ASSESSEMENT OF THE EFFICACY OF AN ORAL SUPPLEMENT PRODUCT THROUGH SELF-ASSESSMENT QUESTIONNAIRE PERFORMED BY THE STUDY SUBJECT, UNDER NORMAL USE CONDITIONS

FINAL REPORT

TYPE OF INVESTIGATIONAL PRODUCT: Oral Supplement
INVESTIGATIONAL PRODUCT NAME: ASOX9 Men's Vitality Supplement

INVESTIGATIONAL PRODUCT CODE AT THE INSTITUTE: E001641A-01
STUDY CODE: All-E-ES-E001641A-01-11-22
REPORT CODE: All-E-ES-E001641A-01-11-22-RFV01-Rev01

REPORT DATE: 04/19/2023

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SUMMARY

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OBJECTIVE OF THE STUDY

The objective of this study was to verify the efficacy of an oral supplement product through the subjective self-perceived questionnaire performed by the study subjects, under normal use conditions.

METHODOLOGY

On the initial visit (T0), the subjects were assessed by a urologist to verify the inclusion and non-inclusion criteria of the study and the subjects included received the investigational product, a daily-log of use at home and the questionnaires of the study. They were instructed to use the product according to the sponsor's intake instructions, under normal use conditions, during 28 ± 2 days, and to complete the questionnaires after 3 hours (T3h) of the first investigational product intake and after 1 (T1d), 3 (T3d), 5 (T5d) and 28 (T28) days of investigational product intake. At the end of the study, a technician asked the subjects about possible discomfort sensations.

PRINCIPAL INVESTIGATOR

Gabrielli Brianezi

STUDY LENGTH

28 ± 2 days.

FREQUENCY OF INTAKE

1 tablet twice a day.

INCLUDED STUDY POPULATION DESCRIPTION

Male subjects, aged between 45 and 65 years old (mean age: 55 years old), self-declared with active sexual life.

NUMBER OF SUBJECTS

A total of 35 study subjects were included in the study and a total of 32 completed the study.

ETHICS

This study was conducted in compliance with the Declaration of Helsinki principles, the applicable regulatory requirements, including Resolution CNS no. 466/12, and according the Good Clinical Practices, Document of the Americas and ICH E6.

RESULTS / CONCLUSION

Self-Assessment Performed by the Study Subjects

Statement	Agreement %				
After X hours/days of product use, I felt:	T3h	T1d	T3d	T5d	T28
Improving the ability to get an erection	50.0%	53.1%	62.5%	71.9%	87.5%
Increased libido and desire for sexual activity	43.8%	53.1%	59.4%	62.5%	65.6%

Longer lasting erections	43.8%	56.3%	68.8%	75.0%	81.3%
The ability to have stronger erections	46.9%	56.3%	62.5%	59.4%	68.8%
Reduced fatigue	46.9%	59.4%	65.6%	65.6%	68.8%
Reduced anxiety	40.6%	46.9%	59.4%	56.3%	65.6%
Increased energy levels	56.3%	68.8%	62.5%	65.6%	75.0%
Enhanced physical function	46.9%	56.3%	56.3%	65.6%	71.9%
Enhanced muscle strength	56.3%	62.5%	62.5%	59.4%	68.8%
Faster sexual recovery time	53.1%	59.4%	65.6%	75.0%	71.9%
Improved erectile function	59.4%	65.6%	71.9%	75.0%	78.1%

Therefore, the following claims can be supported by the Self-Assessment:

- *Improvement on the ability to get an erection*;
- *Increased libido and desire for sexual activity*;
- *Longer lasting erections*;
- *Improvement on the ability to have stronger erections*;
- *Reduced fatigue;*
- *Reduced anxiety;*
- *Increased energy levels;*
- *Enhanced physical function;*
- *Enhanced muscle strength;*
- *Faster sexual recovery time;*
- *Improved erectile function.*

QUALITY ASSURANCE

The study was conducted according to the Resolution CNS n° 466/12, the Good Clinical Practices and in conformity with the Standard Operating Procedures of the Institute.

Data quality is assured, considering that our personnel is trained according to the study to be carried out, our equipment is always duly calibrated and the methods used are recognized and/or validated.

The Quality Assurance Department is in charge of auditing the Management System, and is fully available for any specific study monitoring carried out by the Sponsor.

The signature below indicates that the study was carried out as described above and that the results were checked against the source documents.

Audited by: Cristiane Nunes Coelho Moreira
04/19/2023

CONTENTS

1. ABBREVIATION LIST

ASTM	American Society for Testing and Materials
CNS	Conselho Nacional de Saúde (Brazilian Health Council)
Dr.	Doctor
e.g.	For example
etc.	Et cetera
ICF	Informed Consent Form
LTDA	Limited
NA	Not Applicable
No.	Number
oz.	Ounce
SP	São Paulo State
TX	Study Assessment Time-Points

2. INTRODUCTION

Over the last few years, the cosmetic industry has grown considerably, same as its concern in developing safe and effective products. Industry awareness and consumer's and regulatory agencies requirements caused cosmetic manufacturers to adopt procedures that lead them to know better their products: to conduct clinical tests on safety and efficacy, which are coordinated by expert physicians, before marketing a product. These procedures provide cosmetic companies with greater safety, credibility and reliability among their consumers.

Efficacy studies allow us to assess the product's characteristics, detecting complaints and comments regarding its performance, as well as testing the quality control and the assured quality, analysis of competitors and claims support (what the product offers). In order to evaluate if a claim is appropriate, it is necessary to take into account the general consumers' impression concerning the presentation or the product advertisement (COLIPA, 2008). The claims must be supported by solid, clear and relevant evidences. Such evidences may result from experimental studies (biochemical / instrumental methods, sensory evaluations, technical evaluations and evaluations without the participation of study subjects, in vitro testing in cell cultures, use of hair locks, etc.), and consumers evaluations (ASTM E 1958-06, 2006).

For the efficacy assessment of products, clinical and/or self-assessment studies and instrumental studies can be used. The Self-Assessment by the study subjects is performed by following the "*Standard Guide for Sensory Claim Substantiation*" (ASTM E 1958-06, 2006), by using questionnaires. The ASTM (American Society for Testing and Materials) standards organization has been developed for over a century and represents one of the greatest voluntary organizations for standards development in the world, being a reliable source of technical standards of material, products, systems and services. Known by their high technical quality and relevance on market, ASTM standards have an important role in the infrastructure of the information guiding the study design, product manufacturing and commerce in global economy. The "Standard Guide for Sensory Claim Substantiation" is an ASTM standard that aims to disclose the good practices in sensory studies, approaching reasonable practices for executing sensory studies to validate product claims.

3. OBJECTIVE

The objective of this study was to verify the efficacy of an oral supplement product through the subjective self-perceived questionnaire performed by the study subjects, under normal use conditions.

4. STUDY DESIGN

Non-comparative clinical study.

5. INVESTIGATIONAL PRODUCT

Investigational product was provided by the Sponsor and was labeled with appropriate codes and proper use instructions. All investigational products sent by the Sponsor were initially stored in the samples room at the study site, with controlled temperature and restricted access. Investigational products release was controlled by the principal investigator or by a previously designated technical staff. At the moment of receiving the investigational product, the subjects were instructed on how to correctly store it, emphasizing the importance to keep it out of reach of children and/or animals.

Investigational product information, as declared by the Sponsor, are described in APPENDIX 3. A sample of the investigational product was cataloged and it can be found in the Institute archive for a one-month period after the completion of the study.

5.1. Identification

Table 1. Investigational product identification

Investigational Product Name	Investigational Product Type	Investigational Product Code	Batch	Expiration Date
ASOX9 Men's Vitality Supplement	Oral Supplement	E001641A-01	410247	05/01/2024

5.2. Investigational Product Use Instructions

Subjects were instructed to intake the investigational product as follows:

Take 1 tablet twice a day. For best results, take 20-30 minutes before a meal with a glass of water.

5.2.1. Investigational Product Use Compliance Check

The compliance of investigational product use by the subjects was checked through the daily-log of investigational product use completed by the subjects.

6. STUDY PERIOD

The total length of the study per subject was of 28 ± 2 days.

- **Start of the First Group:** 01/28/2023;
- **End of the Last Group:** 02/25/2023.

7. STUDY SUBJECTS

7.1. Study Subjects Recruitment

The study subjects were recruited by the recruitment department of the Study Center that has a computerized and updated register system. The subjects registered into this system are interested in participating in clinical trials. They were contacted and asked to take part in the selection process and if

they met all required criteria, they would be included in the study in accordance with applicable legislation Resolution CNS n° 466/12 and General Data Protection Law (13.709:2018).

The study was performed in one of Allergisa facilities and the subjects were informed about the site/address when they were contacted.

7.2. Selection and Admission of Study Subjects

During the subjects' selection to this study, the physician in charge certified that the subjects did not present pathologies that could interfere on the study results and is also responsible for the information present on the study subject evaluation form, verifying all the inclusion and non-inclusion criteria for the subjects' admission.

7.3. Study Population

The population sample size predicted to be enrolled on the protocol was 35, aiming complete the study with 30 responses.

7.4. Inclusion Criteria

- Healthy study subjects;
- Intact skin on test site;
- Agreement to adhere to the procedures and requirements of the study and to report to the institute on the day(s) and at the time(s) scheduled for the assessments;
- Ability of giving consent for participation in the study;
- Aged from 45 to 65 years old;
- Male study subjects;
- Subjects that self-declared with active sexual life;
- Subjects willing to use the investigational product during the study and to respond the study questionnaires.

7.5. Non-Inclusion Criteria

- Skin pathology that may interfere on the study and/or subject's safety;
- Type 1 Diabetes Mellitus: insulin-dependent diabetes, presence of complications resulting from diabetes (retinopathy, nephropathy, neuropathy), presence of dermatosis related to diabetes (necrobiosis lipoidica, plantar ulcer, ring granuloma, opportunistic infections); antecedents of episodes of hypoglycemia, diabetic ketoacidosis and/or hyperosmolar coma;
- Immunologic insufficiency;
- Current use of the following topical or systemic medications: corticosteroids, immunosuppressant and anti-histaminic drugs;
- Skin diseases: vitiligo, psoriasis, atopic dermatitis;

- Antecedent of reaction to the category of product tested;
- Other diseases or medications that might directly interfere with the study or put the subject's health under risk.

7.6. Permissions and restrictions during the study

- Do not use any other oral supplement product, which may interfere with the study assessment;
- Do not change any cosmetic habits, including personal hygiene.

8. METHODOLOGY

8.1. General procedures

On the initial visit, the subjects were informed about the study objective, methodology and length, and about the possible expected benefits and the constraints related to the study. After the Informed Consent Form (ICF) signature, the subjects received a copy signed by the person responsible for the application and were referred to the initial assessments.

Initially, a urologist verified the inclusion and non-inclusion criteria of the study and the subjects included received the investigational product, a daily-log of use at home and the questionnaires of the study (T0). They were instructed to use the product according to the sponsor's intake instructions, under normal use conditions, during 28 ± 2 days, and to complete the questionnaires after 3 hours (T3h) of the first investigational product intake and after 1 (T1d), 3 (T3d), 5 (T5d) and 28 (T28) days of investigational product intake. A technician instructed the subject on the correct completion of the questionnaires at home and informed that the subject had to bring the questionnaires completed at the final visit of the study.

At the end of the study, a technician asked the subjects about possible discomfort sensations and, if necessary, the physician would be contacted for examination of the subject.

8.2. Procedure Schedule

Table 2. Study Schedule

Phases	T0	T3h	T1d	T3d	T5d	T28
ICF signature	X	-	-	-	-	-
Urological Clinical Assessment - Eligibility of the inclusion/non-inclusion criteria	X	-	-	-	-	-
Distribution (D) / Restitution (R): • Investigational product • Self-Assessment questionnaires • Daily-log	D	-	-	-	-	R
Self-Assessment Questionnaire completed by study subjects at home	-	X	X	X	X	X
Assessment of investigational product acceptance and compliance by checking the daily-log	-	-	-	-	-	X
Assessment of Adverse Events (if applicable)	-	-	-	-	-	X

8.3. Methods

8.3.1. Urological Clinical Assessment

Subjects were assessed by the urologist at the initial visit (T0) to verify the inclusion and non-inclusion criteria of the study.

Subjects were instructed to contact the study coordinator at any time if they had any complaints. In these cases, they would be referred for evaluation and guidance from the responsible urologist, who would proceed with the examination, classify the reaction and would carry out the appropriate conduct (guidance and/or medication when necessary).

8.3.2. Self-Assessment Performed by the Study Subjects

Subjective questionnaires allow the Sponsor to gauge the subjects' perceptions of the investigational product and its effects. Questions asked for subjects' agreement to a statement with a five-point scale, according to the table below.

Table 3. Time-points, statements and scale of the self-assessment questionnaires

Time-point	Statement	Scale
T3h / T1d / T3d / T5d / T28	After X hours/days of product use, I felt:	5 – Totally agree 4 – Agree 3 – Neither agree, nor disagree 2 – Disagree 1 – Totally disagree
	Improving the ability to get an erection	
	Increased libido and desire for sexual activity	
	Longer lasting erections	
	The ability to have stronger erections	
	Reduced fatigue	
	Reduced anxiety	
	Increased energy levels	
	Enhanced physical function	
	Enhanced muscle strength	
	Faster sexual recovery time	
	Improved erectile function	

8.4. Criteria and Procedures for Study Subjects Withdrawal

The removal of a study subject by the investigator may occur due to the following reasons:

- Study subjects not included: subjects who sign the ICF, but who do not meet the inclusion and non-inclusion criteria of the study;
- Subjects who present complications that affect their eligibility after the study consent;
- Subjects who present - at the Investigator's discretion - any problem that would prevent investigational product applications from continuing, at any time during the study;
- Consent withdrawal by the study subject, regardless of the reason;

- Lack of adhesion of the study subject to the study. A significant lack of adhesion will be recorded if the subject does not visit the study center for assessments;
- Serious Adverse Event;
- Concurrent disorder or treatment: any pathological process or treatment that occurred during the study period and that might interfere with the study investigational product, such as a medication interaction or masking of results.

Those subjects removed from the study by the investigator were supervised in case they presented any event possibly related to the study, even after their removal. Those subjects removed due to occurrence of adverse event were continually supervised until the case is completely resolved.

Those subjects who were removed from study after the inclusion stage were not replaced.

9. ADVERSE EVENTS

An adverse event is any untoward medical occurrence in a patient or clinical investigation subject administered a product and that does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of the investigational product (adapted from ICH, 2016).

According to the Good Clinical Practices (ICH, 2016), a Serious Adverse Event is any untoward medical occurrence that at any dose

- results in death;
- is life-threatening;
- requires inpatient hospitalization or prolongation of existing hospitalization;
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect.

Thus, any new sign, symptom or disease, or clinically significant worsening compared to the condition at the first visit, should be considered an Adverse Event. Lack of clinical or self-assessment efficacy of a cosmetic product or drug is not considered an Adverse Event.

Clinical signs and dermatological or systemic diseases observed during the selection process of the study subjects are not considered as Adverse Events. This information is recorded on the medical assessment form as a reason for non-inclusion and the subjects are then not included in the study.

The adverse events occurred as a result of incorrect investigational product use (either cosmetics or drugs products) - such as inappropriate frequency or incorrect application - are considered as adverse events that do not interfere with the investigational product evaluation, since the subject- in this situation - does not follow the correct use directions stated on the investigational product label.

An Adverse Event Form is completed for all events occurred. The study Sponsor is *notified of an adverse event through a Notification of Occurrence form sent by electronic-mail in the Final* Study Report.

In the case of the appearance of Adverse Event in the current study, images of the signs presented by the subjects would be taken, if applicable. In this image the subject's identity was preserved, and, by signing the informed consent for image release, the subject gave his or her written consented for obtaining and releasing the image.

In case there is an adverse event with doubtful causal nexus, an investigation process is initiated in order to determine if such event is or is not related to the study or investigational product.

The procedures adopted during the event investigation are defined by the physician in charge, based on the nature of the reaction, the subject's medical history and on factors that may interfere with the occurrence of the event, such as medication or other concomitant disorders.

For the conclusion of the final diagnosis, the relation of an Adverse Event can be defined using the decision tree Colipa (2016), according to the following description:

- Very likely: Only cases in which the clinical condition is considered to be evocative will be classified as a very likely nexus, the following conditions occurring together: (i) the temporality of the facts is compatible with an adverse reaction to products and (ii) there is a laboratory test that confirm the relationship with the investigational product (e.g. positive patch test for the investigational product).

- Likely: The cases in which the clinical condition is considered to be evocative will be classified as likely causal nexus, occurring with the following conditions together: (i) the temporality of the facts is compatible with an adverse reaction to cosmetics and (ii) there is no laboratory test to confirm the relationship with the investigational product (e.g. diagnosis of contact dermatitis, without patch test, cosmetic acne - there are no laboratory tests to confirm the relationship with the investigational product).

- Not clearly attributable: Cases in which the clinical scenario is not considered to be evocative or the chronology is not clearly compatible or unknown, will be classified as nexus not clearly attributable.

- Unlikely: The following two cases are associated with an unlikely nexus: the clinical scenario is not considered to be evocative; the chronology is not clearly compatible or unknown, and the result of the investigation with the investigational product is negative (patch test or re-exposure).

- Excluded: The cases in which the diagnosis corresponds to a dermatosis of well-known cause and / or known to be caused by the use of cosmetics will be classified as excluded nexus (e.g. vitiligo, tineas, pityriasis rosea, pityriasis versicolor, psoriasis, folliculitis, solar melanose, ephelides, among others), when there is no correlation between the subject's complaint and the use of a cosmetic product (for example: muscle pain, lack of appetite, stomach pain, diarrhea, insect bites, among others) or the chronology is clearly incompatible with an adverse reaction to the cosmetic product (for example: there is no improvement in the scenario, even with the interruption of the investigational product; there is relapse of the scenario, without the reintroduction of the investigational product; the signs and symptoms started before the start of the investigational product use).

10. APPLICABLE ETHICAL REMARKS

The study was conducted in compliance with the Declaration of Helsinki principles, the applicable regulatory requirements, including Resolution CNS no. 466/2012, and according the Good Clinical Practices (Document of the Americas and ICH E6: Good Clinical Practice).

Before the study starts, the subjects were informed about the study objective, its methodology and length, and about the possibly expected benefits and the constraints related to the study and signed the Informed Consent Form (ICF) (APPENDIX 1) elaborated according to the Declaration of Helsinki and Resolution CNS No 466/2012. The process of obtaining the consent confirmed the voluntary nature of participation in the study.

In order to maintain confidentiality of subjects' data, all data collected were identified by a number given to them at the beginning of the study. No personal information was disclosed in all data analysis. If required, the Principal Investigator must have allowed the study monitor to access all subjects study-related data. This included all documents containing the subject's clinical history for checking suitability for the study, diagnoses and any other document concerning the subject in the study.

All data that were found or proved by the study results are considered as being confidential information and Sponsor's property. No information - as well as all documents generated during the study - will be copied or disclosed without a previous written consent of the Sponsor. All information was kept confidential until the results were published.

The study technical documentation is in the Institute’s files, where it will be stored for a 5-year period.

11. STATISTICAL ANALYSIS

Description of the treatment applied to the data is presented in the table below.

Table 4. Detailed statistical analysis

Data Type	Statistical Method	Data Reported	Sample size
Self-assessment questionnaire	Descriptive Statistics	Positive response percent and frequency (%, n)	32

12. RESULTS

12.1. Protocol Deviations

Subject 037 did not use the investigational product by following the directions checked by verifying the information recorded by the subject in the daily-log. Therefore, subject's data were not considered in the study.

12.2. Population description and Adherence to the Study

Thirty-five (35) subjects were included in the study, from them 32 completed the study. The summarized description of the population and the adherence to the study is available on the following table. The detailed description of the population is available in APPENDIX 2.

Table 5. Included population and adherence to the study

Included population									Adherence		
Recruited[1]	**Non included[2]**	**Withdrawal[3]**	**Included[4]**	**Gender F**	**Gender M**	**Minimum Age (years)**	**Maximum Age (years)**	**Mean Age (years)**	**Absences[5]**	**Removed[6]**	**Completed the Study[7]**
37	02	00	35	00	35	45	65	55	01	02	32
Subjects									022	029 and 037	**-**

[1]*Subjects who attended the Institute and signed the ICF.*
[2]*Subjects that not meet the inclusion criteria or presented any of the non-inclusion criteria.*
[3]*Subjects that withdrew from the study after the study consent for personal reasons and were not included.*
[4]*Subjects that did were approved in the study.*
[5]*Subjects who missed the study for personal reasons unrelated to the study and to the investigational product.*
[6]*Subjects removed from the study are characterized as protocol deviation or another reason recorded by the investigator of the study.*
[7]*Subjects considered in the total who completed the study.*
Caption: F=Female; M=Male

Subject 029 was removed from the study for presenting adverse event as described in the item 12.3.

Subject 037 was removed from the study for characterizing as protocol deviation as described in the item 12.1.

The study achieved its objective to obtain, at its final, a minimum of 30 answers.

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12.3. Adverse Events

During the study 03 subjects presented adverse event. The adverse events are summarized on the following table.

Table 6. Adverse events

Date	Subject Number	Day of the Study	Adverse Event Description	Intensity	Site of the Event	Frequency	Action Taken	Hypothesis or Rational + Diagnosis	Causal Nexus	Data considered in the study
02/28/2023	009	D1	Sleepiness	NA	Systemic	Single Episode	None – End of the study	Since there had been attempts to contact the subject for three consecutive days with no success, the case was closed as loss of follow-up. The information presented in the daily-log were that the subject felt tiredness on the first day of study, not presenting this complaint again on the next days of the study. The case was concluded as not clearly attributable due to a self reexposition and no relapses. The subject finished the study and his data were considered.	Not Clearly Attributable	Yes
02/28/2023	016	D1	Headache	NA	Systemic	Single Episode	None – End of the study	Since there had been attempts to contact the subject for three consecutive days with no success, the case was closed as loss of follow-up. The information presented in the daily-log were that the subject felt headaches on the first day of study not having relapse of complaints on the next days of the study. The case was concluded as not clearly attributable due to a self reexposition and not presenting the complaint again. The subject finished the study and his data were considered.	Not Clearly Attributable	Yes

Table 6. Adverse events (continuation)

Date	Subject Number	Day of the Study	Adverse Event Description	Intensity	Site of the Event	Frequency	Action Taken	Hypothesis or Rational + Diagnosis	Causal Nexus	Data considered in the study
02/08/2023	029	D11 to D14	Stomach Discomfort	Moderate	Stomach	Continuous	None	According to the subject's statement and medical assessment, the case was closed. It was a case of stomach discomfort reported by the subject, that manifested after ingesting food which he was not used to ingest. The scenario lasted around three days, having spontaneous remission and not presenting relapse of the complaint. Since there was negative reexposure on his own and not being possible to establish if there was or not a connection with the investigational product, the case was closed as not clearly attributable.	Not Clearly Attributable	No

NA = Not Applicable

12.4. Self-Assessment Performed by the Study Subjects

The table below present the percentage of subjects who were in agreement (responding “Totally agree” or “Agree”) to the statements presented after 3 hours (T3h) of the first investigational product intake and after 1 (T1d), 3 (T3d), 5 (T5d) and 28 (T28) days of investigational product intake.

Table 7. Percentage and Frequency of Agreement per time-point

Statement	Agreement % (n)				
After X hours/days of product use, I felt:	T3h	T1d	T3d	T5d	T28
Improving the ability to get an erection	50.0% (16)	53.1% (17)	62.5% (20)	71.9% (23)	87.5% (28)
Increased libido and desire for sexual activity	43.8% (14)	53.1% (17)	59.4% (19)	62.5% (20)	65.6% (21)
Longer lasting erections	43.8% (14)	56.3% (18)	68.8% (22)	75.0% (24)	81.3% (26)
The ability to have stronger erections	46.9% (15)	56.3% (18)	62.5% (20)	59.4% (19)	68.8% (22)
Reduced fatigue	46.9% (15)	59.4% (19)	65.6% (21)	65.6% (21)	68.8% (22)
Reduced anxiety	40.6% (13)	46.9% (15)	59.4% (19)	56.3% (18)	65.6% (21)
Increased energy levels	56.3% (18)	68.8% (22)	62.5% (20)	65.6% (21)	75.0% (24)
Enhanced physical function	46.9% (15)	56.3% (18)	56.3% (18)	65.6% (21)	71.9% (23)
Enhanced muscle strength	56.3% (18)	62.5% (20)	62.5% (20)	59.4% (19)	68.8% (22)
Faster sexual recovery time	53.1% (17)	59.4% (19)	65.6% (21)	75.0% (24)	71.9% (23)
Improved erectile function.	59.4% (19)	65.6% (21)	71.9% (23)	75.0% (24)	78.1% (25)

13. CONCLUSION

According to the methodology used to assess the efficacy of the investigational product **ASOX9 Men's Vitality Supplement**, submitted by the company **TH GENESIS**, it could be concluded that:

13.1. Self-Assessment Performed by the Study Subjects

Statement	Agreement %				
After X hours/days of product use, I felt:	T3h	T1d	T3d	T5d	T28
Improving the ability to get an erection	50.0%	53.1%	62.5%	71.9%	87.5%
Increased libido and desire for sexual activity	43.8%	53.1%	59.4%	62.5%	65.6%
Longer lasting erections	43.8%	56.3%	68.8%	75.0%	81.3%
The ability to have stronger erections	46.9%	56.3%	62.5%	59.4%	68.8%
Reduced fatigue	46.9%	59.4%	65.6%	65.6%	68.8%
Reduced anxiety	40.6%	46.9%	59.4%	56.3%	65.6%
Increased energy levels	56.3%	68.8%	62.5%	65.6%	75.0%
Enhanced physical function	46.9%	56.3%	56.3%	65.6%	71.9%
Enhanced muscle strength	56.3%	62.5%	62.5%	59.4%	68.8%
Faster sexual recovery time	53.1%	59.4%	65.6%	75.0%	71.9%
Improved erectile function	59.4%	65.6%	71.9%	75.0%	78.1%

Therefore, the following claims can be supported by the Self-Assessment:

- *Improvement on the ability to get an erection*;
- *Increased libido and desire for sexual activity*;
- *Longer lasting erections*;
- *Improvement on the ability to have stronger erections*;
- *Reduced fatigue;*
- *Reduced anxiety;*
- *Increased energy levels;*
- *Enhanced physical function;*
- *Enhanced muscle strength;*
- *Faster sexual recovery time;*
- *Improved erectile function.*

Gabrielli Brianezi
Principal Investigator
04/19/2023

José Marcos M. Vendramini
Statistician in Charge
04/19/2023

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APPENDIX 1. INFORMED CONSENT FORM

Sub No.: _____

INFORMED CONSENT FORM

STUDY PROJECT TITLE: ASSESSEMENT OF THE EFFICACY OF AN ORAL SUPPLEMENT PRODUCT THROUGH SELF-ASSESSMENT QUESTIONNAIRE PERFORMED BY THE STUDY SUBJECT, UNDER NORMAL USE CONDITIONS.

NAME OF THE INVESTIGATOR IN CHARGE: Gabrielli Brianezi

STUDY CENTER: Allergisa Pesquisa Dermato-Cosmética Ltda.

You are being invited to join a study that will be carried out by Allergisa's staff together with the company that is sponsoring this study.

Before any decision, it is important that you read attentively all information presented, and if you decide to join, you will be requested to sign two originals of this informed consent form and one original will be given to you.

Your participation in this study is completely voluntary and it depends only on your will, and you are also free to withdraw from the study at any time.

Any doubts you might have before, during, or after the study will be promptly solved.

This study is being done with all the safety measures necessary to avoid contamination by coronavirus, which causes the disease COVID-19. If you agree in taking part of this study, please follow the instructions below to keep your own safety.

What are the objectives of this study?

The objective of the study is to assess the efficacy of an oral supplement through the self-assessment questionnaires, based on your perception, under normal use conditions.

Can I join the study?

To participate in the study, firstly you must present good health and meet other requirements called inclusion and non-inclusion criteria, that will be assessed and discussed by a urologist.

You can even be dismissed by the expert physician, after signing the informed consent form, if you present any of the non-inclusion criteria of the study, also in case the total amount of subjects was already reached.

How many people will join this study?

The study will be conducted with up to 35 subjects.

Where will the study be conducted?

The study will be conducted at one of the facilities of ALLERGISA pesquisa dermato-cosmética Ltda., head office located at 452/466 Dr. Romeu Tórtima Avenue – Barão Geraldo – Campinas – SP, with all the necessary precautions for your safety.

What are the study procedures? What will I have to do?

Your participation in the study will last 28 (± 2) days. During this period, 02 visit will be made.

- **In the visit 1:**

You will be informed about the study objective, its methodology and duration, and about the possibly expected benefits and the constraints related to the study and, if you agree, you will sign this Informed Consent Form.

You will be clinically assessed by a urologist.

You will receive the test product to use at home during 28 (± 2) days.

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You will receive a daily-log with the use instructions described on it and you should complete it as the use of the product. By signing this informed consent, you will guarantee the truthfulness of information provided.

You will receive the study questionnaires and will be instructed on how to answer the questionnaires after 3h, 1 day, 3 days and 5 days of using the product at home.

The time of stay in this visit will be up to 01 hour.

- **In the visit 2:**

You will go through a technical assessment.

You must return the test product.

You must return the diary-log completed as the applications made at home.

You must return questionnaires filled.

The time of stay in this visit will be up to 01 hour.

IMPORTANT!!!

During these visits, all the precautions recommended by health experts will be taken to ensure your safety and the safety of the study team, in order to avoid the contagion of COVID-19 disease. Masks will be provided by the Institute for use during your stay at the Institute and during the whole study, and there will be gel alcohol hand sanitizer available. The rooms will be cleaned and disinfected with 70% alcohol, there will be appropriate distancing between people, scheduled and individual appointments and a measurement of your temperature at a distance always when necessary.

We ask you to be at the Institute ONLY at the time informed to you, in order to avoid crowds.

If you present any symptoms related to the disease (coryza, headache, sore throat, fever, shortness of breath, etc.), do not come to the Institute. You must call use so we can schedule a teleconsultation with a physician, we will inform you about the procedures to be followed.

The teleconsultation is a remote appointment performed by a doctor through a telephone call or video conference. During the teleconsultation, you will be ensured of the confidentiality of the medical attention, that is, that it was done in a place where only the physician and the authorized person of the technical department were present during the call.

Your adherence to the visits schedule is important for the study results. In case you cannot come on the scheduled date, please, contact the investigator or the study team and check the possibility of returning as soon as possible for the visit.

What information will be obtained about me?

Personal information such as name, age, usual medications, etc., will be obtained.

For this study, information will be obtained about your health through the clinical assessments, about possible adverse reactions that the product might cause on your skin. If you present an adverse reaction with clinical sign on the skin (reaction that is able to be observed by the naked eye: irritation, redness, swelling, etc.), photos will be taken with the single purpose of investigation of the reaction and of record of these information. Your identity will be preserved.

For this study, answers will also be obtained through applied questionnaires, about product qualities and your opinion about it. You will not be identified in these questionnaires.

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How will the information be protected in order to preserve my privacy?

All information obtained about you, from your participation in this study, will be treated confidentially, and your identity will be kept confidential, under all circumstances. The information collected about you will be used only with the investigation purposes."

Your identity will be kept confidential throughout the process and only the study investigator or people from the team delegated will have access to those records.

If the study results are published, your identity will remain confidential.

If necessary to perform the teleconsultation, it will be performed with a tool that presents data safety, ensuring confidentiality of the medical attention.

It is possible that during the study, a monitor of the sponsor may be present to observe the study.

According to Law No. 13.709, of August 2018, concerning the General Data Protection Law, Allergisa Pesquisa Dermato-Cosmética LTDA, together with the sponsor, declares to be in compliance with all obligations applicable to the Personal Data Processing (including any and all obligations of information to the Data Subject). Allergisa Pesquisa Dermato-Cosmética LTDA guarantees the continuous monitoring of risks and failures of Information Security that may compromise your personal data (such as name, last name, ID, "CPF", address, etc.), and the sensitive personal data (personal information concerning health, ethnic group, racial origin, political party preferences, among others), through our platforms of digital information storage.

In case any of your register data change (e.g., telephone number, address etc.), please ask the study organizers to have them updated.

What are my responsibilities in this study?

You should attend the institute on the days determined for each visit. In addition, there are some restrictions that you will follow, such as:

- Not to use any other product f oral supplement, which may interfere with the study assessment;
- Not to change any cosmetic habits, including personal hygiene.
- You cannot perform any urological treatment during the study. If the treatment is necessary, immediately inform the study center.
- We ask you to communicate the study center about any type of medication or external/skin use, or oral route tablets and liquids (solutions and syrups) or injections, such as cortisone, anti-allergic or any other.

The product must be used exclusively by yourself.

If you change any of your habits, we ask that you please keep us informed, so we can better interpret the results.

We ask that you do not use any other type of oral supplement product while using the product. If you use any of these products or are taking any medication, please, let us know.

Can I withdraw from the study at any time?

Yes, you are completely free to withdraw from the study at any time, not having to worry with any negative consequences. You can also withdraw your data (information given) at any time, if you wish.

In case of new information available that can change your desire to continue your participation in the study,

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you will be timely communicated by the investigator and study team and you will be completely free to withdraw from the study. Just let us know about your desire to give up.

What benefits will I have to join the study?

Studies in the area of health product area aim to prove the safety and action of the products.

By taking part of this study, you will be contributing that these products are used by the population with an action of promoting the improvement in sexual activity if its efficacy is proven. You will also undergo free medical assessments and instructions on how to use the product, in order to assure better results.

Is there any risk related to the study participation?

All raw materials used in the product are approved for use and are not toxic. In case of any reaction to the ingestion of the investigational product, such as gastric intolerance (stomach pain, nausea and vomiting, among others), skin allergies or other complaints and/or signs, the use of the product must be discontinued.

The risks presented are already known, and if they occur, they will be as minimized as possible. You will be clinically supervised by the study site, until your health clinical conditions are reestablished, regardless of the time that it might take.

Any health problems you might have during the study should be informed to the investigator or study team immediately. All immediate or late assistance will be provided.

About the risk of contracting COVID-19, it exists if you decide to join the study or not. If you are vaccinated, the risk of having severe symptoms is lower. All measures required will be taken here at the Institute for your safety. However, if you have symptoms related to the disease such as cough, fever, sneezing, runny nose, body pains, among others, do not attend the institute and notify us immediately. In this case a test for diagnosis of COVID-19 may be performed, as one more measure of safety taken by the Institute.

In case of suspect or confirmation by COVID-19, you must follow the recommendations that the Institute will provide based on the health organs. All immediate or full assistance will be provided and, if a diagnosis by Covid-19 is confirmed, all the instructions to perform a quarantine or seek hospital attention will be given according to the recommendations of the health organizations. The subject will be supervised by the Institute, until his/her health is reestablished.

Will I have any type of reimbursement for the expenses for participating in this study?

As predicted by Brazilian laws, you will not have any type of financial compensation/payment for your participation in the study; however, you will receive a reimbursement in the end of the study due to expenses of your participation.

If you are removed from the study before its conclusion by the investigator in charge, for safety reasons or non-compliance with the study requirements, or even by default, you will be given a compensation for the costs related to transportation and food, referring to the days you participated, if any.

How can I know about the study results?

The study results will be assessed by the investigator in charge after it is completed. The results can be published, but your name will not be mentioned.

You can still ask to the investigator about the study results after the conclusion of the study.

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Can I be removed from the study?

Yes, your participation in this study can finish earlier than predicted.

It is duty of the investigator, at any moment, to remove you from the study, if you present any reaction to the product or if your health has been affected for any reason and you are not in conditions to continue as a study subject.

You can also be removed from the study in case you do not fulfill your responsibilities, according to the study protocol.

What if my participation in the study interferes with any other medication I am currently taking?

It is highly important that you inform the investigator in charge of the study about the use of usual medications, or use of any other different medication when you sign this document and during your participation.

In case you need to take a specific medication, non mentioned previously, you should communicate the study investigator immediately, because he/she will know how to give you instructions about the best conduct for your case.

Who will I be able to contact if I do not feel well during the study or present any reactions to the study?

If you do not feel well or in case of any irritation skin signs, immediately communicate, attending the study site or by telephone 19-3517-6800 (working hours) or 19-99778-0204 (from 5 pm to 10 pm). In case of any doubts or problems, you can contact the investigator in charge (Gabrielli Brianezi) or medical team through the same telephone numbers.

We assure that, for any complications or damages caused by the study, a full assistance will be given to the study subjects together with the sponsors of this study.

Eventual Indemnifications for damages caused by the study are assured.

We ask you to call the Institute at any moment if you feel symptoms such as cough, fever, coryza, sore throat or shortness of breath, or if you would like to cancel your participation in the study, through the telephones 19-3517-6800 (business hours) or 19-99778-0204 (from 5 p.m. to 10 p.m.). Subjects who present these symptoms will not be allowed to participate in the study and if you arrive at the Institute with the symptoms, you will not be allowed inside and will be instructed to go home.

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Important information!

If you have any questions about the study that were not answered yet, you should ask the investigator or study team.

Please, keep this document for your information.

Signatures - ASSESSEMENT OF THE EFFICACY OF AN ORAL SUPPLEMENT PRODUCT THROUGH SELF-ASSESSMENT QUESTIONNAIRE PERFORMED BY THE STUDY SUBJECT, UNDER NORMAL USE CONDITIONS.

I read and understood the information provided in this Informed Consent Form. I have obtained the answers for all my questions and I freely decided to join this study. I offer my consent, freely, to join this study, as explained in this document.

I am aware that the photos taken for the investigation procedure, in case of any reaction, are part of the procedure of this study and I agree with those images capturing, since my identity is preserved.

By signing this document, I did not waive from any legal rights I have when I participate in a study, including the indemnification.

01										
	Initials of the study subject	Date (MM/DD/YYYY)								
	Signature of the Study Subject (as in the ID or Driver's License)									

02										
	Signature of the person in charge of explaining the IC	Date (MM/DD/YYYY)								

APPENDIX 2. STUDY GROUP

SUBJECT	AGE (YEARS)	GENDER	STATUS
001	56	M	I
002	54	M	I
003	54	M	I
004	61	M	I
005	56	M	I
006	65	M	I
007	45	M	I
008	45	M	I
009	58	M	I
010	53	M	I
011	59	M	I
012	45	M	I
013	56	M	I
014	58	M	I
015	64	M	I
016	46	M	I
017	63	M	I
018	60	M	I
019	50	M	I
020	53	M	I
021	49	M	I
022	53	M	I
023	52	M	I
024	47	M	I
025	55	M	I
026	56	M	NI
027	57	M	I
028	46	M	I
029	55	M	I
030	53	M	I
031	64	M	I
032	63	M	I
033	58	M	NI
034	54	M	I
035	56	M	I
036	62	M	I
037	53	M	I

Caption:
M = Male

I = Included

NI = Not Included (to present any non-inclusion criteria and/or not present some of the inclusion criteria)

APPENDIX 3. INVESTIGATIONAL PRODUCT INFORMATION

“FORMULA NOT SUBMITTED”