Stem Cell Exosome Cream

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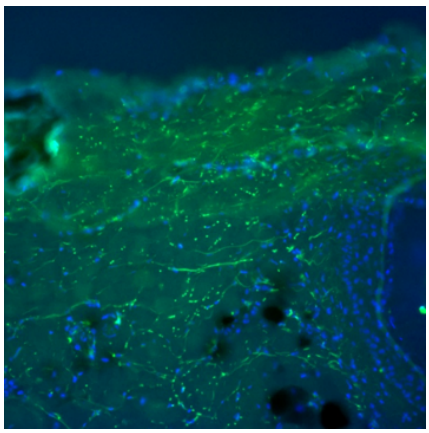
Exosomes in Skin Rejuvenation

Stem cell exosomes and secretome can produce the same therapeutic and rejuvenating effects on skin as live stem cells. Stem cell exosomes are advantageous as they are not live or immunogenic. Mesenchymal Stem Cells (MSCs) secrete exosomes and secretome that contain cytokines and different growth factors such as Epithelial Growth Factor (EGF) and Basic Fibroblast Growth Factor (bFGF). The exosomes and secretome are well known to be a reliable source of important signaling molecules and growth factors for skin rejuvenation and wound healing by improving collagen synthesis of Human Dermal Fibroblasts (HDFs), fibroblast migration and angiogenesis.

Platform Technology

Exosomes are nanoscale spherical vesicles which are released from cells; they are essential for the cell-to-cell communication and can be used to deliver manufactured compounds to targeted tissues. EriVan Bio manufactures scalable exosomes for cosmeceutical applications. Exosomes and secretome from stem cells and milk are used in our products, which are formulated to introduce targeting and improve efficacy.



Cross section of dermis with fibroblast exosomes shown in green and cell nucleus in blue.

Usage Instruction

RejuvEx Cream should be applied to the entire treatment area and rubbed in until the vanishing cream is no longer visible. One pea-sized amount (~0.25g) of RejuvEx Cream should be applied to the treatment facial area at each application. RejuvEx Cream should be applied twice daily. Once in the morning and again prior to normal sleeping hours. The application should be left on the skin for at least 4 hours, after which time the cream could be removed by washing the area with mild soap and water. For best results, it is recommended to wash the treatment area with mild soap and water and allow the area to dry. Contact with the eyes, lips, and nostrils should be avoided.

Clinical Trials and Testing Overview for RejuvEx

Clinically shown to be safe for sensitive skin and tested for antimicrobial safety. In a clinical trial RejuvEx significantly reduce the appearance of fine wrinkles and roughness over a four-week course. Over an eight-week course RejuvEX was shown to significantly reduce the appearance of deep wrinkles, redness, and improved skin clarity. With a high satisfaction favorability rating of 90% amongst of test participants.

Antimicrobial Effectiveness Testing

Purpose

The purpose of this study was to evaluate the effectiveness of antimicrobial preservatives against microbial contamination.

Study Dates

This study was initiated on 30 MAR 2020 and was completed on 04 MAY 2020.

Test Method

The method employed was USP 42, Section 51, Antimicrobial Effectiveness Testing.

Test Organisms

1. *Staphylococcus aureus* ATCC#6538
2. *Escherichia coli* ATCC#8739
3. *Pseudomonas aeruginosa* ATCC#9027
4. *Candida albicans* ATCC#10231
5. *Aspergillus brasiliensis* ATCC#16404

Results

Log10 CFU/g or CFU/ml

Exosome-based anti-aging rejuvenating cream	*Staphylococcus aureus*	*Escherichia coli*	*Pseudomonas aeruginosa*	*Candida albicans*	*Aspergillus brasiliensis*
Inoculum Level	5.03	5.82	5.64	5.78	6.28
Day 14	2.33	<0.70	<0.70	4.03	5.28
Day 28	<0.70	<0.70	<0.70	2.46	2.71

Suitability of Counting Method Validation*

	Product Dilution	*Staphylococcus aureus*	*Escherichia coli*	*Pseudomonas aeruginosa*	*Candida albicans*	*Aspergillus brasiliensis*
Inert Control	N/A	63.5	94	57	102	20
Exosome-based anti-aging rejuvenating cream	10-1	34	98	87	87.5	17
	10-2					
	10-3					

Acceptance Criteria

For category 2 products, the preservative is effective in the sample examined if a) the concentrations of viable bacteria demonstrate no less than a 2.0 log reduction from the initial count at 14 days and no increase from the day 14 count at 28 days; and b) the concentrations of viable yeast and molds demonstrate no increase from the initial calculated count at 14 and 28 days.

Conclusion

The test material, Exosome-based anti-aging rejuvenating cream, conforms to the acceptance criteria for USP 42 <51> category 2 products.

Safety Testing

Objective

The objective of this study was to determine the potential of a test material to elicit dermal irritation and/or induce sensitization following repeated patch applications.

Study Dates

This study was initiated on 29 June 2020 and was completed on 07 August 2020.

Subject Selection

A total of 120 male and female subjects of whom 60 subjects had self-perceived sensitive skin ranging in age from 21 to 70 years, and who met all the inclusion criteria and none of the exclusion criteria as outlined in the study protocol.

Dermal Evaluations

Individual dermal scores recorded during the Induction and Challenge Phases.

Conclusion

Based on the test population of 106 subjects and under the conditions of this study, the test material identified as Exosome-based anti-aging rejuvenating cream did not demonstrate a clinically significant potential for eliciting dermal irritation or inducing sensitization.

Efficacy and Consumer Perception of RejuvEx

Objective

The primary objective of this pilot clinical study was to evaluate the efficacy of a face cream after four and eight weeks of use. The secondary objective of this pilot clinical study was to obtain the consumer perception of product performance of a face cream after four and eight weeks of use.

Study Dates

This study was initiated on 09 September 2020 and was completed on 05 November 2020.

Study Design

Twenty subjects were enrolled in this pilot clinical study to evaluate the efficacy of a face cream after four and eight weeks of use and to obtain the consumer perception of product performance of a face cream after four and eight weeks of use. Study evaluations included BTBP Clarity Research 3D System imaging and analysis and consumer perception questionnaires.

Subject Selection

A total of 20 female subjects, ranging in age from 43 to 60 years, who met all the inclusion criteria and none of the exclusion criteria as outlined in the clinical study protocol.

Adverse Events

No adverse events were reported over the duration of the study.

Results

Clarity 3D System:

Under the condition of this study and in this test population, the test material, RejuvEx, was found to provide a statistically significant improvement for the following parameters/time points:

Wrinkles

- Statistically significant decrease in the surface area (mm^2) of the wrinkles after 8 weeks of twice daily test material use when compared to baseline.

- Statistically significant decrease in the average severity of the wrinkles after 4 weeks and 8 weeks of twice daily test material use when compared to baseline.
- Statistically significant decrease in wrinkle object count (number of wrinkles) after 8 weeks of twice daily test material use when compared to baseline.
- Statistically significant decrease in the average severity of the deep wrinkles after 8 weeks of twice daily test material use when compared to baseline.
- Statistically significant decrease in the surface area of the fine wrinkles after 8 weeks of twice daily test material use when compared to baseline.
- Statistically significant decrease in the average severity of the fine wrinkles after 4 weeks and 8 weeks of twice daily test material use when compared to baseline.

Skin Color

- Statistically significant increase in L star value (brightness) after 4 weeks and 8 weeks of twice daily test material use when compared to baseline.
- Statistically significant decrease in a* value (redness) after 4 weeks and 8 weeks of twice daily test material use when compared to baseline.

Texture

- Statistically significant decrease in the average roughness after 4 weeks and 8 weeks of twice daily test material use when compared to Baseline.

Redness

- Statistically significant decrease in the surface area of the redness after 4 weeks and 8 weeks of twice daily test material use when compared to baseline.

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