

# Clinical Trial Report

GMRC-20928-EA1R

Dareun Cosmetics Co., Ltd.

Clinical study of

Dr. Different VITAACNAL TX Night Cream  
on Suitability for acne skin use &  
Skin keratin improvement effect in Humans

January 15, 2021



# Contents

Authentication.....	3
Quality Assurance Certification.....	4
Facilities & Equipments.....	5
Summary of Clinical Study.....	6
Appendix 1. Measurement Result.....	13
Appendix 2. All ingredients of the test product .....	17



## Authentication

The Global Medical Research Center has been commissioned “Clinical study of Dr. Different VITAACNAL TX Night Cream on Suitability for acne skin use & Skin keratin improvement effect in Humans .” by Dareun Cosmetics Co., Ltd. and evaluated in full accordance with the Standard Operating Procedure (SOP) of Global Medical Research Center, and report the results as follows.



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The Global Medical Research Center Co., Ltd Head of Organization: Whan Cheol Lee

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Principal Investigator: Ji Hee Kim M.D., Ph.D

## Quality Assurance Certification

Title	Clinical study of Dr. Different VITAACNAL TX Night Cream on Suitability for acne skin use & Skin keratin improvement effect in Humans
Protocol identifying number	GMRC-20928-EA1
Study period	2020.09.21 ~ 2020.11.06
Test period	2020.09.28 ~ 2020.10.28

Test Reliability Assurance Check List	Confirmation
1. Were the following basic documents properly achieved? - Research Proposal - Case Report Form(e-CRF) - Written Consent - Contract - Instructions for Participant's Consent	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2. Did the test proceed according to the protocol?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3. Has clinical trial been conducted in accordance with Global Medical Research Center's Standard Operating Procedure (SOP)?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4. Did all Participants sign and written dates on the approved consent?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
5. Have the test results been elicited in accordance with the research ethics and conscience?	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

This test was conducted faithfully under the supervision of the Principal Investigator in accordance with the test protocol and Standard Operating Procedure (SOP) of the Global Medical Research Center and was confirmed by the Quality Assurance Director.

January 15, 2021

Quality Assurance Director/Dermatologist

\_\_\_\_\_  
Chang Wook Park

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Principal Investigator   Ji Hee Kim

## Facilities & Equipments

Facilities	
Wash room & Dry and wet test room Cold and warmth test room & Body test room Wrinkle and whitening test room Skin primary irritation test room Efficacy test room Face photo room Photo room 3D photo room Anti-pollution test room	Doctor's office Archive <sup>2</sup> In vitro test room Tissue culture room Cell culture room Flow cytometry room Microscope room Multipurpose room Dark room
Equipments	
Cutometer dual MPA580 Cutometer Probe(2mm) Ambient Condition Sensor RHT100 Multi Display Device MDD4 Corneometer CM825 Probe Mexameter MX18 Probe Skin pH meter PH905 probe Skin Thermometer ST500 Probe Tewameter TM300 Probe Skin Colorimeter CL400 Probe Glossymeter GL200 Probe Skin Visiometer SV700 USB Visioscan VC98 USB Sebumeter SM815 Moisture Map MM100 Moisture Map Probe Ultrascan applicator Antera3D CS FLIR-E6390 EOS650 Amaran LED lighting Moisturemeter SC Moisturemeter D Ultrascan UC22 InBody720 Mark-Vu Morpheus3D Antipollution chamber SPSS statistics 25 standard Constant Temperature and Humidity system ASW300 D-Squame pressure instrument Folliscope 5.0 Derma Torque Meter Photo Therapy Unit(UVA) Vapometer Spectrophotometer CM-700d Laser doppler PIM3 Exbody 9100 Skin color catch Oral Chroma Indentometer IDM800 Probe	Infrared Ray Irradiator Water bath Pipette Vortex Auto Clave Water apparatus Freezer Refrigerator Fluorescence microscopy Deep freezer Oven Flow cytometry Clean bench Incubator LN2 tank DNA Electrophoresis system Protein Electrophoresis system Microplate reader Thermal cycler Real-Time PCR Nano drop Micro-centrifuge Mini-centrifuge Centrifuge Brightfield microscopy Confocal microscopy Cryostat Microtome Heat-block Shaker pH meter Moisture analyzer Slit Lamp Microscope Ballistometer Translucency Meter Photo Therapy Unit(UVB) Multiport UV Solar Simulator PRIMOS lite Fibra.one Glossmeter DSI-24 Tewameter TM Nano DermaLab Hydration pin probe

## Summary of Clinical Study

<b>Title</b>	Clinical study of Dr. Different VITAACNAL TX Night Cream on Suitability for acne skin use & Skin keratin improvement effect in Humans
<b>Protocol identifying number</b>	GMRC-20928-EA1
<b>Test Organization</b>	Global Medical Research Co., Ltd. Address: 17th floor, 107, Dosan-daero (Sinsa-dong), Gangnam-gu, Seoul
<b>Client</b>	Dareun Cosmetics Co., Ltd. Address: 12th floor, 335, Hakdong-ro, Gangnam-gu, Seoul, Republic of Korea
<b>Study Period</b>	September 21, 2020 ~ November 06, 2020
<b>Test Period</b>	September 28, 2020 ~ October 28, 2020
<b>Person in charge</b>	Hyun Ji Kim Researcher
<b>Test Product</b>	Dr. Different VITAACNAL TX Night Cream
<b>Participant</b>	23 people who were included selection criteria and excluded exclusion criteria (20 Participants completed the test, 3 participants drop out)
<b>Test Methods</b>	The selected 23 participants conducted evaluation of the test product on Suitability for acne skin use & Skin keratin improvement effect in humans. Using the facial area as a test site, the test product should be used once a day for 4 weeks. Instrument measurement and efficacy questionnaire evaluation were conducted before use, 2 weeks after use and 4 weeks after use of the product.
<b>Evaluation Criteria</b>	<ol style="list-style-type: none"> <li>1) Measurement Criteria <ul style="list-style-type: none"> <li>- Visual evaluation by researcher: Number of whitehead and blackhead</li> <li>- Skin sebum measurement: Sebumeter SM815</li> <li>- Skin keratin measurement: Visioscan VC98, D-squame</li> <li>- High resolution photography: Mark-Vu</li> </ul> </li> <li>2) Efficacy questionnaire evaluation: Participative survey evaluation by the feeling of use</li> <li>3) Safety evaluation: Evaluation of adverse effects by the dermatologists and participants</li> </ol>

## Test Results

In this test, the test product was applied 4 weeks for men and women aged between 15 to 40 years old. Through visual evaluation of researcher, skin sebum measurement and skin keratin measurement, the following results were confirmed.

## 1) Visual evaluation of researcher

## 1-1) Whitehead (ea)

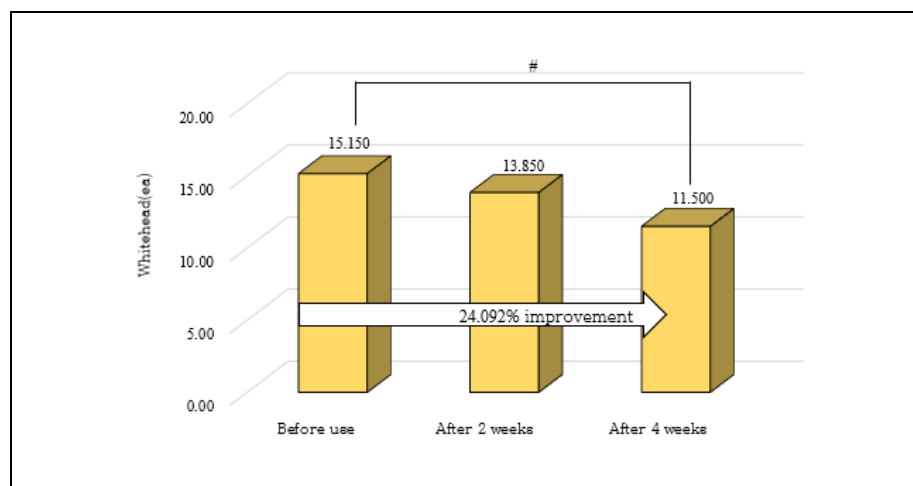
After using the test product, the number of whiteheads decreased to a significant level ( $p < 0.05$ ) after 4 weeks of use compared to before use.

[Table 1], [Figure 1,3]

[Table 1. Visual evaluation of researcher results – Whitehead]

		Before use	After 2 weeks	After 4 weeks
Whitehead (ea)	Mean	15.150	13.850	11.500
	Standard deviation	7.177	7.118	6.022
Rate of change <sup>a</sup> (%)	Before use – After 2 weeks	-8.581		
	Before use – After 4 weeks	-24.092		
Significance (p-value)	Before use – After 2 weeks	0.036		
	Before use – After 4 weeks	<0.001 <sup>#</sup>		

<sup>#</sup> :  $p < 0.025 (=5\%/2)$  by Friedman test, post hoc Wilcoxon signed rank test with Bonferroni correction  
Rate of change<sup>a</sup> :  $\{(Value\ of\ after\ use - Value\ of\ before\ use) / (Value\ of\ before\ use)\} \times 100$



[Figure 1. Visual evaluation of researcher results – Whitehead]

<sup>#</sup> :  $p < 0.025 (=5\%/2)$  by Friedman test, post hoc Wilcoxon signed rank test with Bonferroni correction

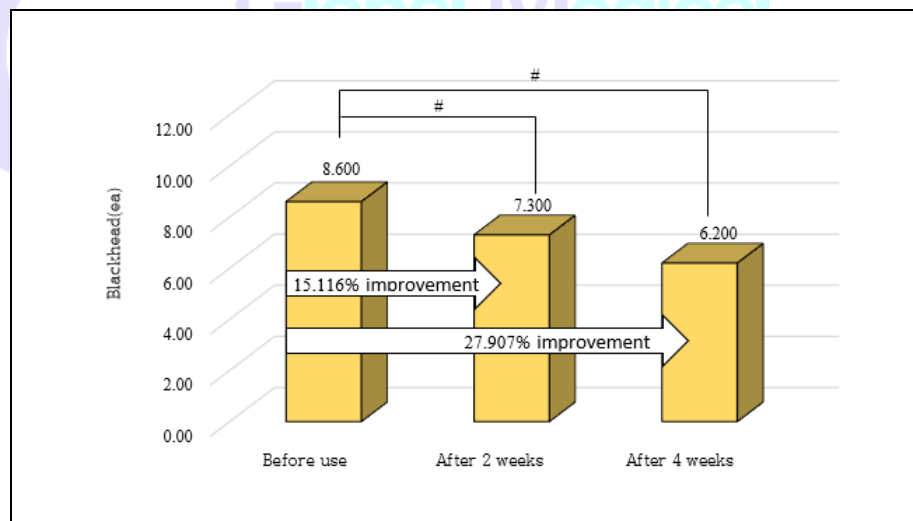
## 1-2) Blackhead (ea)

After using the test product, the number of blackheads decreased to a significant level ( $p < 0.05$ ) after all 2 weeks and 4 weeks of use compared to before use. [Table 2], [Figure 2,3]

[Table 2. Visual evaluation of researcher results – Blackhead]

		Before use	After 2 weeks	After 4 weeks
<b>Blackhead (ea)</b>	<b>Mean</b>	8.600	7.300	6.200
	<b>Standard deviation</b>	5.072	4.402	3.888
<b>Rate of change<sup>a</sup> (%)</b>	<b>Before use – After 2 weeks</b>	-15.116		
	<b>Before use – After 4 weeks</b>	-27.907		
<b>Significance (p-value)</b>	<b>Before use – After 2 weeks</b>	0.001 <sup>#</sup>		
	<b>Before use – After 4 weeks</b>	<0.001 <sup>#</sup>		










<sup>#</sup>:  $p < 0.025 (=5\%/2)$  by Friedman test, post hoc Wilcoxon signed rank test with Bonferroni correction  
Rate of change<sup>a</sup>:  $\{(Value\ of\ after\ use - Value\ of\ before\ use) / (Value\ of\ before\ use)\} \times 100$



[Figure 2. Visual evaluation of researcher results – Blackhead]

<sup>#</sup>:  $p < 0.025 (=5\%/2)$  by Friedman test, post hoc Wilcoxon signed rank test with Bonferroni correction



Participant identification code	Before use	After 2 weeks	After 4 weeks
20928-EA1-S02			
20928-EA1-S06			
20928-EA1-S16			

[Figure 3. High resolution photography]

## 2) Skin sebum measurement ( $\mu\text{g}/\text{cm}^2$ )

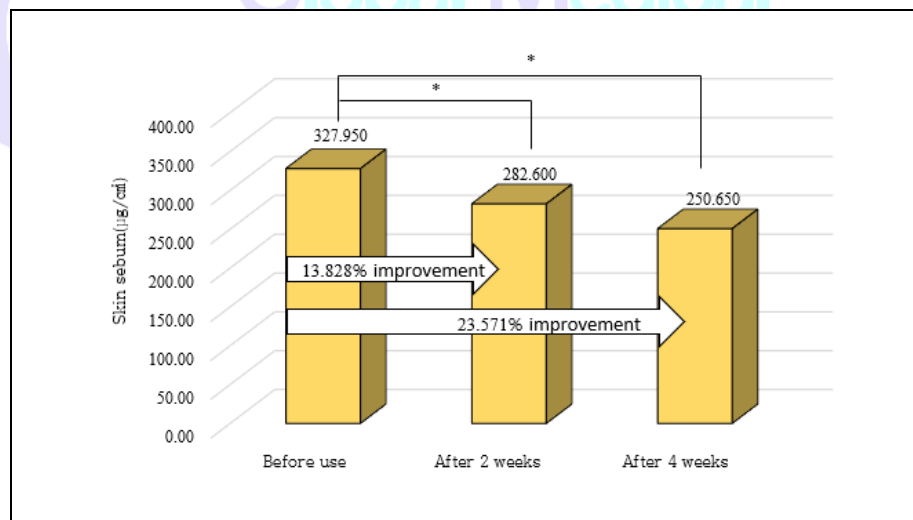
After using the test product, the results of skin sebum measurement decreased to a significant level ( $p < 0.05$ ) after all 2 weeks and 4 weeks of use compared to before use. [Table 3], [Figure 4]

[Table 3. Results of skin sebum measurement]

		Before use	After 2 weeks	After 4 weeks
<b>Skin sebum</b> ( $\mu\text{g}/\text{cm}^2$ )	<b>Mean</b>	327.950	282.600	250.650
	<b>Standard deviation</b>	90.199	99.696	97.263
<b>Rate of change<sup>a</sup></b> (%)	<b>Before use – After 2 weeks</b>	-13.828		
	<b>Before use – After 4 weeks</b>	-23.571		
<b>Significance</b> ( <i>p</i> -value)	<b>Before use – After 2 weeks</b>	<0.001*		
	<b>Before use – After 4 weeks</b>	<0.001*		

\* :  $p < 0.05$  by repeated measures ANOVA, post hoc Bonferroni correction

Rate of change<sup>a</sup>:  $\{( \text{Value of after use} - \text{Value of before use} ) / ( \text{Value of before use} )\} \times 100$



[Figure 4. Results of skin sebum measurement]

\* :  $p < 0.05$  by repeated measures ANOVA, post hoc Bonferroni correction

### 3) Skin keratin measurement (D.I)

After using the test product, the results of skin keratin measurement decreased to a significant level ( $p < 0.05$ ) after all 2 weeks and 4 weeks of use compared to before use. [Table 4], [Figure 5,6]

[Table 4. Results of skin keratin measurement]

		Before use	After 2 weeks	After 4 weeks
<b>Skin keratin (D.I)</b>	<b>Mean</b>	10.990	9.807	8.888
	<b>Standard deviation</b>	1.693	1.102	1.324
<b>Rate of change<sup>a</sup> (%)</b>	<b>Before use – After 2 weeks</b>	-10.764		
	<b>Before use – After 4 weeks</b>	-19.126		
<b>Significance (p-value)</b>	<b>Before use – After 2 weeks</b>	<0.001*		
	<b>Before use – After 4 weeks</b>	<0.001*		

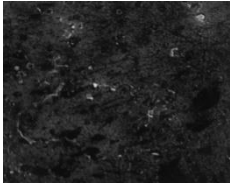
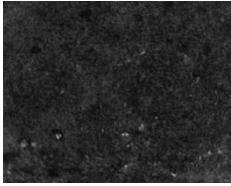
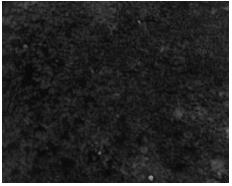
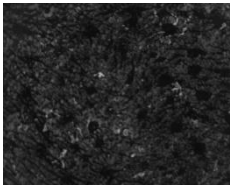
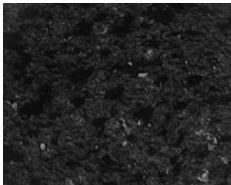

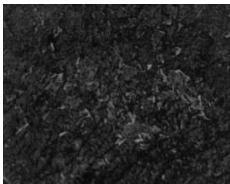
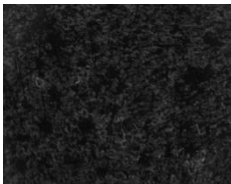
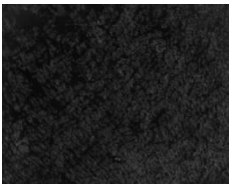
\* :  $p < 0.05$  by repeated measures ANOVA, post hoc Bonferroni correction

Rate of change<sup>a</sup>:  $\{(Value\ of\ after\ use - Value\ of\ before\ use) / (Value\ of\ Before\ use)\} \times 100$



[Figure 5. Results of skin keratin measurement]

4) \* :  $p < 0.05$  by repeated measures ANOVA, post hoc Bonferroni correction

Participant identification code	Before use	After 2 weeks	After 4 weeks
20928-EA1-S05			
20928-EA1-S13			
20928-EA1-S22			

[Figure 6. Skin keratin measurement image]

4) The product is considered to be safe as there were no reports of special adverse effects from the participants while using the test product.

**Therefore, the test product "Dr. Different VITAACNAL TX Night Cream" is considered to improve skin keratin and to be suitability for acne skin use by using 4 weeks.**

## Appendix 1. Measurement Result

### 3-1. Visual evaluation of researcher –Whitehead, ea

Participant identification code	Before use	After 2 weeks	After 4 weeks
20928-EA1-S01	10.000	7.000	6.000
20928-EA1-S02	8.000	6.000	5.000
20928-EA1-S03	25.000	20.000	18.000
20928-EA1-S04	18.000	15.000	13.000
20928-EA1-S05	15.000	18.000	14.000
20928-EA1-S06	12.000	11.000	9.000
20928-EA1-S07	32.000	28.000	24.000
<del>20928-EA1-S08</del>	<del>13.000</del>	N/A	N/A
20928-EA1-S09	8.000	7.000	6.000
<del>20928-EA1-S10</del>	<del>13.000</del>	N/A	N/A
20928-EA1-S11	25.000	31.000	23.000
20928-EA1-S12	15.000	13.000	11.000
20928-EA1-S13	7.000	6.000	5.000
20928-EA1-S14	6.000	8.000	5.000
20928-EA1-S15	6.000	8.000	5.000
20928-EA1-S16	15.000	13.000	10.000
20928-EA1-S17	13.000	10.000	8.000
20928-EA1-S18	17.000	15.000	14.000
20928-EA1-S19	19.000	17.000	15.000
20928-EA1-S20	20.000	18.000	16.000
<del>20928-EA1-S21</del>	<del>7.000</del>	N/A	N/A
20928-EA1-S22	10.000	7.000	6.000
20928-EA1-S23	22.000	19.000	17.000
<b>Mean</b>	<b>15.150</b>	<b>13.850</b>	<b>11.500</b>
<b>Standard deviation</b>	<b>7.177</b>	<b>7.118</b>	<b>6.022</b>

## 3-2. Visual evaluation of researcher – Blackhead, ea

Participant identification code	Before use	After 2 weeks	After 4 weeks
20928-EA1-S01	7.000	5.000	4.000
20928-EA1-S02	5.000	4.000	3.000
20928-EA1-S03	15.000	13.000	13.000
20928-EA1-S04	9.000	8.000	6.000
20928-EA1-S05	9.000	8.000	6.000
20928-EA1-S06	5.000	4.000	2.000
20928-EA1-S07	25.000	20.000	18.000
<del>20928-EA1-S08</del>	<del>5.000</del>	N/A	N/A
20928-EA1-S09	4.000	4.000	4.000
<del>20928-EA1-S10</del>	<del>6.000</del>	N/A	N/A
20928-EA1-S11	13.000	15.000	10.000
20928-EA1-S12	6.000	5.000	5.000
20928-EA1-S13	4.000	4.000	3.000
20928-EA1-S14	3.000	2.000	2.000
20928-EA1-S15	8.000	6.000	5.000
20928-EA1-S16	10.000	8.000	6.000
20928-EA1-S17	10.000	8.000	7.000
20928-EA1-S18	8.000	7.000	6.000
20928-EA1-S19	8.000	7.000	7.000
20928-EA1-S20	5.000	4.000	4.000
<del>20928-EA1-S21</del>	<del>3.000</del>	N/A	N/A
20928-EA1-S22	5.000	4.000	4.000
20928-EA1-S23	13.000	10.000	9.000
<b>Mean</b>	<b>8.600</b>	<b>7.300</b>	<b>6.200</b>
<b>Standard deviation</b>	<b>5.072</b>	<b>4.402</b>	<b>3.888</b>

3-3. Results of Skin sebum measurement,  $\mu\text{g}/\text{cm}^2$ 

Participant identification code	Before use	After 2 weeks	After 4 weeks
20928-EA1-S01	298.000	211.000	176.000
20928-EA1-S02	239.000	199.000	159.000
20928-EA1-S03	339.000	287.000	254.000
20928-EA1-S04	376.000	343.000	339.000
20928-EA1-S05	329.000	301.000	319.000
20928-EA1-S06	220.000	190.000	164.000
20928-EA1-S07	532.000	494.000	404.000
<del>20928-EA1-S08</del>	<del>332.000</del>	N/A	N/A
20928-EA1-S09	407.000	398.000	369.000
<del>20928-EA1-S10</del>	<del>325.000</del>	N/A	N/A
20928-EA1-S11	369.000	346.000	320.000
20928-EA1-S12	435.000	419.000	384.000
20928-EA1-S13	261.000	237.000	105.000
20928-EA1-S14	303.000	277.000	244.000
20928-EA1-S15	126.000	71.000	55.000
20928-EA1-S16	402.000	332.000	279.000
20928-EA1-S17	313.000	164.000	237.000
20928-EA1-S18	232.000	218.000	187.000
20928-EA1-S19	348.000	324.000	284.000
20928-EA1-S20	348.000	289.000	286.000
<del>20928-EA1-S21</del>	<del>301.000</del>	N/A	N/A
20928-EA1-S22	275.000	192.000	131.000
20928-EA1-S23	407.000	360.000	317.000
<b>Mean</b>	<b>327.950</b>	<b>282.600</b>	<b>250.650</b>
<b>Standard deviation</b>	<b>90.199</b>	<b>99.696</b>	<b>97.263</b>

## 3-4. Results of Skin keratin measurement, D.I

Participant identification code	Before use	After 2 weeks	After 4 weeks
20928-EA1-S01	10.530	9.990	9.750
20928-EA1-S02	8.910	8.450	7.590
20928-EA1-S03	11.780	10.170	9.720
20928-EA1-S04	10.640	9.120	8.520
20928-EA1-S05	13.660	10.510	10.350
20928-EA1-S06	9.090	9.230	9.310
20928-EA1-S07	7.160	8.350	9.240
<del>20928-EA1-S08</del>	9.240	NA	NA
20928-EA1-S09	12.530	10.380	6.890
<del>20928-EA1-S10</del>	10.010	NA	NA
20928-EA1-S11	11.260	10.050	8.070
20928-EA1-S12	12.130	10.820	8.880
20928-EA1-S13	11.620	9.280	7.950
20928-EA1-S14	12.460	11.550	11.090
20928-EA1-S15	12.520	11.720	11.300
20928-EA1-S16	9.220	8.860	7.280
20928-EA1-S17	11.570	9.210	8.490
20928-EA1-S18	10.040	10.020	10.010
20928-EA1-S19	11.810	10.400	8.870
20928-EA1-S20	9.480	8.170	7.380
<del>20928-EA1-S21</del>	8.860	NA	NA
20928-EA1-S22	9.850	8.360	6.970
20928-EA1-S23	13.540	11.490	10.090
<b>Mean</b>	<b>10.990</b>	<b>9.807</b>	<b>8.888</b>
<b>Standard deviation</b>	<b>1.693</b>	<b>1.102</b>	<b>1.324</b>



**Appendix 2. All ingredients of the test product**

<b>NO</b>	<b>INGREDIENT NAME</b>
1	Water
2	Glycerin
3	Brassica Campestris (Rapeseed) Sterols
4	Cholesterol
5	Phytosteryl/Behenyl/Octyldodecyl Lauroyl Glutamate
6	Microcrystalline Cellulose
7	1,2-Hexanediol
8	Polyglyceryl-10 Oleate
9	Sodium Hyaluronate
10	Hydrogenated Lecithin
11	Polyglutamic Acid
12	Ceramide NP
13	Retinal
14	Capryloyl Salicylic Acid
15	Stearic Acid
16	Oleic Acid
17	Tocopherol
18	Adenosine
19	Disodium EDTA