

**FANC**  
[Lot No.: UT359M]  
**On the In vivo Human Skin Irritation Evaluation of  
0.10  $\mu$ M FANC**  
**FINAL REPORT**

**Client: GOLDRED NANOBIOTECH CO., LTD.**

**Testing Institution: SGS TAIWAN LTD.**

**Report No.: UB/2016/A1188A-01**

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  4. The amended final report states that it replaces the original version UB/2016/A1188. The amendment will take effect since being signed form study director



## TABLE OF CONTENTS

<b>ADDRESS INFORMATION .....</b>	<b>3</b>
<b>INFORMATION FOR TEST ARTICLE.....</b>	<b>4</b>
<b>SIGNATURE OF STUDY PERSONNEL .....</b>	<b>5</b>
<b>PROCEDURE .....</b>	<b>8</b>
<b>RESULTS .....</b>	<b>9</b>
<b>REFERENCES .....</b>	<b>14</b>
<b>APPENDIX.....</b>	<b>15</b>



## ADDRESS INFORMATION

### Testing Institution

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**Name:** National Tainan Junior College of Nursing

**Address:** 78, Sec. 2, Minzu Rd., Tainan City 700, Taiwan, R.O.C.

### Client / Sponsor

**Name:** GOLDRED NANOBIOTECH CO., LTD.

**Address:** 2F., No.68-1, Jilin Rd., Zhongli District, Taoyuan City 32062, Taiwan(R.O.C.)

## INFORMATION FOR TEST ARTICLE

### 台灣檢驗科技股份有限公司

#### 客戶資料與成分資料表

公司名稱/Sponsor company : 紅嬰生物科技股份有限公司  
 公司地址/Sponsor address : 桃園縣中壢市文化里21鄰吉林路68-1號2樓  
 測試件名稱/Name of test article : 亮金圍顏(FANC)  
 包裝/Package : 2mL  
 測試件外觀型態/External features : 液狀liquid  
 顏色/color : 金黃色

主要成分/Major components :

Example	Ingredient Name(成分名)	CAS or CI Number	%
1	Formaldehyde 亮金圍顏(FANC)	50-00-0 NA	5.00% 132.2uM
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			

客戶簽章/日期 Sponsor signature/ date : \_\_\_\_\_



※ 上述所有資料是由客戶揭露並負責, 且確定所提供的檢品是國內所允許製售化粧品, 其配方及其濃度均合乎國內化粧品標準。(Above all information is disclosed by the sponsor. In addition, provided samples are allowed by domestic selling cosmetics. The formulation and concentration are all allowed in domestic cosmetic regulation.)



**SIGNATURE OF STUDY PERSONNEL**

**On the In vivo Human Skin Irritation Evaluation of 0.10  $\mu$ M FANC  
FANC**

Study Director:

\_\_\_\_\_  
Howard Kao / SGS Taiwan Ltd.

\_\_\_\_\_  
Date

Facility Manager:

\_\_\_\_\_  
Yuanmin Wen / SGS Taiwan Ltd.

\_\_\_\_\_  
Date

**Study Duration:** 2016.10.25~2017.01.23

**Sample Photo:**



**Test Sample Handling:**

According to client's request, test sample was prepared from 132.2 $\mu$ M FANC Solution, Formula as list in following table :

Ingredients \ Formula	0.10 $\mu$ M FANC Solution
132.2 $\mu$ M FANC Solution	0.0757 %
Water	99.9243 %

### Panel Demographics

Number of subjects enrolled	20
Number of subjects completing study	20
Age Range	18-24
Sex	Male.....0 Female..... 20

### Panel Composition:

20 Asian healthy subjects over the age of 18-24 years were recruited for this study. The panel consisted of fair-skin individuals with Fitzpatrick Type II, III and IV. Subjects who will read, understand an informed consent document relating to the specific type of study they are subscribing. Subjects free of any dermatological or systemic disorder which would interfere with the results, at the discretion of the investigator. Skin responses will be evaluated by a Mexameter® MX 18 and visual scoring of an investigator.

### Biophysical Instruments & Evaluation of Responses

Evaluation methods	Marketing Claims	Instruments
Single-application under 24-hour occlusive patch test (Forearm)	<i>No Irritation, For sensitive skin</i>	CK Mexameter® MX 18

Mexameter® MX 18 (Courage + Khazaka, Germany) is used to objectively quantify changes in melanin and erythema levels. Erythema is measured at red 660 nm (for hemoglobin) and green 568 nm to avoid other color influences. The higher the values are the grater the amount of erythema is present.

## PROCEDURE

The products are applied at the skin of the infra-scapular regions of the volar surface of the forearms, which will be placed on a 3 cm x 3 cm patch. The subject is dismissed with instructions not to wet or expose the test area to direct sunlight. The subject will remove the patches approximately 24 hours after application. Skin responses will be evaluated 24 hours and 48 hours after removal of the patch by a Mexameter® MX 18 and visual scoring of an investigator.



## RESULTS

The human eye is very sensitive to the distinction of color viewed side by side. But, as soon as they meet the eye separately, differences can often not be detected. Mexameter is based on absorption and reflection. The probe emits 3 specific light wavelengths, and a receiver measures the light reflected by the skin. For the Erythema measurement corresponding to the spectral absorption peak of hemoglobin, the results are immediately shown as index numbers.

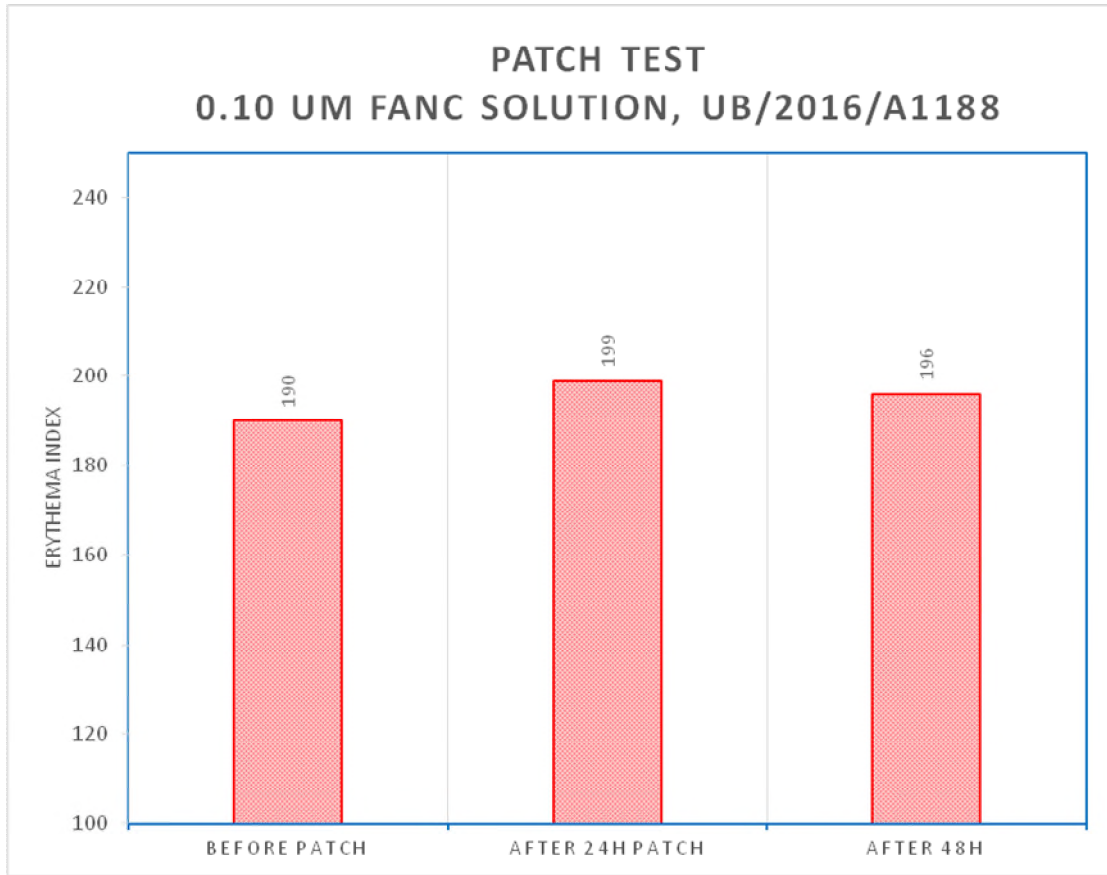
### 1. Erythema Index Determination before and after patch.

Subject ID #	Before Patch	After 24h Patch	After 48h Patch
A01	223	241	234
A02	152	185	152
A03	139	145	122
A04	163	174	166
A05	189	210	208
A06	192	196	204
A07	212	210	212
A08	220	214	221
A09	196	200	203
A10	214	215	210
A11	200	198	215
A12	204	210	212
A13	175	204	186
A14	147	142	162

A15	121	138	142
A16	224	237	234
A17	198	205	189
A18	232	240	232
A19	220	224	221
A20	179	195	193
<b>Mean</b>	190	199	196
<b>SD</b>	32	30	32
<b>RSD</b>	17%	15%	16%
Spooled	Baseline	30.8445	31.7481
t-value	Baseline	0.9381	0.5877
Probability	Baseline	0.3541	0.5602
Sig. Diff.	Baseline	<b>No</b>	<b>No</b>

Erythema Index measured at the forearm at three check points.

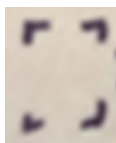




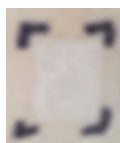
(mean values ± SD are given)

	Mean	SD	t-value	Probability	Sig. Diff.
<b>Before Patch</b>	<b>190</b>	<b>32</b>	Baseline	Baseline	Baseline
<b>After 24h Patch</b>	<b>199</b>	<b>30</b>	0.9381	0.3541	<b>N.S.</b>
<b>After 48h</b>	<b>196</b>	<b>32</b>	0.5877	0.5602	<b>N.S.</b>

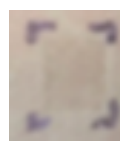
## 2. Visual assessment of skin compatibility



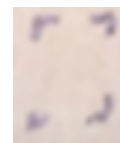
Before patch



Apply patch



After 24hrs patch



After 48hrs

### Score of Skin Reaction

Skin Reaction Check point \ Score	ERYTHEMA						DRYNESS (SCALING)					OEDEMA	
	0	0.5	1	2	3	4	0	0.5	1	2	3	-	+
<b>After 24h Patch</b>	18/20	2/20	0/20	0/20	0/20	0/20	20/20	0/20	0/20	0/20	0/20	20/20	0/20
<b>After 48 h</b>	18/20	2/20	0/20	0/20	0/20	0/20	20/20	0/20	0/20	0/20	0/20	20/20	0/20

### 3. Adverse effect

Subject ID #	After 24h Patch	After 48h
A01	None	None
A02	None	None
A03	None	None
A04	None	None
A05	None	None
A06	None	None
A07	None	None
A08	None	None
A09	None	None
A10	None	None
A11	None	None
A12	None	None
A13	None	None
A14	None	None
A15	None	None
A16	None	None
A17	None	None
A18	None	None
A19	None	None
A20	None	None

**Result:**

In our study, Erythema Index measured at the forearm at baseline and after 24 hours test product occlusive patch condition. No significant difference between the sites treated with the baseline, and also no significant differences were observed clinically in edema, erythema and scaling. Based on the study results the claim “*No Irritation*” and “*For sensitive skin*” for test product is substantiated.

## REFERENCES

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## APPENDIX

### Scoring Scale (Colipa 1997)

#### ERYTHEMA

- 0 = no evidence of erythema
- 0.5 = minimal or doubtful erythema
- 1 = slight redness, spotty and diffuse
- 2 = moderate, uniform redness
- 3 = strong uniform redness
- 4 = fiery redness

#### DRYNESS (SCALING)

- 0 = no evidence of scaling
- 0.5 = dry without scaling; appears smooth and taut
- 1 = fine/mild scaling
- 2 = moderate scaling
- 3 = severe scaling with large flakes

#### OEDEMA

- = absence of oedema
- + = presence of oedema