

Report of Clinical Research  
For Whitening Cosmetics of using VC-IP

May, 2002

Client Name : Nikko Chemicals Co., Ltd.

Research Institution : Yonsei Medical University

## Observation list and Test method

### A. Minimal Erythematous Dose (MED) measurement

Examinees are checked a consumed Minimal Erythematous Dose (MED) to cause a visualized rubefaction in 16-24 hours later after having a ultraviolet B test on examinee's back.

The source of ultraviolet rays for the test is used YS UVB-400 which is produced by FS 72 T12-UVB-HO lamp (Elder). The wave length of lamp is 290-325nm, and the maximum wavelength was 301nm and 302nm.

Radiometer is measured the strength of each source of UVB by using IL700 (International Light Inc.) During the test, we increase the quantity of rays in equal ratio from under 25% and at the same time we also make the size of test area of minimum ultraviolet rays over 0.5cm<sup>2</sup>.

6-24 hours after ultraviolet test, plural examinees are showing MED and we decide the quantity of minimum MED by using arithmetic mean from the test result. The quantity of minimum MED of 25 examinees is 25-70J/CM<sup>2</sup> (Average 39.8mJ/CM<sup>2</sup>)

### B. Tanning

The test area of examinee is determined a clean part of inner surface of the forearm.

Perfect square (1X1cm) type of template, which is used for UV outflow patch test, is attached on the inner surface of the forearms of examinees, and we obtain 2 piece of tanned patch by examining of 2MED UV which is double of minimum MED using by UVB Lamp which we used to obtain the minimum MED

Erythema is appeared after 24 hours and pigmentation is occurred after 1-3 days later.

## The basis of Evaluation

### 1) Effect

We determine to check the procedure by every week for 8 weeks with visual assessment, photograph and the M value of mexameter.

-7    0    7    14    21    28    35    42    49    56 days

Cosmetics Spread

Tanning

### **(1) Visual assessment**

2 researchers perform the visual assessment which is to measure the degree of tanned skin with naked eyes and make a record of the degree divided into 4 levels. If some degree of tanned skin is in between levels, they give 0.5 point for each.

The level of visual assessment

0 : Undetectable

1 : mild pigmented

2 : moderated pigmented

3 : highly pigmented

### **(2) The method of recording instrument evaluation**

M value of Mexmeter (Data : appendix)

Researcher obtains M value from each of tanned patch for three times by using Mexmeter(Winateck co.Ltd. Made in Germany). Smaller the M value means whiter in the test.

### **(3) Photograph**

Researcher makes a photograph for every evaluation with a digital camera(Nikon Coolpix 880)

### **The method of Statistical analysis**

Mixed procedure with using SAS system is performed to check the differences between each of whitening effect of cosmetics. Also Repeated measure ANOVA is performed to check the similarity for the total differences of whitening effect by time consuming.

## Result

### 1) The information of examinees

Total 25 people of examinee are participated in the research and there is no left out.

The information of examinee is as follows

#### (1) Age of Examinees

The average age of examinees is 33.2 year old and the oldest is 37 year old and the youngest is 27year old.

Age group(n=25)	frequency	%
20's	4	16.0
30's	21	84.0
40's	0	0.0

#### (2) Types of Skin

Classification(n=25)	frequency	%
Type □	2	8.0
Type □	18	72.0
Type □	5	20.0

### 2) Effect

#### (1) Visual assessment by researcher

P-value record between test group and placebo group by each

Peroid	Sample A (P-value)	Sample B (P-value)
Before – After 4 weeks	< 0.0001	< 0.0001
Before – After 8 weeks	< 0.0001	< 0.0001

P-value record between test group and placebo group by group

Peroid	Comparison between Group(P-value)
Before – After 4 weeks	0.9046
Before – After 8 weeks	0.0471

Each of Sample A(Control) and Sample B(VG-IP) shows statistically significant differences compared to before and after at 4weeks and at 8weeks of using each products samples. Also, we are able to find a statistically significant differences compared to between Sample A(Control) and Sample B(VC-IP) at 8 weeks in test.

## (2) Mexameter Analysis

P-value record between test group and placebo group by each (by instrument analysis)

Peroid	Sample A (P-value)	Sample B (P-value)
Before – After 4 weeks	< 0.0001	< 0.0001
Before – After 8 weeks	< 0.0001	< 0.0001

P-value record between test group and placebo group by group (by instrument analysis)

Peroid	Comparison between Group (P-value)
Before – After 4 weeks	0.7229
Before – After 8 weeks	0.0014

Each of Sample A (Control) and Sample B (VG-IP) shows statistically significant differences compared to before and after at 4 weeks and at 8 weeks of using each products samples. Also, we are able to find a statistically significant differences compared to between Sample A (Control) and Sample B (VC-IP) at 8 weeks in test.

## Conclusion

### 1) Effect

#### (1) Visual assessment by Researcher

The Sample B, which is using Nikkol VGIP 2%, shows statistically significant whitening effect than the whitening effect of comparison Sample A

#### (2) Instrument Analysis

The Sample B, which is using Nikkol VGIP 2%, shows statistically significant whitening effect than the whitening effect of comparison Sample A