

COSMETIC LABORATORIES

Cosmetic application of a new vitamin D derivative – safety and anti-aging efficacy analysis

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INTRODUCTION

Vitamin D is reported to be effective in treatment of skin conditions such as psoriasis, acne, and atopic dermatitis. The law only allows active forms of vitamin D in drugs therefore cosmetic scientists look for derivatives that will have similar biological activity. Hereby we investigate safety and activity of the newly synthesized derivative of vitamin D called CF-5 in cosmetic formulation.

METHODS

CF-5 derivative (patent pending) was tested for topical application safety. Cytotoxicity was assessed with two independent in vitro tests: MTT cytotoxicity on L929 cells according to ISO 10993-5:2009, and skin irritation on EpiDerm skin model according to OECD test guideline 439.

Genotoxicity and mutagenicity were measured with in vitro Mammalian Cell Micronucleus Test as well as using the Ames Test according to OECD test guideline 471. After the safety was confirmed, a cream including CF-5 as an active ingredient was tested in vivo in a group of 30 female volunteers aged 27-65 with symptoms of skin aging who applied the product on the face every morning and evening for 4 weeks. Before application and after 4 weeks of cream usage, following measurements were taken: erythema level and the firmness of the skin (Mexameter and Cutometer Courage - Khazaka), number of wrinkles in different planes and corner density (Visioscan), collagen content (SIAscope™) as well as the depth of nasolabial fold (Primos).

RESULTS

Results – in vitro

Table 1. The results of in vitro experiments on CF-5 safety. The tests confirmed that CF-5 does not have cytotoxic, genotoxic, mutagenic or irritating effect when applied on the skin.

Safety on 3D skin model		Ames Test
Tissue viability \leq 50% - irritant		(S. typhimurium: TA98; TA100; TA1535; TA1537
Tissue viability \geq 50% - non-irritant		E. coli: WP2 [pKM101]; WP2 uvrA)
Tested product	CF-5 (pure powder)	Nonmutagenic in all tested concentrations (100; 50; 25; 12,5; 6,25; 3,125 μ g/ml of CF-5)
Viability in %	114,6%	
Safety on L929 cells		In vitro Mammalian Cell Micronucleus Test
Viability > 70% of control is equal to non-cytotoxic potential		Nongenotoxic in all tested concentrations (10; 5; 2,5; 1;25 μ g/ml of CF-5)
Viability in % (Concentration of product where viability is > 70% of control)	90,3% (at conc. 0,001% of CF-5)	

Figure 2. The chart shows a decrease in nasolabial fold depth (189 μ m) in the 38 year old volunteer after 4 weeks of CF-5 cream usage (orange line- D0, grey line- D28).

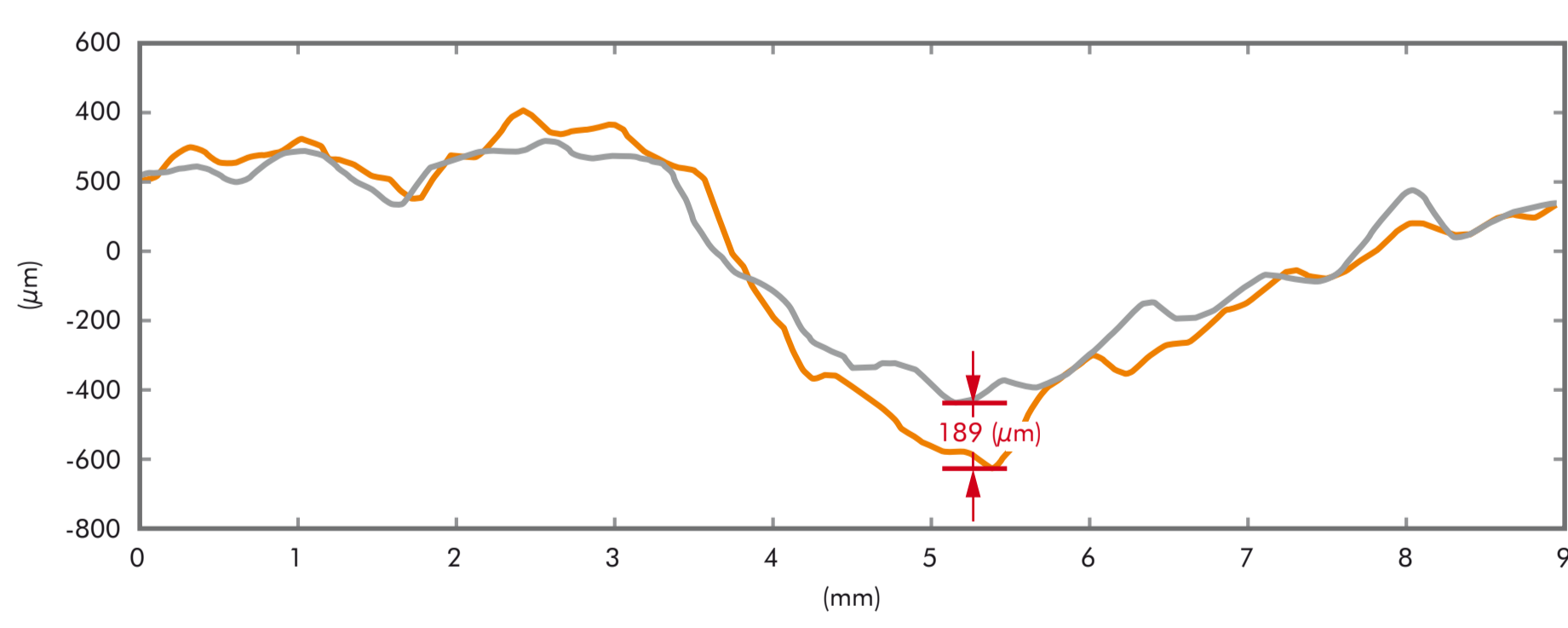
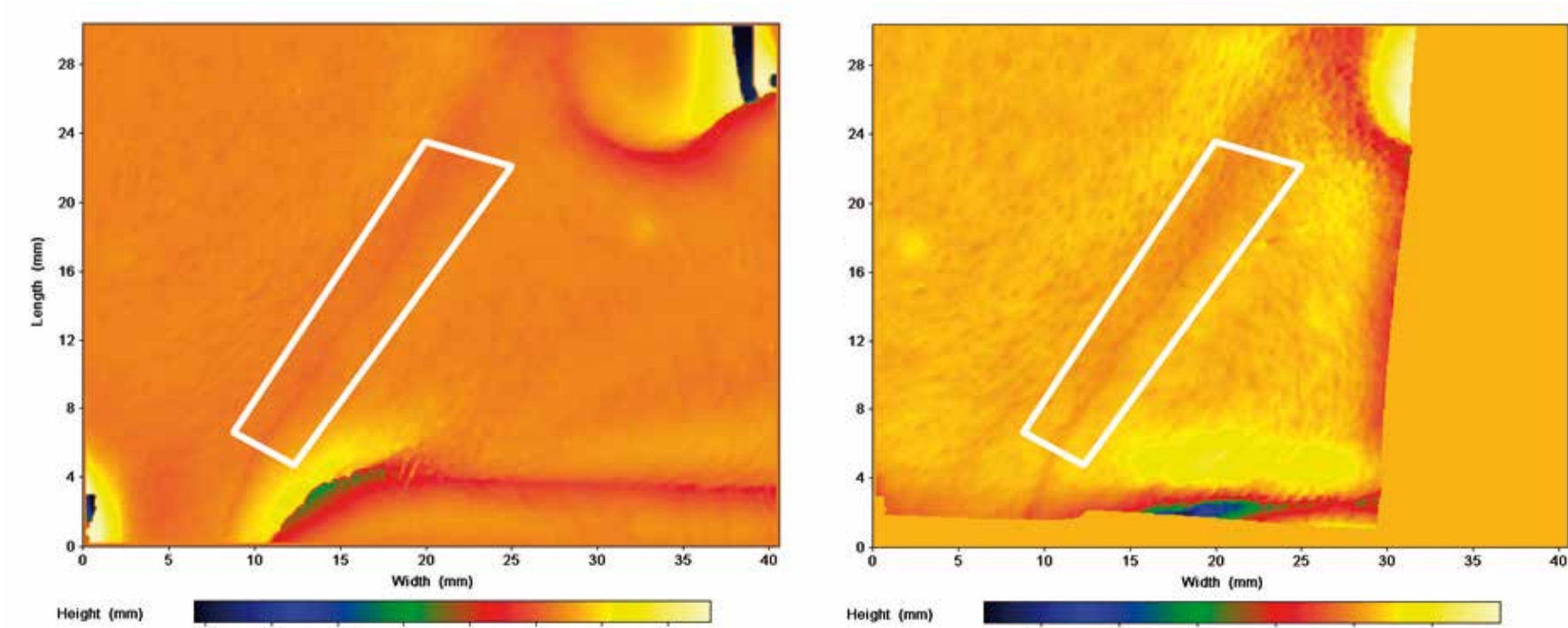


Figure 1. Instrumental skin analysis evaluated by PRIMOS revealed a 39% decrease in nasolabial fold volume. The picture shows a 46 year old volunteer before and after 28 days of application of the product.

	nasolabial fold volume (mm ³)
DO	13,1142
D28	7,946179
change	-5,16802
% change	-39%



Results – in vivo

Table 2. Changes in the level of Corner Density parameter – cross-linking of the skin and Sew parameter – number of wrinkles (Visioscan), after 4 weeks of usage.

Parameters	n	% change in group	actual improvement
Sew – number of wrinkles	18	89%	Reduction in the number of wrinkles by 38% in 50% of volunteers
Corner Density – cross-linking of the skin		110%	Improvement of skin cross-linking by 14% in 81% of volunteers

Table 3. Changes in the level of erythema (Mexameter) and firmness (Cutometer), after 4 weeks of usage.

Parameters	n	% change
erythema	19	Erythema reduction by 14% in 53% of volunteers
firmness (R0)	18	Firmness increase by 29% in 50% of volunteers

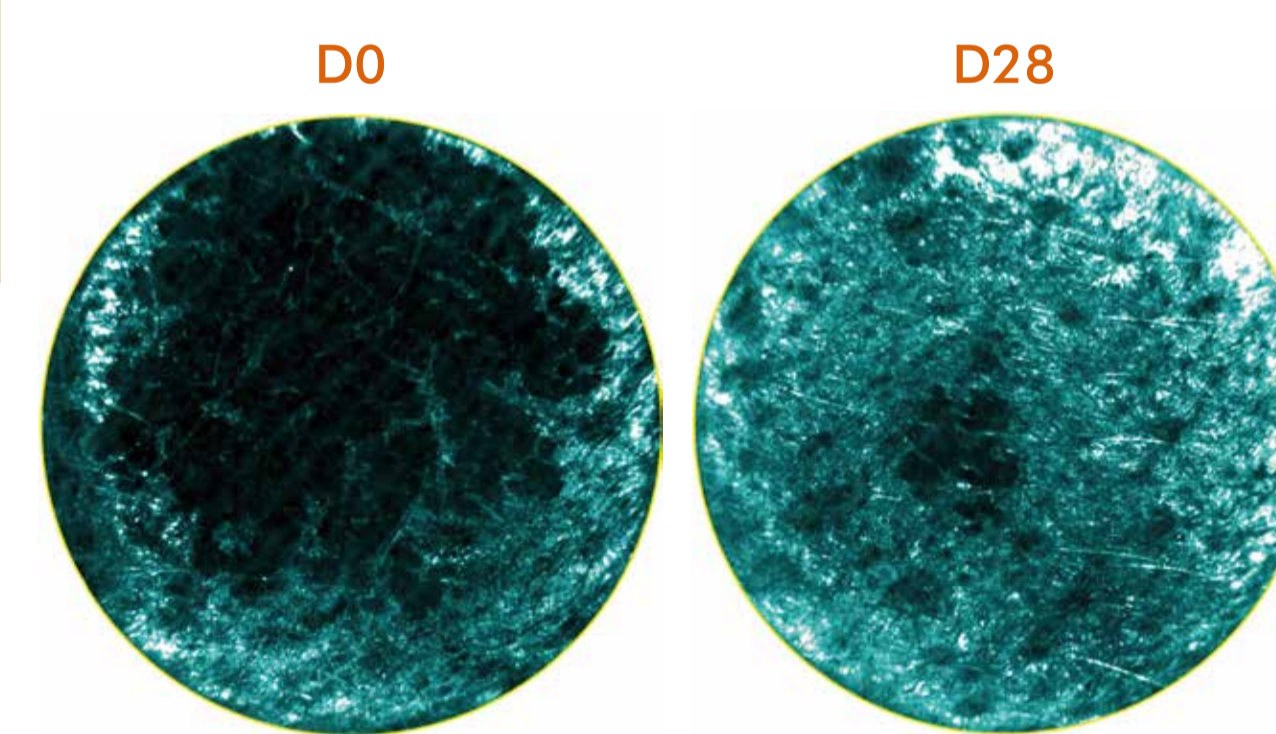


Figure 3. The content of collagen in a 53 year woman before and after 4 weeks of applying CF-5 cream (increase by 55%). The brighter the pixels, the higher collagen content. Prior to application of CF-5 cream, the mean collagen value in the skin was 287.372, after 4 weeks of use mean value had increased to 350.030 (22% improvement) (SIAscope™, MedX Health Corp.).

Table 4. Patients' self assessment after 28 days of application.

Anti-aging properties	% of patients	Brightening properties	% of patients
Improved skin firmness	83%	Adds glow	76%
Revitalization and skin regeneration	83%	Refreshes the appearance of the skin (makes it less ashen)	90%
Leaves the skin smooth	93%	Makes the skin radiant, recovers healthy look	72%
Delays the aging process of the skin	38%	Gives a fresh, healthy look to the complexion	86%
Strengthens the protective barrier of the epidermis	48%	Strengthens the epidermis's protective barrier	52%
Makes skin color evenly	55%	Reduces symptoms of stress and fatigue	66%
Restores skin elasticity	86%	Skin becomes rested, radiant and healthy	62%
Smooths the skin	83%		
Anti-wrinkle action	59%		
Reduces visibility of shallow and mimic wrinkles	55%		

CONCLUSIONS

The tests confirmed that CF-5 does not have cytotoxic, genotoxic, mutagenic or irritating effect when applied on the skin. In vivo tests after 4 weeks of application twice daily showed reduction of erythema levels and increased skin firmness. Moreover, the reduction in number of wrinkles (SEW) by 11%, improvement in corner density by 10%, increase in collagen content by 22% and reduction in the depth of the nasolabial fold by 82 μ m in 89% of patients were observed. CF-5 – newly synthesized derivative of vitamin D – can safely be used in cosmetics. In vivo tests proved its anti-aging and anti-irritation activity.

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