PIGMENT

STUDY TEMPLATE

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ABSTRACT

The objective of this study is to evaluate the efficacy and safety of a new pigment correcting facial serum and its effects on skin tone, skin brightening, hyper pigmentation, skin hydration and the appearance of fine lines and wrinkles on the face.

Participant's captures are taken using Clarity Research 3D System digital photography at Baseline (Visit 2), Week 4 and Week 8.

Measurements for the Participants will be recorded at Baseline (Visit 2), Week 4 and Week 8 after using the test materials.

It was concluded that there was a statistically significant improvement in the Spot Count which ranges from 34.5% to 44.4% and Size Distribution which ranges from 34.5% to 51.9% from Baseline (Visit 2) to Week 8.

Section 1: OBJECTIVE

The objective of this study is to evaluate the efficacy and safety of a new pigment correcting facial serum and its effects on skin tone, skin brightening, hyper pigmentation, skin hydration and the appearance of fine lines and wrinkles on the face.

Section 2: STUDYDESIGN

Approximately 29 female and male participants will be selected between 30-75 years with Fitzpatrick Skin Types I-IV to participate in the evaluation of a facial serum's effect on skin tone and brightness, skin hydration and the appearance of fine lines and wrinkles via Clarity Research 3D System measurements. Participants will use the test product twice a day for 8 weeks and will return for evaluations at weeks 4 and 8.

A study schedule appears below.

Procedure	Day 0	Day 1		Week 4	Week 8
	Screening Visit 1	Baseline Visit 2	15 min Post application	Visit 4	Visit 5
Informed Consent/ HIPAA authorization forms/Medical History forms /Concomitant Medications forms completed	✓				
Inclusion and Exclusion Criteria reviewed	✓				
AE reporting, health/medication changes recorded				✓	✓
Distribution of Non-Moisturizing Soap and Conditioning Phase Diary	✓				

Conditioning Phase Diary Collection		✓			
Distribution of Test Material, Application Instructions, and Daily Diary		✓			
Clarity Research 3D System Measurements Radiance Surface Spots/Sub surface Spots Fine Lines and Wrinkles Smoothness Pore Size		✓		✓	✓
Supervised Test Material Application at the Laboratory		✓			
Consumer Use Questionnaire			✓	✓	✓
Test Material and Daily Diary Collection					

Section 3: TEST MATERIALS

3.1 DESCRIPTION

Storage	Before the beginning of the study, products are kept in test material storage room at room temperature that is locked with access control
Application frequency	Twice a day (morning and evening) during 84(+/- 2 days) days
Application site	Face, neck and neckline
Application method	Under normal conditions of use Apply 4-5 drops of the product in the palm of the hand and massage the face with fingertips doing circular motions on the entire face area, neck and neckline avoiding contact with eyes

3.2 Application Instructions

Apply twice daily (morning and evening) to clean and dry skin, avoiding eye areas. Apply 4-5 drops of the product in the palm of the hand and massage the product with circular motions on the entire face, neck, and neckline, avoiding contact with eyes.

Use of your daily moisturizing cream is allowed as long as it does not contain glycolic acid or retinol. Do not apply the moisturizing cream or other daily routine products at the same time as this product. Avoid sun exposure, if you will be exposed to outdoor natural lighting, use a sunscreen that is SPF 50 or higher.

Section 4: STUDY POPULATION

Up to 29 participants will be enrolled in this study. Participants will be recruited from the Clarity Research Laboratory database. Participants who meet all of the inclusion criteria and none of the exclusion criteria will be enrolled.

4.1 INCLUSION CRITERIA

A participant may be eligible for enrolment provided the all of the following criteria are met:

1. Participant is a female or male between 30 and 75 years of age (approximately 10 Hispanic, approximately up to 10 Asian Pacific Rim and approximately 20 Caucasian; approximately 20% men and approximately 80% women);
2. Participant with Fitzpatrick skin types I to IV in good health condition with moderate to severe facial hyper pigmentation as determined by a technician.(Participants are required to have a baseline score of 4 to 9 on both sides of the face as per the overall hyper pigmentation scale);
3. Female participant who is using an adequate method of birth control;
4. Participant will be required to discontinue use of any skin treatment products on the face, with the exception of the provided test material, non-moisturizing soap, SPF 50 or higher sunscreen, and their daily moisturizers that do not contain glycolic acid or retinols for the duration of the study when exposed to day light
5. Participant agrees not to introduce new facial skincare products, cosmetic or toiletry products, and anti-aging/anti-wrinkle/depigmentation products for the duration of the study;
6. Participant is willing to avoid extended periods of sun exposure for the duration of the study (including artificial tanning);
7. Participant is willing to apply the provided sunscreen SPF 50 prior any to any daytime outdoor activities;
8. Male participants who are clean shaven;
9. Participant is dependable and able to follow directions as outlined in the protocol;
10. Participant is in good health and has a current Panelist Profile on file;
11. Participant has completed a HIPAA Authorization Form in conformance with 45 CFR Parts 160 and 164;

12. Participant understands and is willing to sign an Informed Consent in conformance with 21 CFR Part 50: “Protection of Human Participants.”

4.2 EXCLUSION CRITERIA

A participant may be considered ineligible to participate in this clinical study if any of the following conditions are met:

1. Female participant is pregnant, nursing, planning to become pregnant during the clinical study, or not using adequate birth control;
2. Participant has known allergies to cosmetic/toiletries/any of the ingredients in the test product;
3. Participant exhibits sunburn, rashes, scratches, burn marks, etc. on the face which might interfere with study evaluations;
4. Participant exhibits or reports a history of acute or chronic dermatological, medical, and/or physical conditions that would preclude application of the test material and/or could influence the outcome of the study;
5. Participant uses lotions/creams that contain retinoid, any peeling ingredients and any depigmentant ingredients;
6. Participant being treated by hydroquinone in the past 6 months;
7. Participant being treated by drug depigmentant in the past 6 months;
8. Participant being treated by cosmetic depigmentant in the past 6 months;
9. Participant being treated by Laser depigmentant in the past 12 months;
10. Participant being treated by chemical peels in the past 6 months.

Section 5: STUDY EVALUATIONS

Before starting the evaluation, participants must acclimate to the laboratory environment for at least 15 minutes.

5.1 Population Description

Description of the population will be done by the Sponsor with an independent qualified dermatologist. This description will be based on the photos provided at the inclusion of the study and it will include

participants' age, gender, ethnicity, and Fitzpatrick skin types, classification of the hyper pigmentation, aging spot and anti-inflammatory hyper pigmentation.

5.2 Clarity Research 3D System

The Clarity Research 3D System features the latest technology in 2D and 3D skin modelling. The Clarity Research 3D System features 3 cameras, each with 25 megapixels and SLR image capture in 16-bit. The Automated image recognition includes artificial intelligence for facial and skin area recognition, high precision facial detection, automation for facial zoning and zoning by area of interest, and data tracking by region of interest. The Clarity Research 3D System captures 6 types of skin images, including diffuse white light, melanin, haemoglobin, texture, 3D macro structure, and 3D micro structure. The system also allows for simultaneous front, left and right profile capture with no repositioning requirements.

The Clarity Research 3D system is capable of detecting over 50 facial regions for analysis of fine lines, texture, skin tone evenness and discoloration, and contouring. The system is also able to perform 3D reconstruction of the skin topography and facial contour, and facial fine lines / deep wrinkle surface analysis and to analyze acne scars and lesions, perform lash analysis on length, density, and curl, and lip analysis of the surface, volume, and texture, Additional features include redness scoring, subsurface pigment detection, pore detection, and visible spot detection.

Front and side-view images (one right side and one left side) utilizing the Diffused light, Subsurface Melanin, Subsurface Haemoglobin, Surface, and 3D will be taken at designated time points. Participants will be photographed with their eyes closed. The images will be saved to USB's (2 copies) in high resolution png/jpg format. One copy will be forwarded to the Sponsor with the Final Report and the other copy will be saved in the clinical study binder. An original backup will be saved on the shared drive.

5.3 Questionnaire

Following product use, an assessment of the effects of a test material will be determined by questioning the treated participants. Questionnaire administration using Survey Tracker Plus or similar allows for an efficient and accurate method of determining participant response proportions to assess

the consensus opinion of a clinical study population. Questionnaires will be administered immediately post application, after 4 weeks, 8 weeks of use.

Section 6: TEST METHOD

6.1 Participant Identification

Candidates for study participation will be identified from the Clinical Research Laboratories, LLC (Clarity Research Laboratory) database. All participants will be initially identified by a permanent Clarity Research Laboratory Identification Number. Participants who meet the inclusion and exclusion criteria at the screening visit will be assigned a study participant number. This participant number will be assigned in sequence as participants are enrolled in the study. A master roster will be kept of the permanent Clarity Research Laboratory Identification Number and the corresponding study participant number.

6.2 Screening Visit1 (7+/-3 Days)

Participants will arrive at Clarity Research Laboratory with a clean face, free of make-up or moisturizers. Informed consent will be obtained, HIPAA forms will be completed, and Medical History/ Concomitant medications will be recorded. Inclusion and exclusion criteria will be verified. Overall appearance of the hyper pigmentation will be assessed for qualification. Participants who have moderate to severe signs of facial pigmentation and who meet all of the study requirements will be enrolled. Participants will be provided with a bar of non-moisturizing soap and a conditioning phase diary. Participants will be instructed to use only the provided soap for all facial cleansing for the conditioning phase of the study and for the duration of the study. Participants will record each use in the conditioning phase diary.

6.3 Baseline (Visit 2)

Participants will return in 7 +/- 3 days with a clean face, free of any make-up or moisturizers. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes prior to the study evaluations. Baseline Clarity Research 3D System images will be obtained as per section 5.2. Participants will be provided with the test material, application instructions, and a daily diary.

Participants will perform the first application at the laboratory, under the supervision of a Clarity Research Laboratory technician.

6.4 Visit Four (Week 4)

Participants will return to the clinic after 4 weeks with a clean face, (test material applied after study assessments) free of makeup. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes prior to study evaluations.

Following the acclimation period, Clarity Research 3 D System images will be obtained as per Section 5.2. Participants will be asked about adverse events, changes in medical history, or changes in concomitant medications. Participant responses will be recorded on the appropriate case report form.

The product will be applied after study assessments under the supervisions of a technician.

6.5 Visit Five(Week 8)

Participants will return to the clinic after 8 weeks with a clean face, (test material applied after study assessments) free of makeup. Participants will acclimate to ambient laboratory conditions for approximately 15 minutes prior to study evaluations.

Following the acclimation period, Clarity Research 3D System images will be obtained as per Section 5.2; Participants will be asked about adverse events, changes in medical history, or changes in concomitant medications. Participant responses will be recorded on the appropriate case report form. The product will be applied after study assessments under the supervisions of a technician.

Following the acclimation period, participants will be asked about adverse events, changes in medical history, or changes in concomitant medications. Participant responses will be recorded on the appropriate case report form.

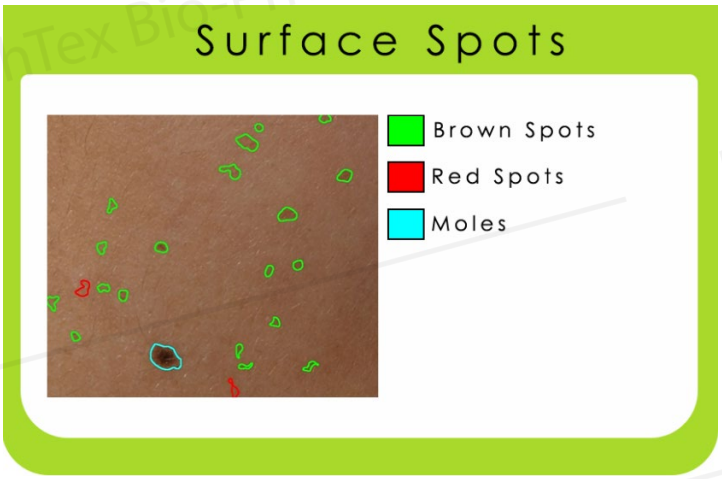
Clarity Research 3D System images will be obtained as per Section 5.2. Test materials will be collected. Daily diaries will be reviewed and collected. If any adverse event is reported, the participant will be followed up until resolution.

SKIN FEATURE TO BE STUDIED

1. Surface Spots

Pigmentation or spots is a localized change in skin color caused by the variation in the amount and type of melanin production underneath the skin.

Surface Spots feature is sub categorized into three types: Brown spots, Red Spots and Moles.

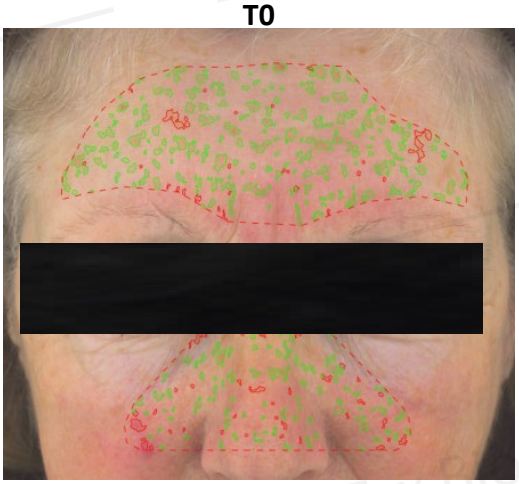


Measured Parameters: Size Distribution, Spot Count

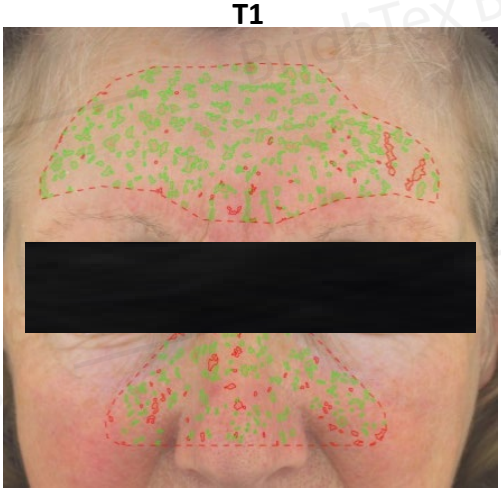
i. **Size Distribution:** It defines the standard deviation of the recognized spots size.

Sample Result Images:

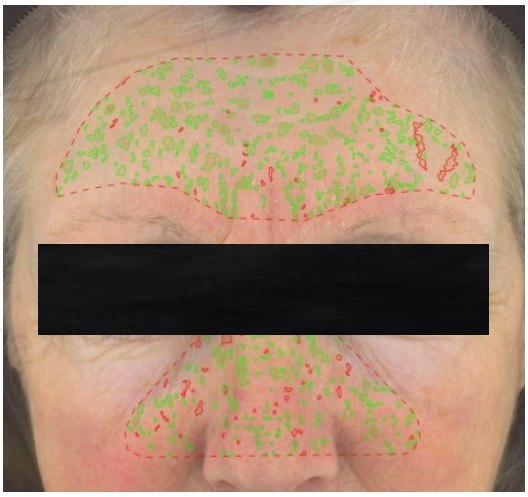
T0



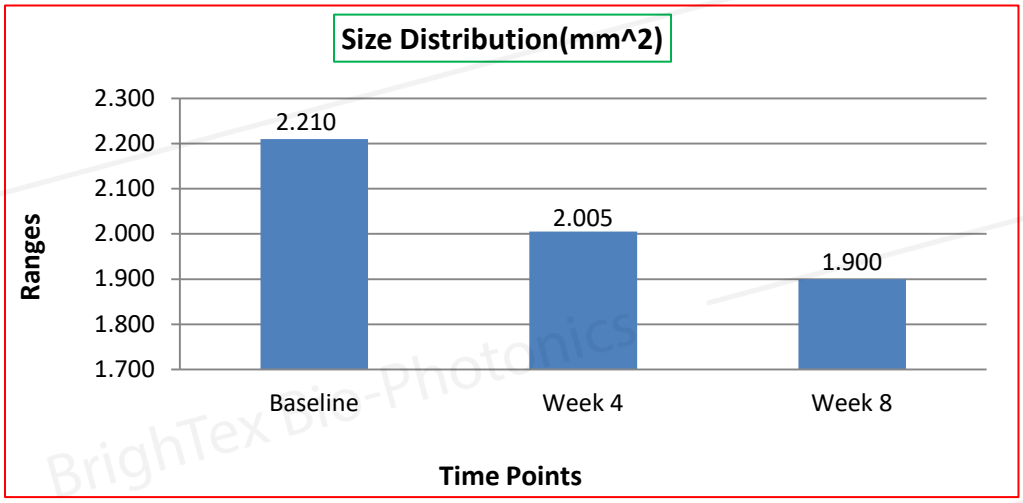
T1



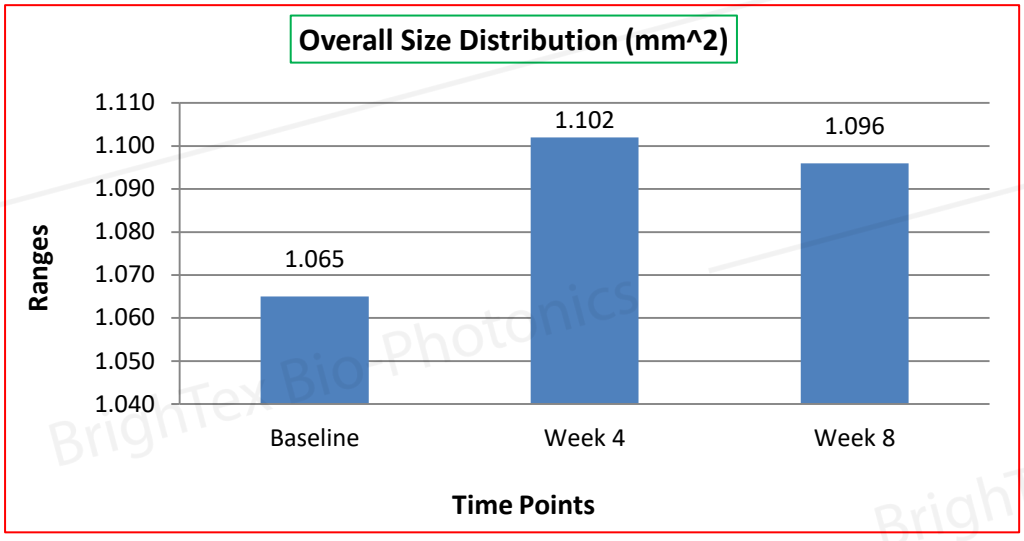
T2



Participant 07 Results



Overall Size Distribution:

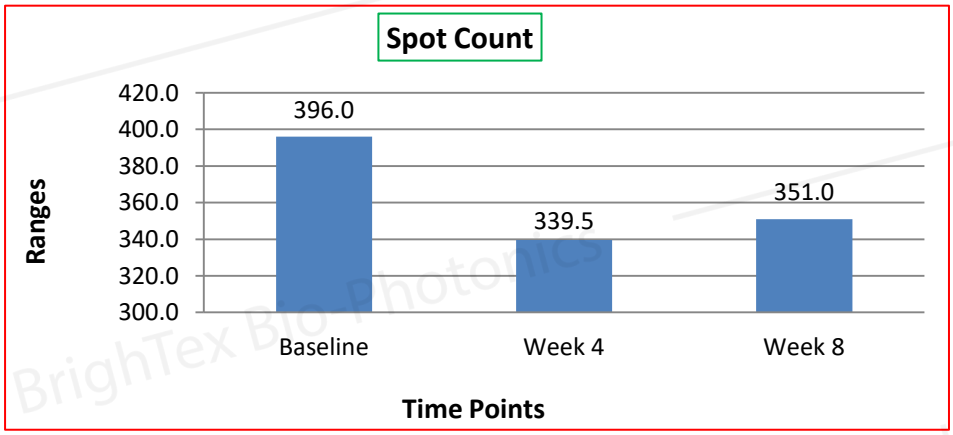


Test Results and Statistical Summary

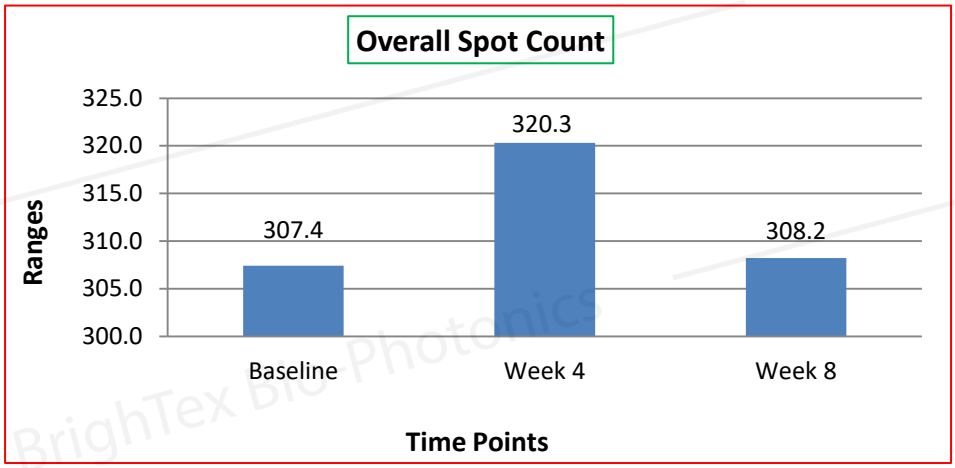
Clarity™ Research 3D System-Size Distribution				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Size Distribution	Skin Care Device	Week 4	10	34.5%
		Week 8	14	51.9%

ii. Spot Count: It is defined as the total number of spots count

Participant 01 Results



Overall Spot Count:



Test Results and Statistical Summary

Clarity™ Research 3D System-Spot Count				
Parameter	Treatment	Visit	Number of Participants showed improvement	% of Participants showed improvement
Spot Count	Skin Care Device	Week 4	10	34.5%
		Week 8	12	44.4%

Section 7: CONCLUSION

There was a statistically significant improvement in the Spot Count which ranges from 34.5% to 44.4% and Size Distribution which ranges from 34.5% to 51.9% from Baseline to Week 8.