolero, Janus, VISIA-CR 2.2, VISIA-CR 2.3, VISIA-CR 4.3, PRIMOS Premium, PRIMOS lite, PRIMOS-CR Small Field, PRIMOS-CR Large Field, Vectra XT, Stereotactic Hair Device Kit, DermaVision-PRO, 3D Raman Microscopy System Nanofinder@30, PNK Blue Light Simulator, Photographing System, Whitening Evaluation Lab, Anti-Wrinkle Evaluation Lab, SPF Evaluation Lab, PFA Evaluation Lab, Moisture Evaluation Lab, Hair Evaluation Lab, Cleansing Room, 30Waterproof System room, Shower room.

1. Object and purpose of the study

Cosmetics are products that are normally used by healthy normal people for a long period of time, not for the purpose of treating certain diseases, and are different from those used for a certain period of time for the treatment of certain diseases. In the case of medicines, the value is determined by considering both the effectiveness of the treatment and the side effects that may follow. However, in the case of cosmetics, the effectiveness and use of cosmetics should be reviewed after ensuring absolute safety.

Skin reactions that can be caused by external preparations including cosmetics are classified into Acute Contact Dermatitis, Irritant Contact Dermatitis, Allergic Contact Dermatitis, Phototoxic Contact Dermatitis, Photoallergic Contact Dermatitis, Contact Urticaria, Sensory Irritation that causes skin discomfort without visual appearance of inflammatory reaction, Hyper/ Hypopigmentation, local side effects, and systemic side effects.

Until now, tests using human skin and tests using animals have been performed as means to secure the safety of cosmetic raw materials and cosmetics.

Tests using human skin have the advantage of predicting skin irritation under actual use conditions, but because of the fact that it takes a lot of time, that there are differences among the test subjects, that it involves subjective factors of the examinee, that it is painful to subjects when using a highly irritating substance, that there are limitations in clarifying the differences between low irritant substances by primary exposure instead of repeated exposure, animal testing has been performed as a pre-test to human testing. However, animal testing at the stage of developing cosmetics faces societal criticism in terms of environmental and animal protection, and in the sixth amendment of the European Community Cosmetics Directive(ECCD) in Europe, animal testing for raw materials and products It was decided to stop and experiment with alternative applicable test methods. Efforts to reduce animal testing have increased interest in in-vitro alternative assays, and in fact, in vitro assays have been developed that incorporate stimulatory mechanisms of the mucosa and skin to date, and research has been continuing in order to utilize it in each country. However, until now, in vitro tests and animal tests have not been able to accurately reflect the mechanism of human skin.

The Food and Drug Administration has designated and notified the use of raw materials that cannot be used in cosmetics and raw materials that require restrictions on their use, and each manufacturer faithfully follows them. The 'NWK A-FV' developed by NAEWOIKOREA Co., Ltd. is manufactured in accordance with the Food Safety Management Notice [Cosmetic Safety Standard, etc.], and it is checked whether the primary stimulus is obtained through the human skin primary stimulation test.

2. Study Purpose

This clinical study was conducted to assess the safety of the ‘NWK A-FV’ provided by NAEWOIKOREA Co., Ltd. on adult aged between 20 to 55 who are suitable for subject selection criteria.

3. Test product

3-1. Test product

<Table 1. Test product information>

No.	Product Name	Product No.	Product type	Concentration
16	NWK A-FV	21707-I7-S1	White fluid phase	100%

*16: Application Order

3-2. Test product storage

The test product was sealed and stored in room temperature.

4. Selection of Subjects

Adult who are satisfied with selection criteria without any of exclusion criteria.

4-1. Inclusion criteria

- Adults aged between 20~55
- Subjects who do not have any acute or chronic disease including skin ailments.
- Subjects who have signed consent form voluntarily after being informed well of object of study and all related contents.
- Subjects who can be observed and traced for the entire experiment period.

4-2. Exclusion criteria

- Subjects who are pregnant or breast-feeding
- Subjects who have traumas such as erythema, wounds, scars or tattoo on the test site that make the evaluation difficult.
- Subjects who have infectious skin diseases
- Subjects who have medical history or treatment history related to skin reaction
- Subjects who have systemic allergies or hyper-sensitiveness to cosmetics, medicines or daily light exposure
- Subjects who are participating in another clinical center
- Subjects who have not done similar clinical test in 3 months

4-3. Withdrawal criteria

Subjects with any of following cases have withdrawn from the study even after subject agreed to participate.

- Subjects who are willing to discontinue the study.
- Subjects who are with serious adverse effect or who want to discontinue the study because of adverse effect such as erythema.
- Subjects who have hypersensitivity due to the test product.
- Subjects who have to stop using test product due to other disease.
- Other unavoidable circumstances.
- Subjects who do not follow the study processes.
- Subjects who were failed to be traced during study period.

5. Number of Subjects and Calculation basis

Selected subject number is over 30 people in accordance to <Korea Food and Drug Administration

(MFDS) regulations for approval regarding the functional cosmetics and other 2017-42>

6. Method of Study

6-1. Test area of application

- Healthy skin on the back free of ointments and excessive sebum, not including area around spine.

6-2. Before applying test product

- Photograph was taken, and survey was done about skin condition, skin type and etc.

6-3. Test product application

- 20 μ l of test product was loaded on IQ Ultimate chamber and fixed to subject's back with 3M Micropore Tape(In the case of facial mask, it is cut by 1cm: 1cm in width and length).
- The IQ Ultimate chamber was attached on test area for 24 hours.
- IQ Ultimate chamber was removed 24 hours after application. Then visual assessment was performed and photograph was taken 1 hour after removal.
- 24 hours after removal, visual assessment was performed and photograph was taken.

6-4. Apparatus

IQ Ultimate chamber (Chemotechnique Diagnostics, Sweden), 3M Micropore Tape, Marking Pen, Micropipette

6-5. Test guidelines: This clinical study was conducted in accordance of following standard.

Test guidelines for assessment of skin compatibility of cosmetic finished products in man., Task Force of COLIPA, the European Federation of national Cosmetic, Toiletry and Perfumery Associations, Walker AP, Basketter DA, Baverel M, Diembeck W, Matties W, Mouglin D, Paye M, Rothlisverger R, Dupuis, J. Food Chem Toxicol., 1996 34(7): 651-660.

7. Method of evaluation

7-1. Subject pre-survey : subject survey

- Skin type : dry, dry to normal, normal, normal to oily, oily, trouble
- Skin condition : skin diseases, itching, pricking, erythema, cosmetic adverse event, medicinal adverse event, sensitive to light, eczema or atopic history

7-2. Evaluation item

- Visual assessment by researcher : Evaluated skin irritation degree on test area

7-3. Examination of skin reactions

- Skin reactions are scored and recorded according to the grades in the following table 2, modified by Frosch & Kligman, CTFA guideline and Dermal irritation levels of test materials were identified by referring to the Skin Irritation Index table (Table 3) produced using the Draize method.

<Table 2. Recording of skin reactions>

Mark	Grade	Evaluation criteria
+	1	Slight erythema, either spotty or diffuse
++	2	Moderate uniform erythema
+++	3	Intense erythema with edema
++++	4	Intense erythema with edema & vesicles

<Fig 1. Clinical standard photographs of visual assessment for human patch test>



- Skin response was determined according to the following formula.

$$\text{Skin reaction grade} = \left(\frac{\sum_{i=1}^{32} \text{Evaluation value}}{32(\text{No. of Subject})} \right)_{1h} + \left(\frac{\sum_{i=1}^{32} \text{Evaluation value}}{32(\text{No. of Subject})} \right)_{24h}$$

(i: Number of subjects who completed the test)

- The skin irritation index of the test substance was determined according to the following formula.

$$\text{Skin irritation score} = \frac{\text{Skin reaction grade}}{n} \quad (n : \text{number of evaluation})$$

- The product is classified according to the Skin irritation index (Table 3).

<Table 3. Skin Irritation Index>

Skin irritation Score	Classification
0.00 - 0.25	No irritation
0.26 - 1.00	Mild irritation
1.01 - 2.50	Moderate irritation
2.51 - 4.00	Severe irritation

7-4. Adverse events and combined medicine

Any adverse events after product use and throughout the study period were considered together to find the incidence of adverse events and use it is safety evaluation data. Also any combined medicine history which may affect skin reactions was surveyed.

When an adverse event was reported, the researcher informed the chief researcher, and the chief researcher determined the severity of symptoms and whether it was related to the test product, and decided appropriate measures for symptoms and whether to further participate in the study.

8. Regulations and Others

8-1. Safety protection of Subjects

This clinical study is based on the Helsinki declaration for human dignity and interests to prevent any of subject disadvantages. The researcher checked subject health to confirm the study participation before the study begins. Also, the researcher was well informed about the test product and did best to guarantee safety of subject.

8-2. Subject consent and information for consent

The chief researcher and researchers fully explained about all the study processes to the subjects who are satisfied with selection criteria without any exclusion criteria before the study initiation. Also provided enough chances to understand all the predictable results. The subject agreed contents were recorded as documents and the chief researcher confirmed by signing the subject consent form.

8-3. Confidentiality of Identity

All subject names who participated study have maintained confidentially. The consent form which subjects signed have been stored by researcher. Also, the lists with subject identification code, subject initials, and subject names have been administrated specially by researcher or monitor to use them as verification data in further recordings or evaluations.

8-4. Other subject protections

P&K Skin Research Center is equipped with necessary facilities and experts to follow the study protocols and regulations to ensure the safety of subject as priority. The researcher was well informed about adverse events and notifications that were stated in study protocol to notice requester after appropriate treatment of any adverse events during study. When direct or indirect injury occurs due to this study participation, the chief researcher or researchers will do best to treat them. When any adverse events or side effects of treatment process occur due to test product usage, the requester NAEWOIKOREA Co., Ltd. will compensate all the inquiries. However, subjects will afford any hospital bills, inspection expenses, consultation fees that are unrelated to this clinical study.

9. Test results

9.1. Subject information

The average age of total 32 subjects who finished this study was 39.094. 9 subjects were in 20s, 6 subjects were in 30s, 8 subjects were in 40s and 9 subjects were in 50s. All of the 32 subjects were female (Table 4~5).

<Table 4. Subjects age(n=32)>

Age	Number	%
20-29	9	28.125
30-39	6	18.750
40-49	8	25.000
50-55	9	28.125

<Table 5. Subjects gender(n=32)>

Gender	Number	%
Male	0	0.000
Female	32	100.000

9-2. Withdrawn subject

The total 32 subjects completed the study.

9-3. Skin types of subjects

Among 32 subjects who participated in and completed this study, 13 were of dry skin, 6 were of dry to normal skin, 11 were of normal skin, 1 was of normal to oily skin, and 1 was of oily skin(Table 6).

<Table 6. Subject skin type(n=32)>

Skin type	Number	%
Dry	13	40.625
Dry to normal	6	18.750
Normal	11	34.375
Normal to oily	1	3.125
Oily	1	3.125

9-4. Skin characteristics of subjects

All subjects do not have any skin ailments such as skin disease, itching, sting, erythema, adverse effect on cosmetics, adverse effect on drugs, hyper-photosensitiveness, atopic dermatitis and etc(Table 7).

<Table 7. Subject skin characteristics>

	Number	%
Skin disease	0	0.000
Itching	0	0.000
Sting	0	0.000
Erythema	0	0.000
Adverse event on Cosmetic	0	0.000
Adverse event on drugs	0	0.000
Hyper-photosensitiveness	0	0.000
Atopic dermatitis	0	0.000

9-5. Skin irritation degree by Primary Skin Irritation Test

The 'NWK A-FV' has been patched for 24 hours, and the comprehensive result of visual examination by researcher regarding the skin reaction for one hour and 24 hours after the removal of patch has shown that the test product, NWK A-FV can be considered to have no irritation(Table 8).

<Table 8. Skin reaction degree due to Primary Skin Irritation Test>

Test product	Skin irritation no.	Irritation degree
NWK A-FV	0.02	No(non) irritation

9-6. Adverse events and combined drug use

There was no adverse events or combined drug usages during study period.

10. Conclusion

The safety evaluation of "NWK A-FV" was conducted on adults aged between 20 to 55.

1) All 32 subjects were female, with an average age of 39.094. The skin types were 13 of dry skin, 6 of dry to normal skin, 11 of normal skin, 1 of normal to oily skin, 1 of oily skin. Selected subjects did not show any adverse effects or have any medical or drug history that might affect the study.

2) Result

Test product	Irritation degree
NWK A-FV	No(non) irritation

3) There was no report about adverse effect by subjects during the application period of test product.

The test product "NWK A-FV" was applied to the test site of the subjects for 24 hours, and the researcher visually evaluated the skin reaction of the test site 1 hour and 24 hours after the patch was removed. As the result, "NWK A-FV" has no (none) stimulation.

.

References

1. Association of Food and Drug Officials of the United States. Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. USA, 1965.
2. Cosmetic, Toiletry and Fragrance Association. CTFA Safety Testing Guideline. USA, 1991.
3. Draize J, Woodard G, Calvery H. Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. *J. Pharm. Exp. Ther.* 1994;82:377-390.
4. Fischer T, Maibach H. Finn chamber patch test technique. *Contact dermatitis.* 1984;11(3):137-40.
5. Frosch PJ, Kligman AM. The soap chamber test. A new method for assessing the irritancy of soaps. *J Am Acad Dermatol.* 1979;1(1):35-41.

Appendix 1. Information for Subject Consent form

Skin Irritation Test in Human Subjects

We request you to participate in this clinical study. However, it is important that you understand why this study should be done and what procedure would be performed, before deciding participation in this clinical study. We have prepared information for agreement about your role when you participate in this study. Please read this information for subject's agreement carefully and discuss about this with your family and other people. If you have any question, please ask to chief researcher or other researchers.

1. Purpose of Clinical study

P&K Skin research center is going to perform the Clinical study of The Safety Assessment of 'NWK A-FV' with adults aged between 20~55, by Skin Primary Irritation Test requested by NAEWOIKOREA Co., Ltd.

- ① This clinical study is conducted to healthy adults aged between 20 to 55, evaluating the safety of the test product.
- ② The test product is applied for once using patch for 24 hours, and then skin irritation was evaluated 1 hour and 24 hours after patch removal.
- ③ If you participated in this clinical study, you will visit 3 times at before, 1 hour and 24 hours after patch attachment. Photograph will be taken and skin irritation will be visually evaluated.

2. Method of clinical study

① Number of subjects and period of study

Number of subjects that we require is over 30 people. If you are appropriate to participate in clinical study and you or your representative sign on agreement, you will participate in this clinical study for 3 days according to study process.

② Selection of subject

This study targets adults ranging in age from 20 to 55. You can participate in this study if you satisfy all the inclusion criteria but not exclusion criteria.

③ Test product application

20 μ l of test product was loaded on IQ Ultimate chamber and fixed to subject's back with 3M Micropore Tape(In the case of mask pack, it is cut by 1cm: 1cm in width and length).

④ Visiting schedule

On the 2nd and 3rd day of the test, visit the center at the same time as the specimen collection and remove the patch and evaluate the test site.

⑤ Test product

There is 1 kind of product.

No.	Test product
1	NWK A-FV

3. Forecasted allergy and side effect

We expect that allergy or other side effects are not occurred, because the samples are made with cosmetic materials accordance of MFDS. However, in subjects who have sensitive skin, severe itching, rash, sting and eruption may occur. Therefore, we will inform you any new information about safety during the clinical study.

4. Appropriate contraception method for female

If you are pregnant or are doing breast-feeding or have a plan to be pregnant or do not agree with following suggested appropriate contraception method, you cannot participate in this study.

- ① Intrauterine Device : Loop etc.
- ② Barrier method : Femidom, Spermicide etc.

5. Benefits in respect of participation of clinical study

All the testing product and required processes are provided. If you finish the appointed study, some transportation expenses will be provided.

6. Compensation and treatment in case of any side effects

During study period, researcher will perform the study with taking subject's safety as the highest priority.

When side effects are occurred by using the test product, you can receive needed examination and treatment. And we will do a follow-up until the side effects resolved.

If you have any side effect by using the clinical test product, NAEWOIKOREA Co., Ltd. will take charge for all the following treatment cost.

7. Withdrawal of participation after agreement

Participating in this study depends on your voluntary intention. Even if you agreed to participate in this study, you can discontinue the participation at any time. Even though you discontinue the study, you can receive treatment for side effects related with the study and you will not have any disadvantages. If you want to discontinue the study, please contact to the person in charge of the P&K Skin Research Center.

8. Confidentiality of Identity

Your personal data which has gained during the progress of study, is protected not to be opened to others. Even though the results of study are published, your personal information is kept in secret. In addition, photographs taken in study could be used to article, book, periodical publication, report and the broad cast media.

9. Duty of Subject

You should follow the below list to protect yourself and to perform study correctly.

- ① You should keep using the test product and follow examination schedule.
- ② Do not wet or remove the patch while attaching.
- ③ You can clean the test area with water but cannot cleaned with soap or bath salt.
- ④ Do not give any physical irritation, scratching or rubbing on the test area.
- ⑤ Please avoid the exercise that can make you sweat or use both arms aggressively.
- ⑥ Please avoid heavy drinking or exercise before each visit.
- ⑦ Please notify researcher when taking or using medication for physical treatment.

10. Signature

If you want to participate in this study after being informed about this study, please sign on participation agreement sheet.

11. Inquiry

If you want to know more about this study or have any side effects related to this study or need to contact to the chief research and other researchers for medical consultation, you can contact any time to following contact number and consult the person in charge.

	Name	Belongs to	Tel.
Chief Researcher	Beom Joon Kim	Chung-Ang University Hospital Dermatology Department	02-6925-1501
Researcher	Jong Ho Park, Myeong Rae Kim, A Reum Kim, Eun Kyoung Lee, Jin Sol Park, Min Kyeong Lee, Da Som Kim, Su Hyun Lee, Ye Ji Kim, Su Ji Lee, Ra Yeon Park, Eun Ju Lee, Saet Byul Park, Won Kyeong Choi, Ye Jin Park, Ha Young Lee, So Jeong Hong, Ji Hye Park, Min Jeong Yoon, Na Young Lee, So Hyun Pack	P&K Skin Research Center Co., Ltd.	02-6925-1502 02-6925-1503

P&K Skin Research Center Co., Ltd..

Appendix 2.

Informed Consent form

Skin Irritation Test in Human Subjects

I received a satisfactory explanations about study purpose, method, expected effects and side effects, benefits of participation, progress of the study. I received explanations about compensation and treatment when physical, psychological, social and economical damages occur. I also received explanations about collecting personal information by research center from chief researcher or person in charge of the study.

Agreement for collection and use of personal information

Personal Information	Purpose	Duration
Name, Date of birth, Contact number, Address, Photographs with portrait rights	Participation in clinical study, Article, Book, Periodical publication, Report, Broad cast media	5 years from agreement

You have a right to refuse agreement for collection and use of personal information. However, if you disagree with the agreement, you cannot be participated in this clinical study.

Subject: _____ (signature)

I received an explanation that it does not become a problem that I disagree to participate in the study, and I can discontinue at any time even though I agreed to participate the study. I do not have any disadvantage after withdrawal of agreement and personal information will be offered to the third party. All data related to the study will be kept in secret.

Agreement for providing personal information to the third party

Third party	Personal Information	Purpose	Duration
NAEWOIKOREA Co., Ltd.	Name, Date of birth, Contact number, Address, Photographs with portrait rights	Article, Book, Periodical publication, Report, Broad cast media	5 years from agreement

You have a right to refuse agreement for collection and use of personal information. However, if you disagree with the agreement, you cannot be participated in this clinical study.

Subject: _____ (signature)

So, I agree to participate in this clinical study with my own free will.

1. Subject/Representative

Subject: _____ (sign) _____ (Date) _____, _____, _____

Representative: _____ (sign) _____ (Date) _____, _____, _____ (Relationship) _____

Date of birth: _____ year _____ month _____ date (age) Tel: _____

Address: _____

I explained fully about the outline of clinical study and, effectiveness and side effects of products. I answered to questions sincerely. I have a duty to manage this clinical study as a dermatologist, and I also have a duty to discontinue the study immediately if the progress of clinical study adversely affects the health of subject.

2. Researcher/Person in charge of the study

Name: _____ (signature) _____ (Date) _____, _____, _____

P&K Skin Research Center Co., Ltd.

Appendix 3. Subject Information

Subject ID No.	Name	Date of birth	Age	Skin type	Gender
21707-I7-01	KSM	1976-12-13	44	Normal	F
21707-I7-02	KKH	1969-06-27	52	Normal	F
21707-I7-03	KKS	1976-03-28	45	Normal to oily	F
21707-I7-04	KDB	1999-07-29	21	Dry	F
21707-I7-05	JSS	1967-06-25	54	Dry	F
21707-I7-06	LMS	1968-02-28	53	Dry	F
21707-I7-07	LHJ	1978-02-18	43	Dry	F
21707-I7-08	CYB	1995-12-15	25	Normal	F
21707-I7-09	SSA	1999-01-14	22	Dry	F
21707-I7-10	LSH	1971-11-21	49	Dry	F
21707-I7-11	JSH	1995-08-02	25	Dry	F
21707-I7-12	YBY	1981-04-21	40	Dry to normal	F
21707-I7-13	KCY	1991-01-18	30	Dry	F
21707-I7-14	AHJ	1987-01-01	34	Normal	F
21707-I7-15	KDY	1979-02-14	42	Dry	F
21707-I7-16	SSB	1991-01-30	30	Normal	F
21707-I7-17	YSH	1971-03-07	50	Normal	F
21707-I7-18	MYS	1994-03-08	27	Dry	F
21707-I7-19	YKH	1966-01-04	55	Normal	F
21707-I7-20	KIS	1967-12-24	53	Dry to normal	F
21707-I7-21	KEK	1983-11-21	37	Dry to normal	F
21707-I7-22	KHJ	1992-01-27	29	Oily	F
21707-I7-23	CDR	1992-07-19	28	Normal	F
21707-I7-24	SMJ	1996-12-18	24	Dry	F
21707-I7-25	KMK	1974-02-27	47	Dry	F
21707-I7-26	HSJ	1968-10-25	52	Normal	F
21707-I7-27	LEH	1978-04-18	43	Dry to normal	F
21707-I7-28	HHJ	1982-01-12	39	Normal	F
21707-I7-29	ASH	1991-01-25	30	Dry	F
21707-I7-30	SMK	1966-12-11	54	Dry to normal	F
21707-I7-31	SJH	1967-12-16	53	Dry to normal	F
21707-I7-32	KMS	2000-05-08	21	Normal	F

Appendix 4. Subject skin characteristics and skin condition

Subject ID No.	Name	Skin type	Skin characteristics
21707-I7-01	KSM	Normal	None
21707-I7-02	KKH	Normal	None
21707-I7-03	KKS	Normal to oily	None
21707-I7-04	KDB	Dry	None
21707-I7-05	JSS	Dry	None
21707-I7-06	LMS	Dry	None
21707-I7-07	LHJ	Dry	None
21707-I7-08	CYB	Normal	None
21707-I7-09	SSA	Dry	None
21707-I7-10	LSH	Dry	None
21707-I7-11	JSH	Dry	None
21707-I7-12	YBY	Dry to normal	None
21707-I7-13	KCY	Dry	None
21707-I7-14	AHJ	Normal	None
21707-I7-15	KDY	Dry	None
21707-I7-16	SSB	Normal	None
21707-I7-17	YSH	Normal	None
21707-I7-18	MYS	Dry	None
21707-I7-19	YKH	Normal	None
21707-I7-20	KIS	Dry to normal	None
21707-I7-21	KEK	Dry to normal	None
21707-I7-22	KHJ	Oily	None
21707-I7-23	CDR	Normal	None
21707-I7-24	SMJ	Dry	None
21707-I7-25	KMK	Dry	None
21707-I7-26	HSJ	Normal	None
21707-I7-27	LEH	Dry to normal	None
21707-I7-28	HHJ	Normal	None
21707-I7-29	ASH	Dry	None
21707-I7-30	SMK	Dry to normal	None
21707-I7-31	SJH	Dry to normal	None
21707-I7-32	KMS	Normal	None

Appendix 5. Result of visual assessment

Subject ID No.	NWK A-FV	
	1h	24h
21526-I3-01	0	0
21526-I3-02	0	0
21526-I3-03	0	0
21526-I3-04	0	0
21526-I3-05	0	0
21526-I3-06	0	0
21526-I3-07	0	0
21526-I3-08	0	0
21526-I3-09	0	0
21526-I3-10	0	0
21526-I3-11	0	0
21526-I3-12	0	0
21526-I3-13	0	0
21526-I3-14	0	0
21526-I3-15	0	0
21526-I3-16	0	0
21526-I3-17	0	0
21526-I3-18	0	0
21526-I3-19	0	0
21526-I3-20	0	0
21526-I3-21	0	0
21526-I3-22	0	1
21526-I3-23	0	0
21526-I3-24	0	0
21526-I3-25	0	0
21526-I3-26	0	0
21526-I3-27	0	0
21526-I3-28	0	0
21526-I3-29	0	0
21526-I3-30	0	0
21526-I3-31	0	0
21526-I3-32	0	0

Appendix 6. Test product ingredients

- | |
|----------------------------------------------------------------------------------------------------------|
| <ol style="list-style-type: none">1. Cochlearia Armoracia(Horseradish)2. Gelatine |
|----------------------------------------------------------------------------------------------------------|

Researcher Profile

1. Researcher in charge

[Personal data]

Name : Beomjoon Kim, M.D. PhD. and Dermatologist

Present : Head of Professor & Chairman, Department of Dermatology, Chung-Ang University College of Medicine, Seoul, Korea

Tel : +82-2-6299-1525

Fax : +82-2-798-9573

Mobile phone : +82-10-5310-2419

E-mail : beomjoon74@gmail.com

License number : 71628

[Education]

- | | |
|-----------|-------------------------------------------------------------------|
| 2000 | Graduated College of Medicine, Chung-Ang University, Korea |
| 2000-2001 | Internship, Chung-Ang University Hospital, Korea |
| 2001-2005 | Resident, Chung-Ang University Hospital, Korea |
| 2003 | Master of Science, Graduate school of Chung-Ang University, Korea |
| 2007 | Doctorate of Philosophy, Dermatology, Chung-Ang University, Korea |

[Professional Career]

- | | |
|--------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2005-2015 | -Invited reviewer of 'British Journal of Dermatology'
-Reviewer of 'Journal of American Academy of Dermatology'
-Reviewer of 'International Journal of Dermatology' |
| 2007-2015 | -Invited reviewer, Clinical and experimental dermatology, Dermatologic Surgery, Pediatric dermatology |
| 2007-present | -Editorial board, Chung-Ang Journal of Medicine |
| 2009-present | -Editorial board, Annals of Dermatology |
| 2010-present | -Editorial board, Asian Aesthetic Guide |

- 2011-2014 -Clinical specialist of medical equipment, National Institute of Food and Drug Safety Evaluation
- 2011-present -Committee member of Medical Equipment Board, Ministry of Food and Drug Safety Evaluation
- 2012 -Vice president, Aesthetics Asia 2012
- 2012-present -Editorial board, Journal of Cosmetics, Dermatological Sciences and Applications
- 2013-2015 -Committee member of Self-regulatory Boards, Ministry of Food and Drug Safety
- 2013-present -Professor, Department of Dermatology, Chung-Ang University Hospital, Korea
- Editorial board, Dermatology Aspects
- Committee member of Korea Institute of Planning & Evaluation for Technology in Food, Agriculture Forestry and Fisheries
- Project Manager board member, Ministry of Food and Drug Safety
- 2014 -Organizing committee member for 3rd Eastern Asia Dermatology Congress
- 2014-2016 -Review board, Division of Basic Research of Medical and Pharmaceutical Science, National Research Foundation of Korea
- 2014-present -The chief instructor of Dermatology, Chung-Ang University Hospital, Korea
- Educational board, The Korean Academy of Asthma, Allergy and Clinical Immunology
- Editorial board, Plastic and Aesthetic Research
- Editorial board, Allergy Asthma & Respiratory Disease
- Editorial board, International Journal of Dermatology Research and Therapy
- Expert, Central Pharmaceutical Advisory Committee, Ministry of Food and Drug Safety Evaluation
- Advisory panel, National Institute of Food and Drug Safety Evaluation
- 2015-present -Editorial board, Investigative Dermatology and Venereology Research
- Editorial board, Journal of Cosmetology & Trichology

- Specialized examination commissioner, National Court Administration
- 2016-present
 - Editorial board, World Journal of Methodology
 - Director of Biomedical Research Institute, Chung-Ang University Hospital, Korea
 - Professional advisor of Korean Industrial Standards, Ministry of Food and Drug Safety Evaluation
 - Review board of medical device adverse event, Medical Device Information and Technology Assistance Center
 - Editorial board, Journal of Dermatology and Plastic Surgery
 - Editorial board, Source Journal of Investigative Dermatology
 - Editorial board, Journal of the Society of Cosmetic Scientists of Korea
 - Editorial board, Current Updates in Dermatology Research
 - Editorial board, Journal of Case Reports & Imaging
 - Committee member of Policy Advisory Board, Ministry of Food and Drug Safety
 - Committee member of Communication Advisory Board, Ministry of Food and Drug Safety
 - Committee member of Plastic and Aesthetic Research
- 2017
 - Faculty Member of the 1st World Congress of Dermatologic and Aesthetic Surgery and 38th Annual Meeting of the International Society for Dermatologic Surgery (ISDS)
 - International Scientific Committee of the 8th edition of the International Congress of Aesthetic Dermatology (ICAD)
- 2017-present
 - Committee member of Medical Device Revaluation Professional Association, Ministry of Food and Drug Safety
 - Editorial board, Journal of Dermatology & Cosmetology
 - Associate editor, Clinical Dermatology Open Access Journal
 - Editorial board, The Scientific Pages of Surgical Dermatology
 - Editorial board, MDfaculty

- Review Committee, National Institute of Food and Drug Safety Evaluation
- Review board of medical device adverse event, Medical Device Information and Technology Assistance Center
- Editorial board, Allergy Asthma & Respiratory Disease
- 2018 - Course Coordinator of the International Master Course on Aging Science (IMCAS), Asia
- 2018.08~2020.07 -cause-and-effect relationship an investigator, National Institute of Medical Device Safety Information
- 2018-present - Consultant of Health Insurance Dispute Mediation Committee
- Editorial board, Journal of Dermatology Forecast
- 2018.11~2020.10 - Review board of medical device adverse event, National Institute of Medical Device Safety Information

[Awards]

- 2003 -Scholarship, The Korean Society for Investigative Dermatology
- Novartis award, Korean Society for Medical Mycology
- 2006 -Best Paper, Symposium of Korea Information Processing Society
- 2007 -Dr. Paul Janssen Award, Korean Dermatological Association
- International Health Professional of the Year 2007, International Biographical Center, Cambridge, England
- Best Poster, Symposium of Korean Dermatological Association
- 2008 -Scholarship, The American Academy of Dermatology, USA
- 2009 -Academy award, Chung-Ang University, Korea
- 2010 -Outstanding book, ‘Aesthetic Dermatology’, Ministry of Culture, Sports and Tourism, Korea
- 2011 -Chungsan Academic Award, Korean Academy of Asthma, Allergy and Clinical Immunology
- Excellent assessor of R&D projects, National Research Foundation of Korea, Ministry of Educational Science and Technology, Korea

- 2012 - Dong-Ah academy award, Korean Dermatological Association
- Excellent professor of Industrial Academic Cooperation Foundation, Chung-Ang University Industrial Academic Cooperation Foundation, Korea
- 2013 -Academic Contribution Award, Chung-Ang University Hospital, Korea
- Citation of Textbook Compliation Committee of Dermatology 6th edition, Korean Dermatological Association
- BRIC “Korea’s Honorable People” Records
- 2014 -Citation of President, Science and Technology Promotion Merit
- 2015 -Excellent Author of Science and Technology Journal, Korean Federation of Science and Technology Societies
- 2016 -Academic Contribution Award, Chung-Ang University Hospital, Korea
- Public Relation special award, Chung-Ang University Hospital, Korea
- 2017 -Academic Contribution Award, Chung-Ang University Hospital, Korea
- Outstanding research paper award, Chung-Ang University Hospital, Korea
- 2018 -Ming-Chien Kao Award, Laser therapy Journal
- 2018 -BRIC “Korea’s Honorable People” Records
- 2018 -Academic Contribution Award, Chung-Ang University Hospital, Korea
- Outstanding research paper award, Chung-Ang University Hospital, Korea
- 2018 -DAEWOONG, Best Clinical Investigator of NABOTOR[®]

[Societies]

Korean Medical Association, Committee of Public Information (2000 - present)

Korean Dermatological Association (2001 - present)

Committee member of The Korean Society for Investigative Dermatology (2001 - present)

Committee member of The American academy of dermatology (2006 – present)

Committee member of Education, Korean Dermatological Association(2007-2011)

Committee member of Korean Society for Medical Mycology (2009-present)

Reviewer, Annals of Dermatology (2009-present)

Reviewer, Korean journal of Dermatological Association (2009-present)

Committee member of Text compilation, Korean Dermatological Association (2011-2013)

Committee member of Publication, Korean Dermatological Association (2011-present)

Director of the Korean Society of Pigment Cell Research (2011-present)

Committee member of Korean Society Hair Restoration Treatment (2012-present)

Director of the Korean Society for Aesthetic and Dermatologic Surgery (2013-2014)

Committee member of the Korean Atopic Dermatitis Association (2013-present)

Director of the Korean Hair Research Society (2014-present)

Review Board, Division of Basic research of Medical and Pharmaceutical Sciences, National Research Foundation of Korea (2014-2016)

Committee member of External Relations, Korean Dermatological Association (2014-present)

Assistant administrator, Committee of Finance, Korean Dermatological Association (2014-present)

Committee member of Information and Communications, Korean Dermatological Association (2014-present)

Director of planning, Korean Society for Anti-Aging Dermatology (2015-present)

Committee member of Legislation Department, Korean Academy of Asthma, Allergy and Clinical Immunology (2015-present)

Advertisement Director of the Korean Hair Research Society (2016-present)

member of board of directors, The Journal of Skin Barrier Research (2016.10-2018.09)

Director of international relations of Korean Society for Anti-Aging Dermatology (2017-present)

Examination committee member of Korean Dermatological Association (2017-present)

Director's cooperation of The Korean Society for Investigative Dermatology(2017-present)

Information commission of The Korean Society for Investigative Dermatology(2017-presnet)

An advertising executive of The Korean hair Reserch

Committee member of The Korean Society for Skin Barrier Research (2018 - present)

Director of the Korean Hair Research Society (2018.06-2020.05)

Expert, Central Pharmaceutical Advisory Committee, Ministry of Food and Drug Safety

2. Quality assurance

[Personal data]

Name : Jin Hee Shin

Gender : Female

Date of birth : January 03rd, 1977

[Education]

1995.03 ~ 1999.02 Bachelor's degree in Genetic Engineering, Kyung Hee University, Korea

2003.03 ~ 2008.02 Master's degree in Neurology, Graduate school of Medicine, A Jou University, Korea

[Career]

2007. ~ 2012. Senior Researcher/Project manager, Central research institute, GNT pharma Co., Ltd.

2012. ~ 2015. Chief researcher/Researcher professor, Samsung Advanced Institute for Health Sciences & Technology, Samsung Seoul Hospital

2015. ~ 2015. Research instructor, Microbiology class, Graduate school of A Jou University, Korea

2016. ~ Present Chief researcher, P&K Skin Research Center

3. Researcher

[Personal data]

Name : Jong Ho Park

Gender : Male

Date of birth : February 18, 1974

[Education]

1993.03 ~ 1997.02 Bachelor's degree in Food Science and Technology, Dankook University, Korea

2000.08 ~ 2002.08 Master's degree in Food Chemistry, Graduate School of Dankook University, Korea

[Career]

2005. ~ 2010. Head of Research Team, Dawon Food Research Institute.

2012. ~ 2015. Director of Research, Huel Co., Ltd.

2010. ~ 2015 Team leader, Natural Products Research Institute, Daebong LS

2010. ~ 2012 Researcher, P&K Skin Research center
2015. ~ 2017 Professor of Industrial-Academic Cooperation, Dankook University
2017. ~ 2017 Senior Researcher, Joint Equipment Center, Industry-University Cooperation Group
2017. ~ 2019. Principal Researcher, KC Skin Research Center
2020. ~ Present Chief researcher, P&K Skin Research Center

[Personal data]

Name : Myeong Rae Kim

Gender : Male

Date of birth : January 16, 1977

[Education]

1996.03 ~ 2003.02 Bachelor's degree in Life Science, Konkuk University

2003.03 ~ 2005.02 Master's degree in Biomedical Science, Catholic University

[Career]

2006. ~ 2007. Planning Researcher, SK Bioland Co., Ltd.

2007. ~ 2009. Senior Researcher, Dermapro Co., Ltd.

2009. ~ 2019. Senior Researcher, Coway Co., Ltd. Cosmetics Business Division

2021. ~ Present Chief researcher, P&K Skin Research Center

[Personal data]

Name : A Reum Kim

Gender : Female

Date of birth : January 22nd, 1988

[Education]

2006.03 ~ 2011.02 Bachelor's degree in Cosmetic pharmacology, Daegu Haany University

2011.03 ~ 2013.02 Master's degree in Fine Chemistry, Graduate School of Industry, Seoul national university of science and technology

[Career]

2013.04 ~ Present : Researcher, P&K Skin Research center

[Personal data]

Name : Yoon Kim

Gender : Female

Date of birth : April 26, 1989

[Education]

2008.03 ~ 2012.02 Bachelor's degree in Plant and Applied Science, Chung-Ang University

[Career]

2012. ~ 2018. Researcher, Korea Institute of Dermatology

2018. ~ Present. Researcher, P&K Skin Research center

[Personal data]

Name : Jeong Ok Lee

Gender : Female

Date of birth : February 09, 1988

[Education]

2006.03 ~ 2011.02 Bachelor's degree in Chemical & Biological Engineering, Suwon Univeristy

[Career]

2011. ~ 2013. Cosmo 21 Co., Ltd.

2014. ~ 2014. Abbott Korea Co., Ltd.

2015. ~ 2016. B.C.M Co., Ltd.

2016. ~ Present. Researcher, P&K Skin Research center

[Personal data]

Name : Jin Sol Park

Gender : Female

Date of birth : October 07, 1994

[Education]

2013.03 ~ 2017.08 Bachelor's degree in Medical Biotechnology, Soonchunhyang University

[Career]

2018. ~ Present : Researcher, P&K Skin Research center

[Personal data]

Name : Min Kyoung Lee

Gender : Female

Date of birth : October 06, 1995

[Education]

2014.03 ~ 2018.02 Bachelor's degree in Genetic Engineering, Dong-A University

[Career]

2018. ~ Present : Researcher, P&K Skin Research center

[Personal data]

Name: Da Som Kim

Gender: Female

Date of birth: May 09, 1997

[Education]

2016.03 ~ 2018.02 Suwon University of Science and Technology, Department of Beauty Coordination,
Bachelor of Science

[career]

2017.12. ~ Present Researcher at P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Soo Hyun Lee

Gender: Female

Date of birth: February 13, 1998

[Education]

2016.03 ~ 2018.02 Department of Cosmetics, Incheon National University of Arts, Bachelor of
Science

[career]

2018.01. ~ Present Researcher at P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name : Ye Ji Kim

Gender : Female

Date of birth : February 13, 1996

[Education]

2015.03 ~ 2019.02 Bachelor's degree in Medicinal Biosciences, Konkuk University

[Career]

2020. ~ Present : Researcher, P&K Skin Research center

[Personal data]

Name : Su Ji Lee

Gender : Female

Date of birth : February 18, 1997

[Education]

2015.03 ~ 2020.02 Bachelor's degree in Applied Chemistry, Dandong Women's University

[Career]

2020. ~ Present : Researcher, P&K Skin Research center

[Personal data]

Name: Ra Yeon Park

Gender: Female

Date of birth: September 03, 1994

[Education]

2013.03 ~ 2020.02 Konkuk University Convergence Biotechnology, Bachelor of Engineering

[career]

2020.11. ~ Present Researcher at P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Eun Joo Lee

Gender: Female

Date of birth: July 08, 1994

[Education]

2015.01 ~ 2018.05 New York State University Albany Department of Chemistry, Bachelor of Science

2018. 08 ~ 2020. 05 New York State University Albany Department of Analytical Chemistry, Master of Science

[career]

2020.12. ~ Present Researcher at P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Saet Byul Park

Gender: Female

Date of birth: July 18, 1997

[Education]

2016.03 ~ 2020.02 Department of Chemistry, Gyeonggi University, Bachelor of Science

[career]

2021.01 ~ Present Researcher at P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Won Kyung Choi

Gender: Female

Date of birth: February 23, 1996

[Education]

2015.03 ~ 2021.02 Department of Life Science, Chung-Ang University, Bachelor of Science

[career]

2021.01 ~ Present Researcher at P&K Skin Clinical Research Center Co., Ltd.

4. Assistant

[Personal data]

Name: Ye Jin Park

Gender: Female

Date of birth: March 12, 1998

[career]

2019.04. ~ Present Assistant Researcher, P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Ha Young Lee

Gender: Female

Date of birth: July 19, 1999

[career]

2019.11. ~ Present Assistant Researcher, P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: So Jung Hong

Gender: Female

Date of birth: November 30, 1998

[career]

2019.11. ~ Present Assistant Researcher, P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Ji Hye Park

Gender: Female

Date of birth: April 19, 1999

[career]

2020.02. ~ Present Assistant Researcher, P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Min Jung Yoon

Gender: Female

Date of birth: November 26, 1999

[career]

2020.02. ~ Present Assistant Researcher, P&K Skin Clinical Research Center Co., Ltd.

[Personal data]

Name: Na Young Lee

Gender: Female

Date of birth: November 7, 1998

[Education]

2018.03 ~ 2020.02 Incheon National University of the Arts, Cosmetics, Bachelor's degree

[career]

2020.01 ~ 2020.12 Employee of Beauty & Pack Quality Management Team

2021.01 ~ Present Assistant Researcher, P&K Skin Clinical Research Center Co., Ltd.

2019.11. ~ Present Assistant Researcher, P&K Skin Clinical Research Center Co., Ltd.

Accomplishment of Chief Researcher

* 2006~2016 : Ethnical characteristics of the eyelashes : a comparative analysis in Asian and Caucasian females.

Br J Dermatol. 2006;155(6):1170-6 and 321 others.

* Research achievements in the last 3 years

	Title	Journal
1	Botulinum toxin injection for contouring shoulder	J Eur Acad Dermatol Venereol 2017;31(1):46-47
2	Chronic, intractable nodules after filler injection successfully treated with a bipolar radiofrequency device	Dermatol Ther 2017;30(1):e12400:1-2
3	<i>Inhibitory effect of 660-nm LED on melanin synthesis in in vitro and in vivo</i>	Photodermatol Photoimmunol Photomed 2017;33(1):49-57
4	Non-invasive tumescent cryolipolysis using a new 4D handpiece : A comparative study with a porcine model	Skin Res Technol 2017;23(1):79-87
5	Transcutaneous pneumatic injection of glucose solution: a morphometric evaluation of <i>in vivo</i> micropig skin and tissue-mimicking phantom	Skin Res Technol 2017;23(1):88-89
6	Multiple brownish macules on the trunk in a 32-year-old man	J Am Acad Dermatol 2017;76(2):45-46
7	A case of gram negative bacterial folliculitis resistant to conventional acne therapy	J Kor soc acne res 2017;5(1):15-17
8	Hyaluronic acid injection via a pneumatic microjet device to improve forehead wrinkles	J Eur Acad Dermatol Venereol 2017;31(3):164-166
9	Hyaluronic acid filler combined with antioxidants for infraorbital rejuvenation: Report of two cases	Dermatol Ther 2017;30(2):e12448
10	Multiple papular eruptions at insertion site of gold-coated polydioxanone 1 thread	Dermatol Ther 2017;30(2):e12416
11	Impending skin necrosis after dermal filler injection: A “golden time” for first-aid intervention	Dermatol Ther 2017;30(2):e12400
12	Localized and recurrent angioedema of the lips successfully treated with a radiofrequency device	J Clin Invest Dermatol 2017;5(1):1-2
13	Targeting of sebaceous glands to treat acne by micro-insulated needles with radio frequency in a rabbit ear	Lasers Surg Med 2017;49(4):395-401
14	Assessment of equivalence of adipose tissue treatment with a noncontact field RF system delivering 200 w for 30 min and 300 w for 20 min: an <i>in vivo</i> porcine study	Laser ther 2017;26(1):39-52
15	Fixed drug eruption caused by sildenafil citrate	Ann Dermatol 2017;29(2):247-248
16	Improved methods for evaluating pre-clinical and histological effects of subcutaneous fat reduction using high-intensity focused ultrasound in a porcine model	Skin Res Technol 2017;23(2):194-201
17	Effect of isosicotanapartholide isolated from <i>Artemisia princeps Pampanini</i> on IL 33 production and STAT-1 activation in HaCaT keratinocytes	Mol Med Rep 2017;15(5):2681-2688

18	Vibration anesthesia for pain reduction during intralesional steroid injection for keloid treatment	Dermatol Surg 2017;43(5):724-727
19	Pattern analysis of laser-tattoo interactions for picosecond- and nanosecond-domain 1,064-nm neodymium-doped yttrium-aluminum-garnet lasers in tissue-mimicking phantom	Sci Rep 2017;7(1):1533
20	Combination treatment of propranolol, minocycline, and tranexamic acid for effective control of rosacea	Dermatol Ther 2017;30(3):e12349
21	Skin necrosis after filler-associated vascular compromise: successful treatment with topical epidermal growth factor	Int Wound J 2017;14(3):587-588
22	Lower facial rejuvenation using absorbable casting barbed thread	Dermatol surg 2017;43(6):884-887
23	Reduction of early nodules after injection of hyaluronic acid filler	J Am Acad Dermatol 2017;77(1):e5-e6
24	JMJD3 and NF- κ B-dependent activation of Notch1 gene is required for keratinocyte migration during skin wound healing	Sci Rep 2017;7(1):6494
25	The clinical experience and efficacy of radiofrequency device for wrinkle treatment	Lasers Med Sci 2017;32(6):1449-1450
26	Three-dimensional imaging as a novel method of evaluating the longevity of hyaluronic acid fillers in a mouse model	Dermatol surg 2017;43(8):1108-1112
27	Inhibitory effects of Stichopus japonicus extract on melanogenesis of mouse cells via ERK phosphorylation	Mol Med Rep 2017;16(2):1079-1086
28	A fingertip tender papule in an elderly woman	대한피부과학회지 2017;55(7):477-478
29	Collapse of human Skin microbiome network in dandruff and seborrheic dermatitis	Exp Dermatol 2017;26(9):835-838
30	A multicenter, randomized, double-blind clinical study to evaluate the efficacy and safety of a new monophasic hyaluronic acid filler with lidocaine 0.3% in the correction of nasolabial fold	J Cosmet Dermatol 2017;16(3):327-332
31	Correlation between socio-economic status and atopic dermatitis in Korean adults: the Korea national health and nutrition examination survey (2007-2014).	J Eur Acad Dermatol Venereol 2017;31(9):1509-1515
32	Efficacy and safety of a new microneedle patch for skin brightening: a randomized, split-face, single-blind study	J Cosmet Dermatol 2017;16(3):382-387
33	Differences in Hyaluronic Acid Filler Persistence Depending Upon Facial Site: A Consideration of Anatomical Factors.	Dermatol Surg 2017;43(10):1306-1308
34	Topical application of palmitoyl-RGD reduces human facial wrinkle formation in Korean women	Arch Dermatol Res 2017;309(8):665-671
35	Periorbital melasma: hierarchical cluster analysis of clinical features in Asian patients	Skin Res Technol 2017;23(4):552-557
36	Efficacy and safety of non-invasive body tightening with high-intensity focused ultrasound (HIFU)	Skin Res Technol 2017;23(4):558-562

37	Hyaluronic acid microneedle patch for the improvement of crow's feet wrinkles	Dermatol Ther 2017;30:12546
38	The formation of multiple milia induced by pneumatic injector therapy for scar remodeling	J Clin Invest Dermatol 2017;5(2):1-2
39	Successful treatment of smallpox scars by using radiofrequency device with single microneedle	Int Wound J 2017;14(6):1399-1400
40	Tattoo granuloma restricted to red dyes	Ann Dermatol 2017;29(6):824-826
41	The utility of color Doppler ultrasound to explore vascular complications after filler injection	Dermatol Surg 2017;43(12):1508-1510
42	Randomized clinical trial to evaluate the efficacy and safety of combination therapy with short-pulsed 1,064-nm neodymium-doped yttrium aluminium garnet laser and amorolfine nail lacquer for onychomycosis	Ann Dermatol 2017;29(6):699-705
43	Efficacy and safety of a novel picosecond laser using combination of 1064 and 595nm on patients with melasma: A prospective, randomized, multicenter, split-face, 2% hydroquinone cream-controlled clinical trial	Lasers Surg Med 2017;49(10):899-907
44	Ultrasonography-guided curettage of poly-DL-lactic acid filler granulomas	J Am Acad Dermatol 2018;78:e5-6
45	Successful treatment of trichoepithelioma with a novel insulated monopolar radiofrequency microneedle device	Clin Exp dermatol 2018;43(1):108-109
46	α -Viniferin Improves Facial Hyperpigmentation via Accelerating Feedback Termination of cAMP/PKA Signaled Phosphorylation Circuit in Facultative Melanogenesis	Theranostics 2018;8(7):2031-2043
47	A review of hydrolifting: A new modality for skin rejuvenation	J Cosmet Laser Ther 2018;20(1):28-33
48	Investigating skin penetration following needle-free injection combined with fractional laser and subcision	Ann Dermatol 2018;30(1):102-104
49	Protective effects of fermented honeybush (<i>Cyclopia intermedia</i>) extract (HU-018) against skin aging: a randomized, double-blinded, placebo-controlled study	J Cosmet Laser Ther 2018;1:1-6
50	Anti-apoptotic effects of glycosaminoglycans via inhibition of ERK/AP-1 signaling in TNF- α -stimulated human dermal fibroblasts	Int J Mol Med. 201841(5):e3090-e3098
51	Clinical application of botulinum toxin A for calf hypertrophy followed by 3-dimensional computed tomography	Plast Reconstr Surg 2018;6(2):e1071
52	Randomized, patient/evaluator-blinded, intraindividual comparison study to evaluate the efficacy and safety of a novel hyaluronic acid dermal filler in the treatment of nasolabial folds	Dermatol Surg 2018;44(4):542-548
53	Noninvasive size reduction of lipoma with an insulated monopolar radiofrequency microneedle device	Dermatol Ther 2018;31:e12608
54	Prospective randomized study of sexual function in men taking dutasteride for the treatment of androgenetic alopecia	J Dermatol 2018;45(7):799-804
55	Multipolydioxanone scaffold improves upper lip and forehead wrinkles: A 12-month outcome	J Cosmet Dermatol 2018;1-6

56	Physical properties of a novel small-particle hyaluronic acid filler: In vitro, in vivo, and clinical studies	J Cosmet Dermatol 2018;17(3):347-354
57	Topical administration of EGF suppresses immune response and protects skin barrier in DNCB-induced atopic dermatitis in NC/Nga mice	J Cosmet Dermatol 2018;17(3):347-354
58	Fractional CO2 laser treatment for vaginal laxity: A preclinical study	Lasers Surg Med 2018;50:940-947
59	Pregnancy outcomes in patients with vitiligo: A nationwide population-based cohort study from Korea	J Am Acad Dermatol 2018 Nov;79(5):836-842
60	Pulsed-dye laser as a novel therapeutic approach for post-filler bruises	Dermatol Ther 2018;31(6):e12721
61	Effects on skin of Stichopus japonicus viscera extracts detected with saponin including Holothurin A: Down-regulation of melanin synthesis and up-regulation of neocollagenesis mediated by ERK signaling pathway	J Ethnopharmacol 2018;15(226):73-81
62	A pilot study to evaluate the efficacy and safety of treatment with botulinum toxin in patients with recalcitrant and persistent erythematotelangiectatic rosacea	Ann Dermatol 2018;30(6):688-693
63	Antioxidant effect of human placenta hydrolysate against oxidative stress on muscle atrophy	J Cell Physiol 2019;234(2):1643-1658
64	Therapeutic potential of topically administered γ -AlOOH on 2,4-dinitrochlorobenzene-induced atopic dermatitis-like lesions in Balb/c mice	Exp Dermatol 2019;28(2):169-175
65	Factors affecting the psychosocial distress of patients with alopecia areata: A nationwide study in Korea.	J Invest Dermatol 2019;139(3):712-715
66	Effects of Intradermal Radiofrequency Treatment and Intense Pulsed Light Therapy in an Acne-induced Rabbit Ear Model	Sci Rep 2019;9(1):5056
67	A comparison study of prabotulinumtoxinA versus onabotulinumtoxinA in myostatin-deficient mice with muscle hypertrophy	Basic Clin Pharmacol Toxicol 2019;124(4):491-499
68	Effect of high-intensity focused ultrasound on eyebrow lifting in Asians	Ann Dermatol 2019;31(2):223-225