The efficacy and safety of a type of Biotec Essence Lipstick on Chinese female lip skin

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1. Introduction

The face and most areas of the skin are protected by a sebum film[1], whereas the lips lack this natural barrier[2]. After removing makeup such as lipstick, lips tend to become dry, cracked, and prone to peeling. Thin stratum corneum and low moisture content, which is the direct reason leading to dry and rough lips[3].It also suggests that the signs of aging of the lips (fine lines, texture) increase with age [4]. Lip prints, as one of the dermatoglyphics, have been used as genetic markers in many congenital and clinical diseases. Very few studies have been conducted in the North Indian population with a large sample size [5] [6].

The Biolip Essence Lipstick is an innovative lip product that integrates the cosmetic effects of lipstick with the nourishing benefits of lip essence and the protective functions of a lip mask. Utilizing its patented Biolip technology - a pomegranate peptide complex combined with the proprietary biomimetic membrane ingredient L311 - this product forms a protective biomimetic lip sebum membrane upon application. While delivering vibrant color, it actively strengthens the lip barrier, defends against external irritants, and soothes delicate lip tissue. The patented dynamic cold-temperature extraction process preserves 46 active molecules from pomegranate extracts, which synergize with signaling peptides to effectively repair epithelial cells and stimulate collagen synthesis.

This is a single center, 14 days duration, before and after comparison clinical trial to evaluated the product's moisturizing, repairing, anti-wrinkle and nourishing efficacy, while also assessing the safety and tolerance by assessing changes in lip skin parameters before and after using the biotec essence lipstick.

2. Materials and Methods

2.1 Study Population

Chinese female subjects who meet the key eligibility criteria:

- Healthy female aged from 25 to 40, could be extended to 18-45 years old depends on the recruitment;

- Subjects' self-assessment of lip skin as sensitive skin and be included through a questionnaire;

- Subjects exhibit visible lip dryness, flaking/scaling, and lip lines;

- Lips show dullness in skin tone and lack of radiance;

- Baseline of lip skin stratum corneum hydration less than 45 C.U.;

General inclusion criteria:

- No obvious skin lesions, scars, or hair growth in the test area.

- No medical aesthetics (e.g., laser treatments or chemical peels) performed.

- Be able to follow the requirements of the evaluation protocol and keep regular life habit during the evaluation period;

- Capable of reading and understanding all contents of the informed consent form, and sign voluntarily;

General exclusion criteria:

- Pregnant or lactating women, or those planning for pregnancy in the near future;

- Individuals with current skin diseases, or those who have used oral or topical corticosteroids, other anti-inflammatory medications within the past 1 month, or those who participated in other clinical trials involving the test area within the past 3 months;

- Individuals who used antihistamines within the past week, or immunosuppressants, immunomodulatory biologics, or small molecule drugs within the past month;

- Individuals with insulin-dependent diabetes mellitus, or with severe systemic health conditions (e.g., cancer), or with immunodeficiency or autoimmune diseases;

- Individuals with a highly sensitive constitution, or asthma or chronic respiratory diseases undergoing active treatment;

- Subjects concurrently participating in any other clinical studies, or other unsuitable situation assessed by the investigator(s).

2.2 Sample Size

Sufficient subjects will be enrolled to ensure at least 30 of them complete the study. Additional 10 to 20% of subjects will be enrolled, considering the possibility of dropouts during the study due to various reasons.

Subjects should sign and fully understand all contents of the informed consent form which approved by the IEC approval No.(2023) 383.

2.3 Investigational Product, Dose And Method Of Application

Investigational Product: Biotec Essence Lipstick;

Dose: 3 times per day, 14days;

Method of application: Apply evenly to the whole lips. For daytime use, reapply as needed (such as after meals). During the testing period, subjects need to replace their regular lipstick with the Investigational Product.

2.4 Instruments and Methodology

2.4.1 Corneometer® CM 825 (Courage Khazaka, Germany)

Corneometer measurement will be done on lower-lip. Average of 3 consecutive valid measurements will be calculated. Standard Deviation among 3 results should <±10% average of 3 results.

2.4.2 VapoMeter SWL5201 (Delfin, Finland)

VapoMeter measurement will be done on lower-lip.

2.4.3 Glossmeter GL200 (Courage Khazaka, Germany)

Glossmeter measurement will be done on lower-lip. Average of 3 consecutive valid measurements will be calculated. Standard Deviation among 3 results should <±10% average of 3 results.

2.4.4 PRIMOS-CR (Canfield Scientific, USA)

PRIMOS images will be taken on lips (upper and lower lip). Images will be analyzed at each time points to compare with baseline for anti-wrinkle assessment from the amount, length, area and volume of the wrinkles.

2.4.5 Clinical Grading

Efficacy Grading: The skin profile of all eligible subjects will be assessed by the dermatologist on test area with 10 (0-9) score scale at different timepoints.

For efficacy evaluation at Baseline/ Day1 /Day7 /Day14, the evaluation items include: Dryness; Overall Smoothness; Overall Radiance; Dry lines; Softness; Lip tone (Rosy) ; Lip wrinkle (Type I, I', II, III, IV) from the amount, length and depth.

Tolerance Grading: The dermatologist will assess the tolerance effect with 4 (0-3) score scale. The evaluation items include erythema, edema, desquamation, papule, sting, itching and burning on test area.

2.5 Statistical Method

Appropriate software must be used for data management and statistical calculations. The software should have been used extensively for clinical trials (e.g., SPSS Statistics).

The following descriptive statistics will be presented for each time point:

• Demographic description (Tolerance part included);

• Instrument measurements: Mean (X), Standard Deviation (SD), Minimum (Min) and Maximum (Max), percentage difference relative to BL;

• Clinical grading: Percentage difference relative to BL(baseline value);

Hypothesis test:

Comparison between time points: all parameters describing overall skin condition including clinical evaluation, instruments, and image analysis between Day1, Day7, Day14 vs. BL.

Standard Normality and Equality of Variance Tests will be performed for each parameter of instrumental readings to determine whether data are parametric and/or non-parametric.

Paired T-test (for parametric data) or Paired Wilcoxon Test (for non-parametric data) will be performed for each parameter to determine difference of readings between time points vs baseline. All hypothesis tests will be two-side tests with the significance level (alpha) of 5%.

3. Results

3.1 Skin Hydration

Determination of skin hydration with Courage+Khazaka Corneometer® CM825. The higher the measured value, the higher the skin hydration content.

Table 1. the mean value and change rate of Skin Hydration on the lower-lip measured at different time points

Time Point	Baseline	Day1	Day7	Day14
Mean	46.35	50.37	50.86	57.67
SD	13.39	15.27	12.12	16.70
Min	23.57	20.20	18.73	19.93
Max	77.40	86.03	70.67	96.90
Chage rate(%)	/	8.66	9.74	*24.43**

Remark: "*" means significant difference comparing with Baseline (p value<0.050).
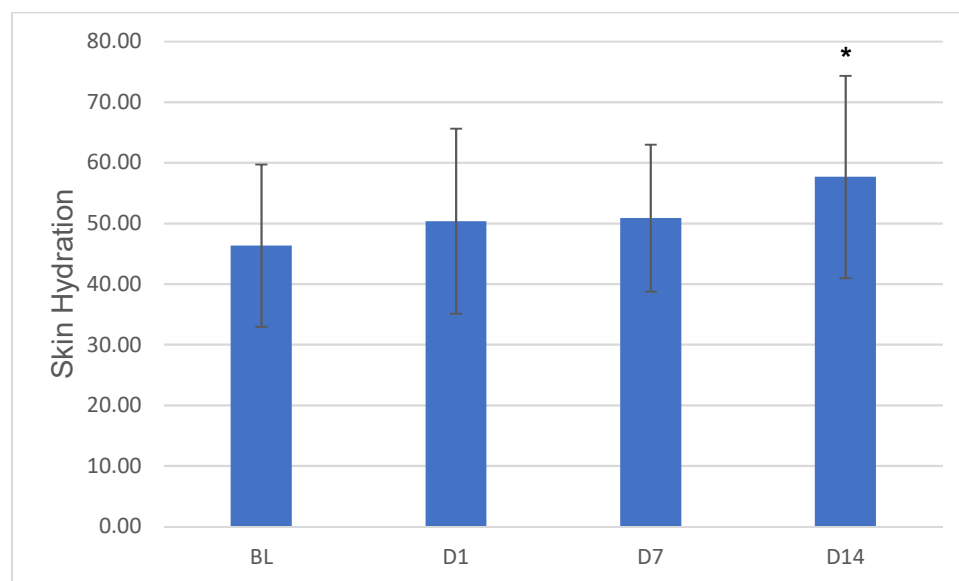

Figure 1. the mean value of Skin Hydration (Unit: C.U.)

3.2 Trans-epidermal Water Loss

Determination of Trans-epidermal Water Loss with Delfin VapoMeter SWL5201. The smaller the measured value, the less the water loss per unit time and per unit cross-sectional area is.

Table 2. the mean value and change rate of Trans-epidermal Water Loss on the lower-lip measured at different time points

Time Point	Baseline	Day1	Day7	Day14
Mean	17.86	14.12	13.88	12.59
SD	5.86	2.96	1.90	2.03
Min	11.10	9.70	9.90	8.70
Max	28.90	22.70	17.30	17.40
Chage rate(%)	/	*-20.95**	*-22.29**	*-29.50**

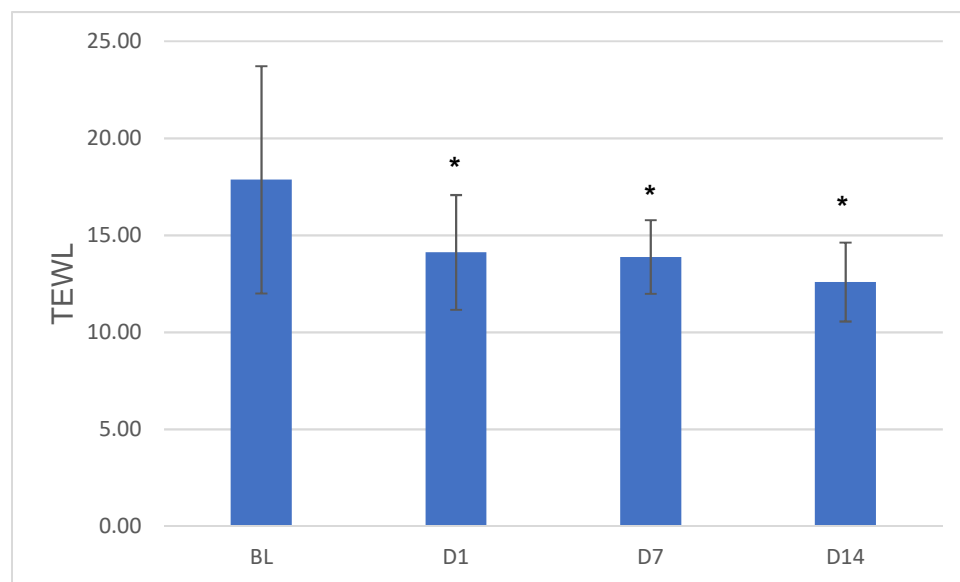Remark: "*" means significant difference comparing with Baseline (p value<0.050).

Figure 2. the mean value of Trans-epidermal Water Loss (Unit: g/m^2/h)

3.3 Skin Gloss

Determination of skin gloss with Courage+Khazaka Glossmeter GL200. The higher the measured value, the better the skin gloss is.

Table 3. the mean value and change rate of Skin Gloss on the lower-lip measured at different time points

Time Point	Baseline	Day1	Day7	Day14
Mean	4.12	4.18	4.16	4.63
SD	1.14	0.88	0.79	0.91
Min	2.23	2.60	2.29	3.39
Max	7.91	6.86	5.83	8.25
Chage rate(%)	/	1.51	0.95	*12.27**

Remark: "*" means significant difference comparing with Baseline (p value<0.050).
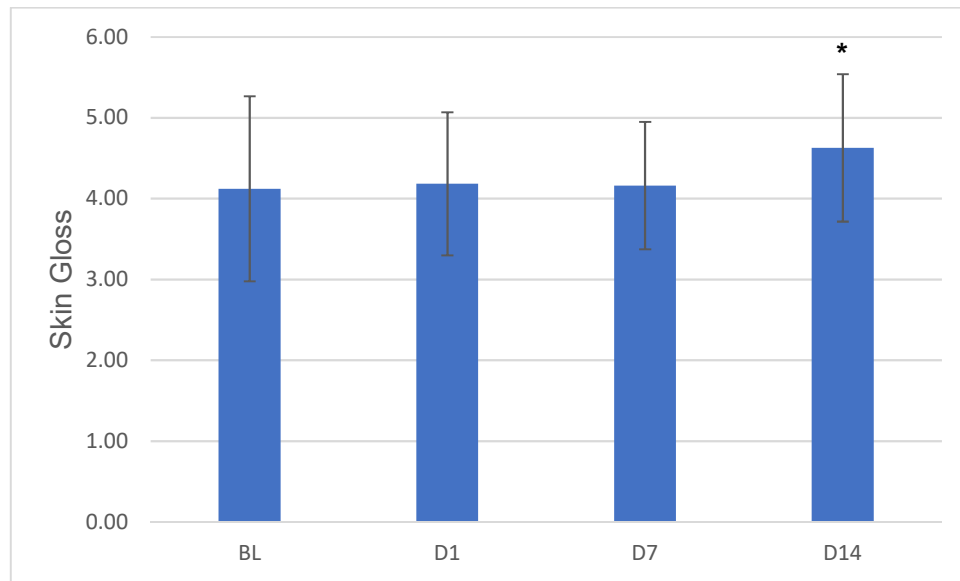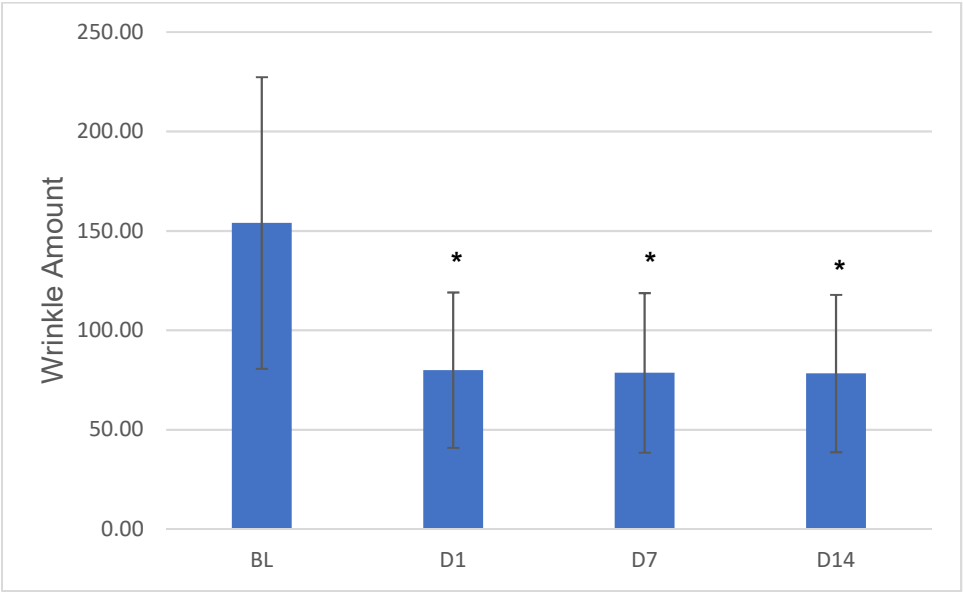

Figure 3. the mean value of Skin gloss

3.4 Skin Wrinkle

Collection and image analysis of the amount, length, volume and area of skin wrinkles with Canfield Scientific Primos-CR. The smaller the analyzed value, the less the number of skin wrinkles feature count.
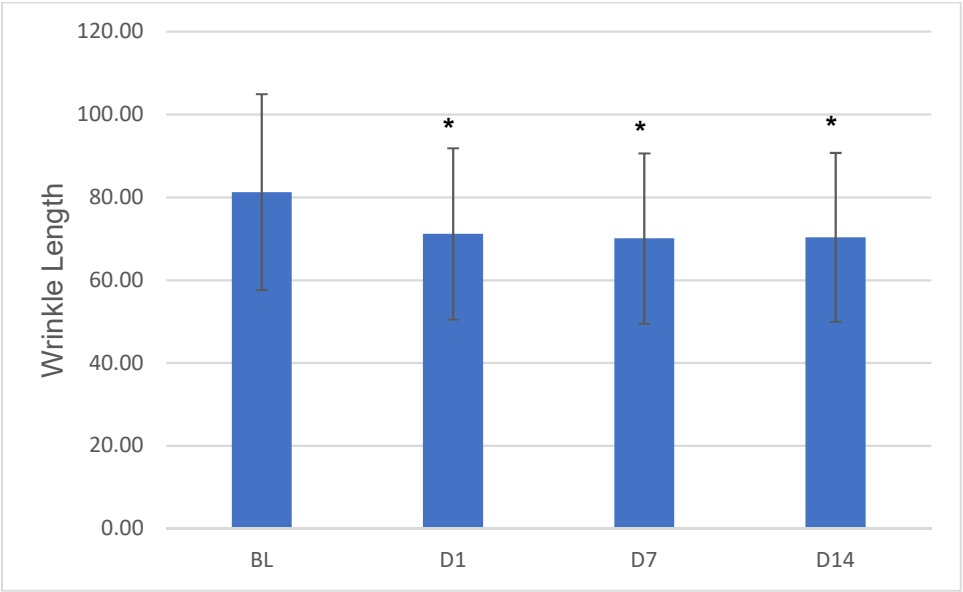
Table 4. the mean value and change rate of amount, length, volume and area of Skin wrinkles on the lip analyzed at different time points

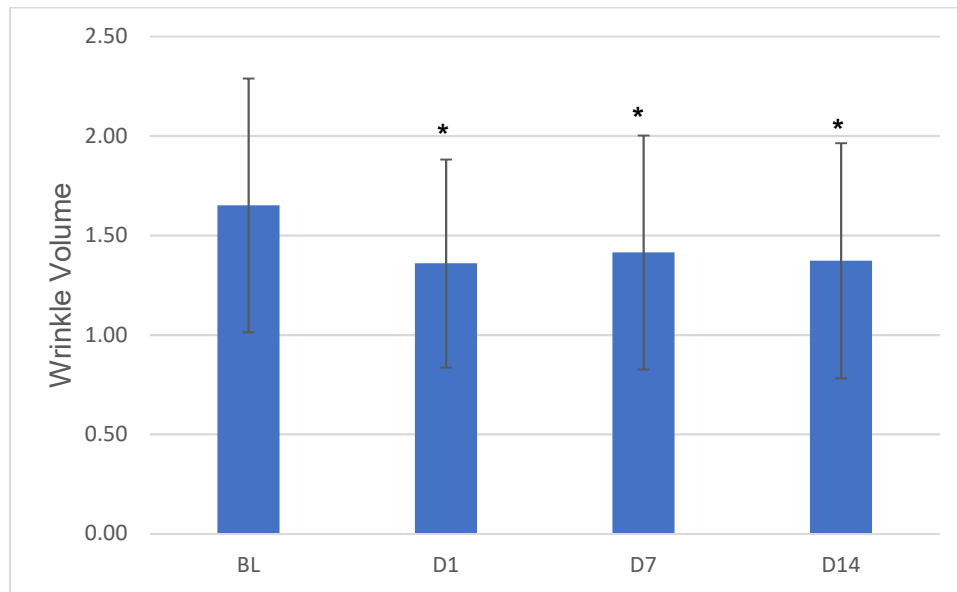| Item	Time Point	Baseline	Day1	Day7	Day14
Amount	Mean	153.94	79.91	78.58	78.24
	SD	73.32	39.10	40.14	39.54
	Min	47.00	21.00	19.00	18.00
	Max	393.00	201.00	212.00	212.00
	Chage rate(%)	/	*-48.09**	*-48.96**	*-49.17**
Length	Mean	81.24	71.18	70.06	70.33
	SD	23.65	20.66	20.54	20.39
	Min	32.00	33.00	30.00	28.00
	Max	127.00	108.00	110.00	111.00
	Chage rate(%)	/	*-12.38**	*-13.76**	*-13.43**
Volume	Mean	1.65	1.36	1.41	1.37
	SD	0.64	0.52	0.59	0.59
	Min	0.69	0.40	0.54	0.42
	Max	3.02	2.65	2.92	2.69
	Chage rate(%)	/	*-17.70**	*-14.38**	*-16.88**
Area	Mean	29.16	25.57	25.30	25.42
	SD	8.03	7.33	7.20	7.00
	Min	13.11	11.58	11.17	10.75
	Max	44.50	41.35	42.11	40.46
	Chage rate(%)	/	*-12.29**	*-13.22**	*-12.81**

Remark: "*" means significant difference comparing with Baseline (p value<0.050).
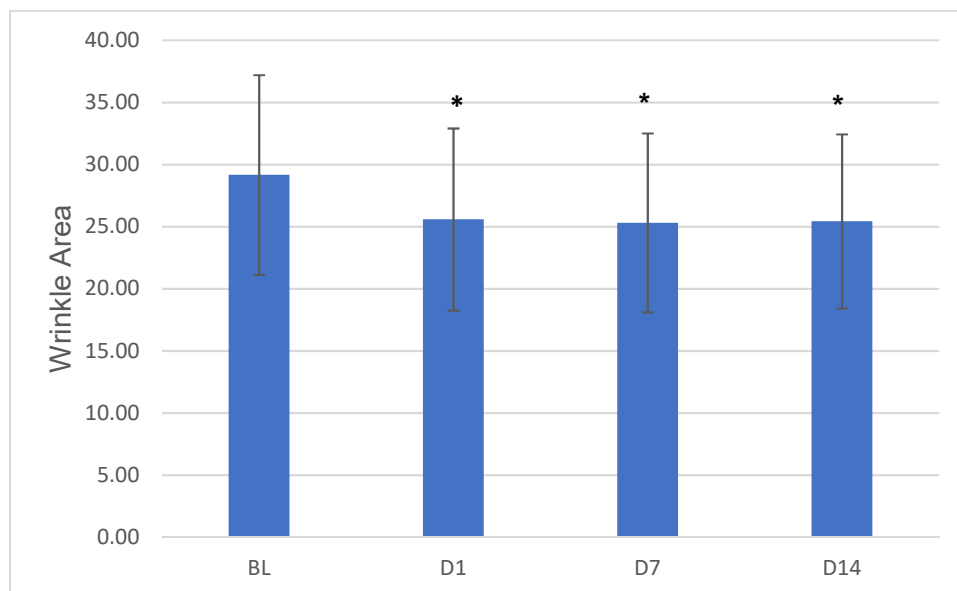

(a)

(b)

(c)

(d)

Figure 4. the mean value of amount(a), length(b), volume(c) and area(d) of Skin wrinkles

3.5 Clinical Grading

The lip skin profile was assessed by the dermatologist on test area with 10 (0-9) score scale at different timepoints.

Table 5. Clinical grading results of Efficacy - change rate of Lip wrinkle (Type I, I', II, III, IV) on the amount, length and depth

Type	Item	Day1	Day7	Day14
Type I (Complete straight)	Amount	*-8.33**	*-12.50**	*-15.83**
	Length	*-7.50**	*-12.50**	*-17.50**
	Depth	*-7.50**	*-24.17**	*-30.00**

Type I' (Partial straight)	Amount	*-6.15**	*-10.00**	*-13.85**
	Length	*-6.15**	*-10.00**	*-14.62**
	Depth	*-6.87**	*-22.14**	*-25.95**
Type II (Branched groove)	Amount	-0.83	-4.97	*-9.95**
	Length	-0.83	-4.97	*-9.95**
	Depth	-0.83	*-13.26**	*-19.90**
Type III (Intersected groove)	Amount	-4.45	*-8.90**	*-9.79**
	Length	-4.45	*-8.90**	*-10.68**
	Depth	-4.45	*-10.68**	*-17.79**
Type IV (Reticular pattern)	Amount	-0.95	-5.70	*-17.11**
	Length	-9.82	*-14.29**	*-25.00**
	Depth	-1.88	*-10.36**	*-21.65**

Remark: "*" means significant difference comparing with Baseline (p value<0.050).

4. Discussion

In this study, we innovatively introduced the concept of lip line subtypes—a human biological characteristic—into cosmetic efficacy evaluation systems. Through clinical assessment, it quantified lip lines by precisely categorizing into Type I (Complete straight), Type I' (Partial straight), Type II (Branched groove), Type III (Intersected groove), and Type IV (reticular pattern), while evaluating the improvement throughout the testing period.

In the future, we maybe could leverage images capture and analytical technologies to precisely enable automated identification and quantification of lip line subtypes, thereby minimizing reliance on dermatologists as subjective assessment method, enhancing evaluation efficiency, and reducing the impact of subjective judgement.

Furthely, the lip wrinkles subtype information will be investigated deeply in different angles, such as age, living habits, external circumstance impact, UV impact. It will strongly help to understand the lip wirnkles mechanism and the development of skin care and make up cosmetics.

5. Conclusion

In this study, 33 Asian adult female subjects with sensitive lip skin were enrolled , who used the investigational product (A type of Biotec Essence Lipstick) consistently for 14 days under normal conditions, the efficacy and safety were evaluated through instrumental measurements and dermatologist assessments. Results demonstrated that the product has moisturizing, repairing, nourishing and anti-wrinkle effects. Additionally, the product is mild (non-irritating) and suitable for sensitive skin (lips).

Reference:

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