

## PANEL

The study was performed on 44 volunteers:

- > The **Placebo** was tested on 15 healthy female volunteers aged between 41 and 60 (average age: 55±1),
- > **Cream 2 (1% SYN<sup>®</sup>-COLL)** was tested on 14 healthy female volunteers aged between 50 and 60 (average age: 57±1),
- > **Cream 3 (2.5% SYN<sup>®</sup>-COLL)** was tested on 15 healthy female volunteers aged between 41 and 60 (average age: 54±1),

All the subjects matched precise inclusion and non-inclusion criteria.

## PRINCIPLE AND MEASUREMENTS

### ANTI-WRINKLE EFFECT

#### PRIMOS<sup>®</sup>



> PRIMOS<sup>®</sup> SYSTEM

For this technique, parallel stripe patterns are projected, via a system of optics, on the sample (directly on the skin's surface or a skin replica) with successive phase shifts. The resulting images are captured on a digital matrix camera. The analysis of fringe deformations provided a qualitative, as well as quantitative, evaluation of each height profile.

An automatic system of repositioning allows the precise re-identification of the measurement zone.

The acquisition of measurement data is achieved using the PRIMOS<sup>®</sup> software package. The following cutaneous parameters could be analyzed:

- > **Ra**: average roughness (ratio between the integrated surface around the mean value and the length of skin evaluated).
- > **Rt**: maximum difference between the highest peak and the deepest furrows registered over the entire profile.
- > **Rz**: mean value of these different maxima, obtained on five successive regions of the profile. It reflects local differences.

A decrease of the Ra expresses a smoothed relief.

A decrease of the Rt and Rz expresses a decrease of the wrinkles' depth.



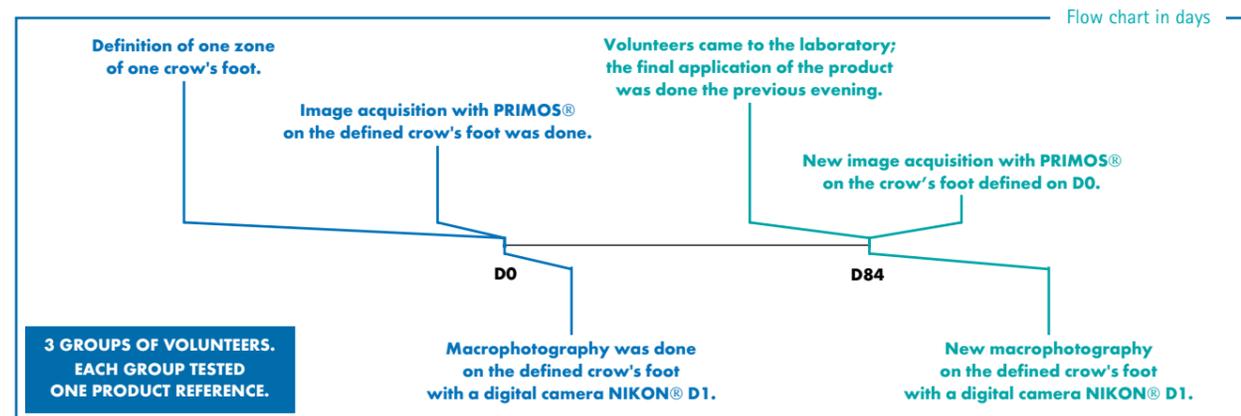
> DETAIL OF FRINGE PROJECTION

#### MACROPHOTOGRAPHS

Macrophotographs are done with a digital camera. The camera used is a Nikon<sup>®</sup> D1.

The photographs are taken in standardized, indirect light, as is the aperture, speed and distance of the camera.

## TRIAL SCHEDULE



Extract of Study  
#1030640

## Clinical Evaluation on Human Subjects

# SYN<sup>®</sup>-COLL Cream 2 & Cream 3

## Versus Placebo

- > **Anti-wrinkle effect**  
**PRIMOS<sup>®</sup>**  
**Macrophotographs**

Sponsor

Investigator

**pentapharm**  
benefiting society through science



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# Clinical Evaluation on Human Subjects SYN®-COLL Versus Placebo

## AIMS

> To evidence, on volunteers, the anti-wrinkle effect of SYN®-COLL (Cream 2 & Cream 3), versus Placebo, after 84 days of twice-daily application, using PRIMOS® and Macrophotographs.

## ANTI-WRINKLE EFFECT

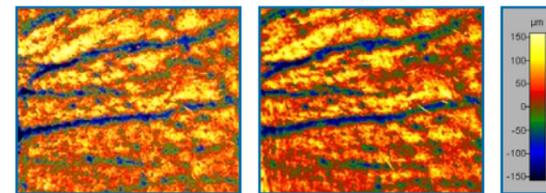
### PLACEBO

#### PRIMOS®

##### Decrease in cutaneous relief

The average roughness (Ra), average relief (Rz) and maximum relief amplitude (Rt) did not vary significantly on D84.

However a decrease of these three parameters was observed on D84, characterizing a smoothing effect after 84 days of twice-daily application of the Placebo.



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#### MACROPHOTOGRAPHS

No visible difference in the decrease of wrinkles after 84 days of twice-daily application of Placebo.



Vol. #6 - D0

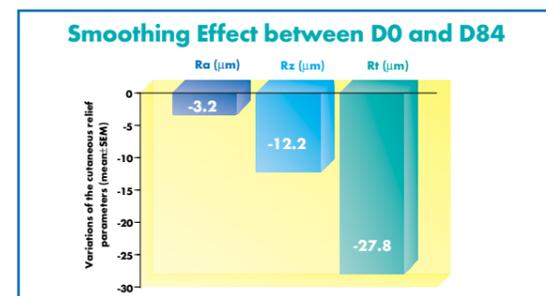
Vol. #6 - D84

### CREAM 2 (1% SYN®-COLL)

#### PRIMOS®

##### Decrease in cutaneous relief

Even if not significant, a decrease in roughness (Ra), average relief (Rz) and maximum relief amplitude (Rt) was observed on D84, characterizing a slight smoothing effect of Cream 2.



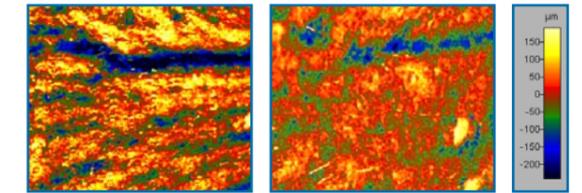
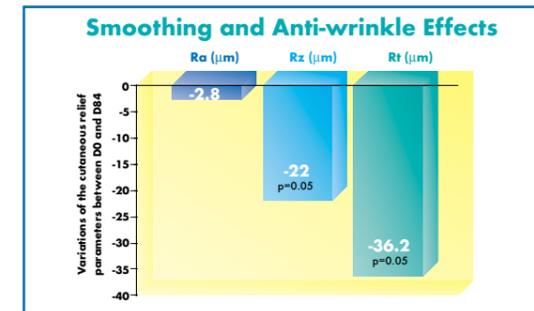
## ANTI-WRINKLE EFFECT

### CREAM 3 (2.5% SYN®-COLL)

#### PRIMOS®

##### Significant decrease in cutaneous relief

After 84 days of twice-daily application of product Cream 3 parameters average relief (Rz) and maximum relief (Rt) significantly decreased by -12%: -22 µm and -36 µm respectively (p=0.05) characterizing smoothing and anti-wrinkle effects.



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#### MACROPHOTOGRAPHS

Anti-wrinkle and smoothing effect were observed after 84 days of twice-daily application of product Cream 3.



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#### COMPARISON OF PRODUCTS' EFFICACY

After 84 days of twice-daily application parameters Rt and Rz show a significant difference between Cream 3 and the Placebo. Indeed, the maximum relief amplitude (Rt) and average relief (Rz) was significantly lower in the group treated with Cream 3 than in the group treated with Placebo.

This means that Cream 3 has a significant smoothing and an anti-wrinkle effect in comparison with the Placebo.

## CONCLUSION

Under these study conditions

### PLACEBO

- > **No significant smoothing effect** was observed for Placebo after 84 days of twice-daily application.
- > There is **no visible difference** between the macrophotographs taken before and after treatment.

### CREAM 2 (1% SYN®-COLL)

- > A slight **smoothing effect** was observed for CREAM 2 after 84 days of twice-daily application.

### CREAM 3 (2.5% SYN®-COLL)

- > CREAM 3 induced **a significant anti-wrinkle effect** after 84 days of twice-daily application : -12% for the two parameters average relief (Rz) and maximum relief amplitude (Rt).

- > This anti-wrinkle effect is **visible on macrophotographs**.
- > The comparison between the products reveals that after 84 days of treatment, the mean value of depth (Rz) and the maximum depth of the wrinkle (Rt) were **significantly lower in the group treated with the CREAM 3 than in the group treated with PLACEBO**, which is in keeping with the **anti-wrinkle effect of CREAM 3**.
- > For all the products, a **good to very good safety was observed**.