Study of the effect and cosmetic properties of a product through evaluations and instrumental analysis performed by professionals under medical supervision and consumer self-assessments

RDV SRL

Gel Aquavis anti-acne

Report no.

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INTRODUCTION

The clinical trial protocols are audited and approved by the Technical Scientific Committee (TSC) of Bio Basic Europe S.r.l., whose functions, compositions and procedures are described in the document "Statute - Regulation" (Ann. C). The TSC ascertains the protocol's completeness, confirms the adequacy of the documentation and the conformity of the procedures and methodologies followed in designing and developing the research project, in compliance with the applicable legislation. The protocol is audited by at least the following mandatory members of the TSC:

a) The Chairman and/or the Vice Chairman of the TSC
b) The University of Pavia Director of Research
c) The Investigator/Medical Director of the CDC Dermo Clinical Research Institute
d) The expert of Bio Basic Europe S.r.l. depending on the issue on which the opinion is formulated

The final report is signed by the Investigator/Medical Director of the CDC Dermo Clinical Research Institute and, subsequently, by the Safety Assessor, who attests the document's validity, affixing a digital signature.

PERSONS RESPONSIBLE FOR SIGNING THE PROTOCOL

Safety Assessor
CLAUDIO ANGELINETTA, Vice Chairman of the Technical Scientific Committee, Chemist/Cosmetic Chemist, Degree in Chemistry, Specialisation in Cosmetic Sciences and Technologies, University of Milan.

Investigator
Dr. FERNANDO MARCO BIANCHI M.D., Bio Basic Europe S.r.l. CDC Dermo-Clinical Research Institute Health Director, medical surgeon specialist in dermatology and venereology.

LEGAL AND CONTRACTUAL INFORMATION

- The protocols are drafted in accordance with the applicable legislation, the guidelines of the Technical Scientific Committee and the provisions of the research contracts in force between Bio Basic Europe S.r.l. and the University of Pavia (contract dated 01/09/2019 and further renewals with the L. Spallanzani Faculty of Biology and Biotechnologies).
- In accordance with the applicable regulatory framework and the Helsinki declaration (Regulation (EC) no. 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products), the volunteers are adequately informed of the purpose, the methods and the characteristics of the clinical study, the beneficial effects and the possible side effects. Each volunteer signs the informed consent form as a sign of acceptance, which is managed and archived in accordance with the internal procedures of the Quality Management System of Bio Basic Europe S.r.l.
- This clinical trial was conducted at the CDC Dermo Clinical Research Institute, in accordance with the guidelines dictated by the Technical Scientific Committee.
-
- Based on the experience of Bio Basic Europe, it is recommended to check, once every three years, its harmonisation with any regulatory update.
- This final technical report was drafted by: SARA CIRILLO, Bio Basic Europe Clinical Protocol Researcher, Bachelor's Degree in Biotechnology, University of Sannio and Master's Degree in Pharmaceutical Biotechnology, University of Milan.

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ABSTRACT

The primary objective of this clinical trial is to assess whether the cosmetic product Gel Aquavis anti-acne has a sebum-balancing effect and an effect in reducing skin redness and visibility of acne imperfections. The activity of the product was evaluated analysing the reduction of the sebum and the improvement of skin redness and visibility of acne imperfections.

The trial also has the following secondary objectives: to assess whether a positive pleasantness and effect of the product are perceived.

It was performed a clinical study and the tested product was assigned to 20 enrolled subjects. They were asked to apply the product on the zone to be treated, three times a day for 28 consecutive days. Specific end-point variables were analysed at baseline time (before the use of the product) and after 28 days of treatment.

The results obtained by the test demonstrated the primary objective of the study: the sebum-balancing effect and the effect in reducing skin redness and visibility of acne imperfections. It was observed an improvement of all studied primary end-points, after product use.

Along with this phenomenon, it was also perceived a good pleasantness and effect of the product.

OBJECTIVES

Primary objective

The aim of this study is to assess whether the cosmetic product Gel Aquavis anti-acne has a sebum-balancing effect and an effect in reducing skin redness and visibility of acne imperfections.

Primary endpoints:

- Sebum (quantitative endpoint)
- Skin redness (qualitative endpoint)
- Visibility of acne imperfections (pimples) (qualitative endpoint)

Secondary objectives

A series of sensory self-evaluations were collected by the enrolled subjects, with the aim of evaluating the effect and pleasantness of use of the product.

Secondary endpoints:

- Subjective evaluations (quantitative discrete endpoint)

STUDY CHARACTERISTICS

Study design

The effect of the product was evaluated by comparing the results obtained after the application with the baseline data.

The perceived pleasantness and effect were evaluated by analysing the results obtained after the application of the product.

Sample size

Based on Bio Basic Europe experience, by considering the type of product, the objectives of the trial and taking into account any possible drop-out, the sample size is composed of 20 subjects.

Eligibility criteria

The subjects participating in the study were screened under medical supervision and enrolled according to the following inclusion criteria:

- both male and female sex;
- age between 18 and 60 years;
- with acne-prone skin;
- good general health status/absence of psychological and/or cognitive disorders;
- absence of dermatological and allergological pathologies (cosmetological or to other specific excipients) or other pathologies (such as irritative reactions of unknown origin);
- absence of ongoing pharmacological treatments which may affect the outcome of the test;
- non-participation in other clinical trials in the previous 30 days;
- informed consent obtained.

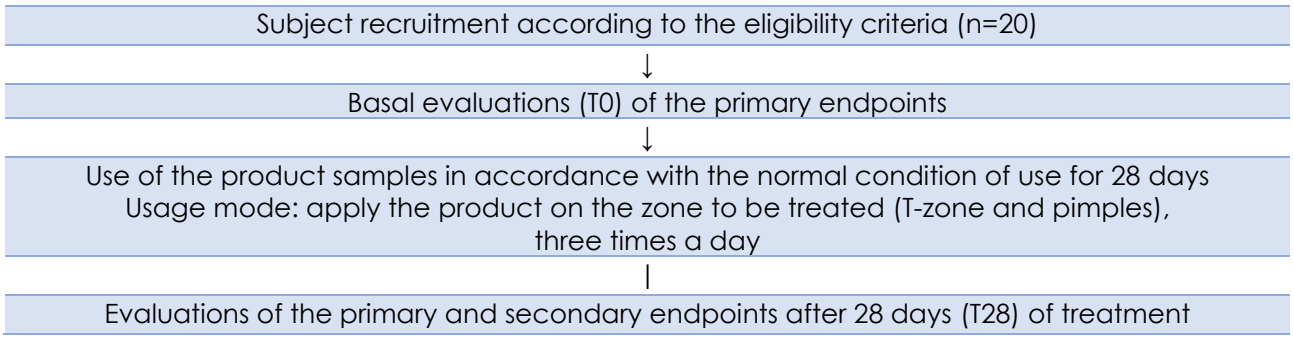
Randomization

Not applicable.

Blindness

The subjects received the product without packaging or indications regarding the manufacturer's brand to avoid the distortions caused by the conditioning effect of the awareness of the product.

Trial scheme



Criteria for the subject withdrawal

The following rules were imposed on a possible subject withdrawal which may occur during the trial:

- breach of one of the inclusion/exclusion criteria;
- development of adverse effects.

Endpoints

- Quantitative endpoints

o Sebum (instrumental analysis)
Measured by SEBUMETER SM 815 (µg/cm2)

The measuring principle is based on a photometric method: a mat surface in contact with sebum becomes more transparent; the instrument measures the transparency of a tape before and after placing it on the measurement skin area or sculpt, thus allowing the calculation of the deposited sebum.

- Qualitative endpoints

o Skin redness (clinical evaluation)
o Visibility of acne imperfections (pimples) (clinical evaluation)

The variables are evaluated by the professionals responsible for the trial according to the following ordinal scale: Very marked – Marked – Moderate – Slight – Absent.

- Quantitative discrete endpoints

The subjects enrolled in the trial are asked to fill in a survey, which consists of numerical rating scale questions.

Specifically, it is used the 11-point Numerical Rating Scale (NRS), which ranges from 0 to 10 (0 is the minimum value and 10 the maximum one). The answerers are asked to indicate the numeric value which best describe their response.

The basal and long-term measurements and evaluations are carried out in the treatment sites following a rest period of at least 20 minutes in an air-conditioned room with controlled and regulated temperature and humidity (temperature = 21°C +/- 2°C and humidity 40%-60%).

Data analysis and statistical analysis

- Quantitative endpoints

  The data on the quantitative endpoint were described using the normal position and dispersion measurements: mean and standard deviation/median and interquartile range.

  A Shapiro-Wilk test was used to verify the normality of the distribution of the differences between the paired measurements. Furthermore, it was checked the independence of the observations.

  When assumptions were fulfilled, a paired samples Student t-test was used for comparing the data obtained at the two observation times.

  When assumptions were violated, a non-parametric approach was applied.

  The symmetry of the distribution of the differences between the paired evaluations was verified and the most appropriate paired samples non-parametric test (Wilcoxon signed rank test/Sign test) was used for comparing the data obtained at the two observation times.

  A significance level of <0.05 was considered.

  Analyses were performed using RStudio 2022.07.1 Build 554 © 2009-2022 RStudio, PBC.

- Qualitative endpoints

  The data on the qualitative endpoints were described using the normal position and dispersion measurements: median and interquartile range. Furthermore, the absolute frequencies of the number of feedbacks given at each observation period were summarized.

  For each end-point variable it was checked that the distribution of the differences between the paired evaluations were symmetric.

  The most appropriate paired samples non-parametric one-tailed or two-tailed test was then used (Wilcoxon signed rank test/ Sign test) for comparing the data obtained at the two observation times.

  A significance level of <0.05 was considered.

  Analyses were performed using RStudio 2022.07.1 Build 554 © 2009-2022 RStudio, PBC.

- Quantitative discrete endpoints

  The data on the quantitative discrete endpoints were described using the median. For each self-evaluation question, the percentage frequencies of each score were calculated, at each observation time.

  Finally, the percentage frequencies of the responses were summarized: responses ≥7 and ≥6 were considered respectively as fully positive and positive.

  The conclusions about the self-assessment test were drawn from an overall analysis of the medians of responses to all the questions, as shown in the table below:

Overall median	Conclusion
$x < 6$	Insufficient pleasantness and perceived effect
$6 \leq x < 7$	Sufficient pleasantness and perceived effect
$7 \leq x < 8$	Moderate pleasantness and perceived effect
$8 \leq x < 9$	Good pleasantness and perceived effect
$x \geq 9$	Excellent pleasantness and perceived effect

RESULTS

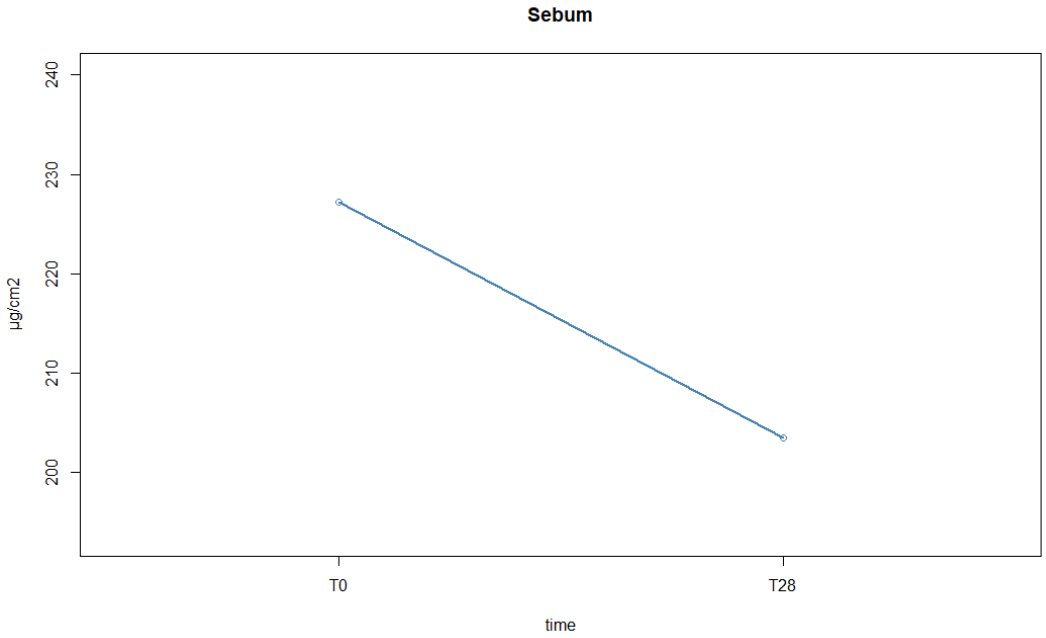
During the trial, no subject developed undesirable effects or breached the established inclusion/exclusion criteria. Furthermore, there were no cases of drop-out. Therefore, the analysis refers to a sample of 20 subjects.

Sebum

Descriptive analysis

Survey times	Mean	±	Standard deviation	Median	IQR		
T0	227	±	28	226	210	-	245
T28	204	±	21	208	189	-	222

Description of the variable sebum at the two time points



Trend of the variable sebum at the two time points

Compared to the baseline value (T0), it is observed a 10% decrease of the variable sebum after 28 days of treatment.

Paired t-test

p-value and significance		
	T0	
T28	<0,001	**yes**

Paired samples t-test comparing the means of the variable sebum at the two time points

The table shows a statistically significant difference between the means of the two comparison groups. The treatment had a significant effect on the parameter sebum.

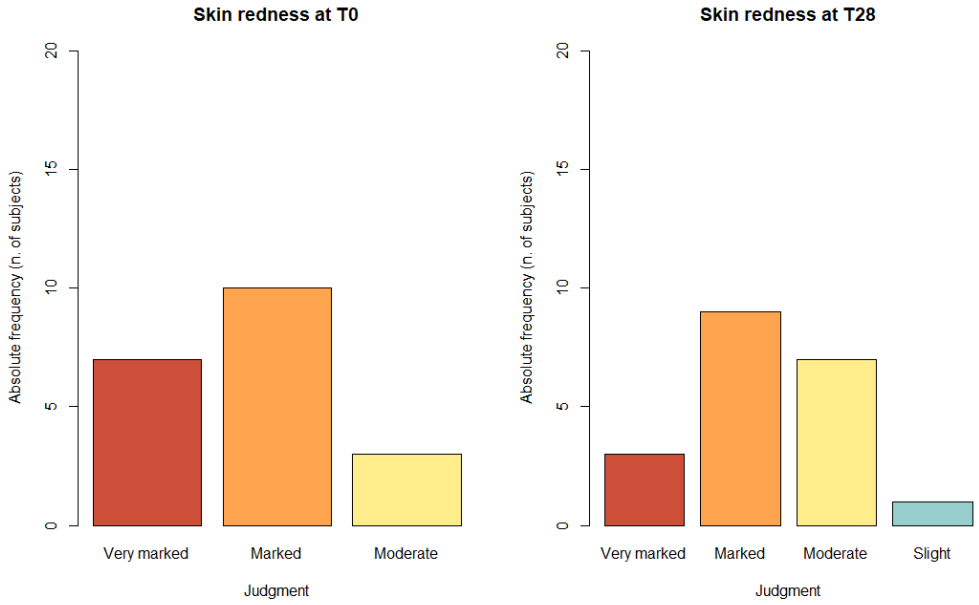
Skin redness

Descriptive analysis

Survey times	Median	IQR		
T0	Marked	Very marked	-	Marked
T28	Marked	Marked	-	Moderate

Absolute frequency (n. subjects)		
Judgement	**T0**	**T28**
Very marked	7	3
Marked	10	9
Moderate	3	7
Slight	0	1
Absent	0	0

Description of the variable skin redness and table of the absolute frequencies of the judgments at the two time points



Graphs of the absolute frequencies of the judgments on the variable skin redness at the two time points

Analysing the frequencies of the judgments on the variable skin redness, it can be seen that they tend to have a distribution shifting to more positive categories after 28 days of treatment.
Specifically, the variable skin redness shows an improvement in the 50% of volunteers.

Wilcoxon signed rank test

p-value and significance		
	T0	
T28	0,002	**yes**

Wilcoxon signed rank test used to compare the variable skin redness at the two time points

The table shows a statistically significant difference between the two comparison groups. The treatment had a significant effect on the variable skin redness.

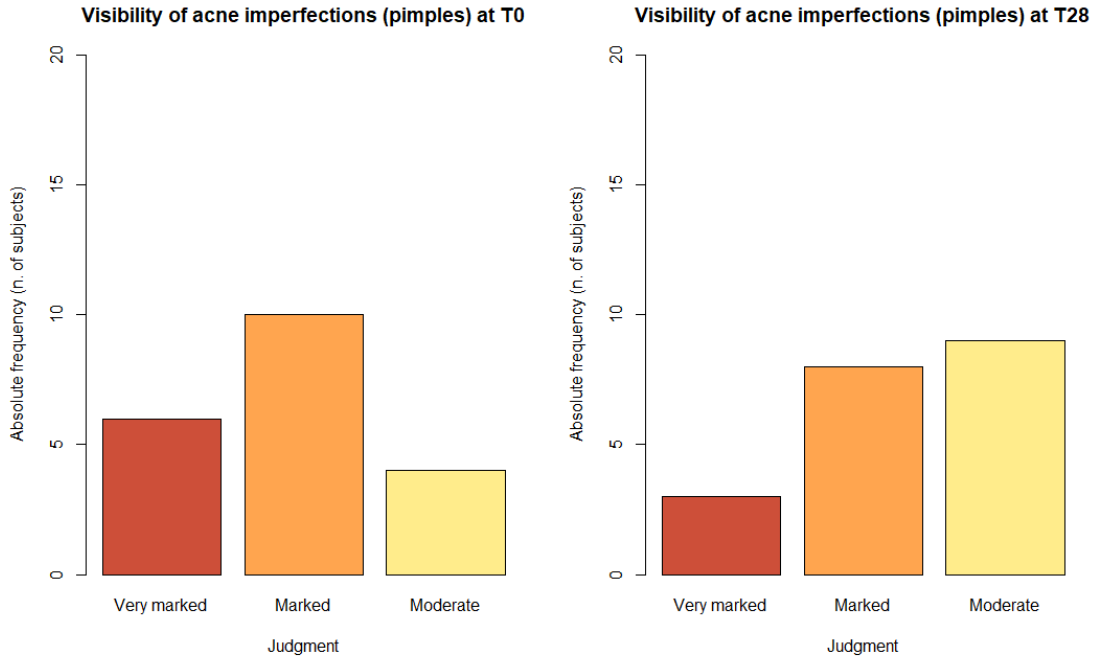
Visibility of acne imperfections (pimples)

Descriptive analysis

Survey times	Median	IQR	
T0	Marked	Very marked	Marked
T28	Marked	Marked	Moderate

Absolute frequency (n. subjects)		
Judgement	**T0**	**T28**
Very marked	6	3
Marked	10	8
Moderate	4	9
Slight	0	0
Absent	0	0

Description of the variable visibility of acne imperfections (pimples) and table of the absolute frequencies of the judgments at the two time points



Graphs of the absolute frequencies of the judgments on the variable visibility of acne imperfections (pimples) at the two time points

Analysing the frequencies of the judgments on the variable visibility of acne imperfections (pimples), it can be seen that they tend to have a distribution shifting to more positive categories after 28 days of treatment.
Specifically, the variable visibility of acne imperfections (pimples) shows an improvement in the 40% of volunteers.

Sign test

p-value and significance		
	T0	
T28	0,008	**yes**

Sign test used to compare the variable visibility of acne imperfections (pimples) at the two time points

The table shows a statistically significant difference between the two comparison groups. The treatment had a significant effect on the variable visibility of acne imperfections (pimples).

Subjective evaluations

Questions	Median of responses	% Frequency of responses	
		positive ≥6	fully positive ≥7
Do you think the product controls sebo production/is sebum-balancing?	8	100%	80%
Do you think this product helps reduce acne blemishes (pimples, pustules, etc.)?	8	100%	90%
Do you think this product helps reduce redness and inflammation around acne blemishes (pimples, pustules etc.)?	7,5	75%	60%
Have you noticed an improvement in the general condition of your skin?	8	100%	90%
Do you find the gel texture of the product pleasant?	8	90%	85%
Overall product assessment	8	100%	90%
Would you buy the product?	8	100%	85%

Summary table of the medians calculated on the responses to the self evaluation survey and percentage frequencies of positive and fully positive answers

The table above shows that the 75%-100% of enrolled subjects gave a positive reply to the questions and the 60%-90% a fully positive one, after 28 days of treatment.

Furthermore, the medians show overall that the subjects perceived a good pleasantness and effect of the product, after 28 days of treatment.

CONCLUSIONS

The results obtained by the test demonstrated the primary objective of the study: the sebum-balancing effect and the effect in reducing skin redness and visibility of acne imperfections of the product **Gel Aquavis anti-acne**. It was observed an improvement of all studied primary end-points, after product use.

Along with this phenomenon, it was also perceived a good pleasantness and effect of the product.

Investigator	Safety Assessor/Technical Scientific Committee Vice Chairman
Dr. Fernando Marco BIANCHI, M.D.	Dr. Claudio ANGELINETTA

BIBLIOGRAPHY

[1] "Regulation (EC) no. 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products".

[2] "Declaration of Helsinki - ethical principles for medical research involving human subjects adopted by the 18th wma general assembly, Helsinki, Finland, june 1964, and consecutive amendments (last amendment: 64th wma general assembly, Fortaleza, Brasil, Oc".

[3] "GUIDELINES FOR COSMETIC PRODUCT CLAIM SUBSTANTIATION Revising and expanding the Colipa Guidelines on Efficacy (2001/rev. 2008) 22 May 2019 Cosmetics Europe – The personal care association".

PRODUCT INFORMATION - INGREDIENT LIST

INCI

Annex B

DATA TABLES

The results reported in this document are to be referred exclusively to the tested sample, whose safety was previously assessed.

Sebum (µg/cm2)		
Vol. n°	**T0**	**T28**
1	242	208
2	230	210
3	204	193
4	178	164
5	253	227
6	210	194
7	212	188
8	275	235
9	258	231
10	231	207
11	241	210
12	210	190
13	241	223
14	266	235
15	262	221
16	176	164
17	218	196
18	220	185
19	197	182
20	221	208

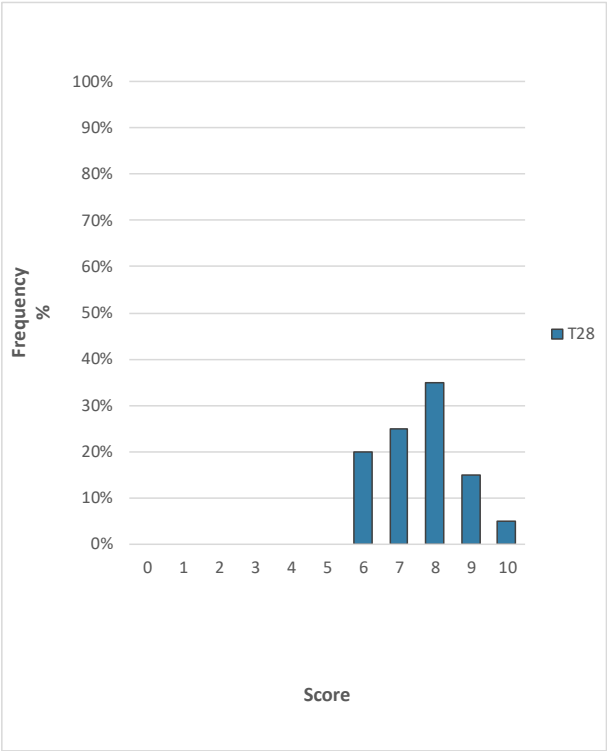
Skin redness		
Panellist code	**T0**	**T28**
1	Marked	Moderate
2	Marked	Moderate
3	Marked	Marked
4	Moderate	Slight
5	Very marked	Very marked
6	Marked	Marked
7	Marked	Moderate
8	Very marked	Very marked
9	Very marked	Marked
10	Marked	Marked
11	Very marked	Marked
12	Marked	Marked
13	Very marked	Very marked
14	Very marked	Marked
15	Marked	Moderate
16	Moderate	Moderate
17	Very marked	Marked
18	Marked	Moderate
19	Moderate	Moderate
20	Marked	Marked

Visibility of acne imperfections (pimples)		
Panellist code	**T0**	**T28**
1	Very marked	Marked
2	Marked	Marked
3	Moderate	Moderate
4	Moderate	Moderate
5	Very marked	Very marked
6	Marked	Marked
7	Marked	Moderate
8	Marked	Marked
9	Very marked	Marked
10	Marked	Moderate
11	Very marked	Marked
12	Marked	Marked
13	Very marked	Very marked
14	Very marked	Very marked
15	Marked	Moderate
16	Moderate	Moderate
17	Marked	Moderate
18	Marked	Moderate
19	Moderate	Moderate
20	Marked	Marked

Do you think the product controls sebo production/is sebum-balancing?

Vol. n°	Judgement T28
01	7
02	9
03	8
04	6
05	7
06	10
07	8
08	6
09	8
10	8
11	8
12	9
13	6
14	7
15	7
16	6
17	8
18	9
19	7
20	8
Median	8,0

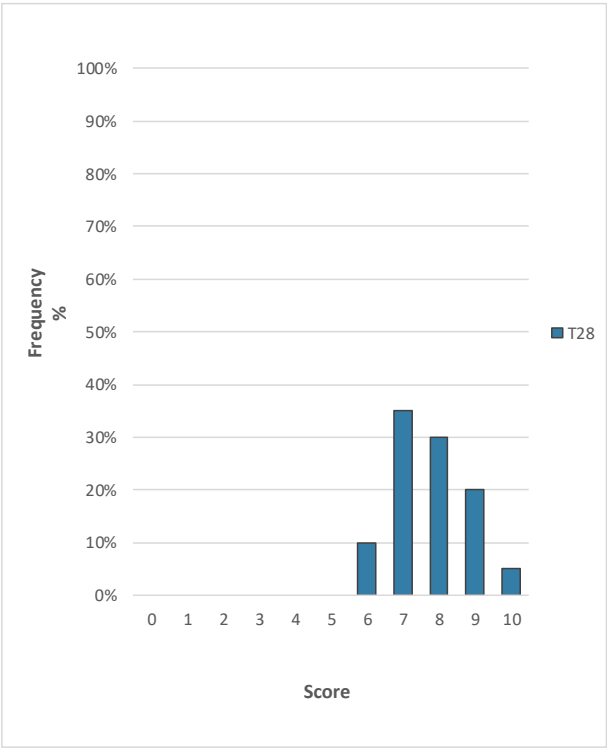
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	0%
6	20%
7	25%
8	35%
9	15%
10	5%



Do you think this product helps reduce acne blemishes (pimples, pustules, etc.)?

Vol. n°	Judgement T28
01	8
02	7
03	8
04	7
05	8
06	10
07	9
08	7
09	7
10	9
11	8
12	9
13	6
14	7
15	7
16	8
17	8
18	9
19	6
20	7
Median	8,0

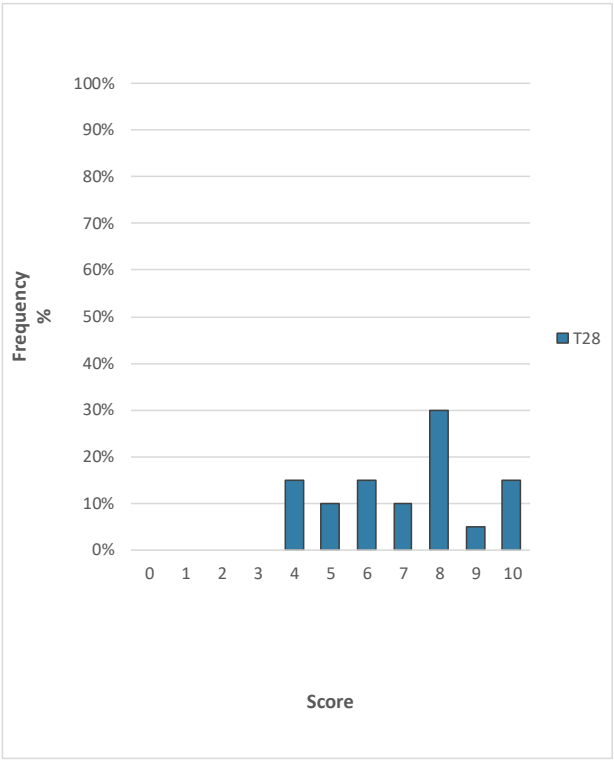
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	0%
6	10%
7	35%
8	30%
9	20%
10	5%



Do you think this product helps reduce redness and inflammation around acne blemishes (pimples, pustules etc.)?

Vol. n°	Judgement T28
01	8
02	10
03	8
04	10
05	7
06	10
07	8
08	6
09	8
10	5
11	9
12	5
13	4
14	7
15	8
16	4
17	8
18	6
19	6
20	4
Median	7,5

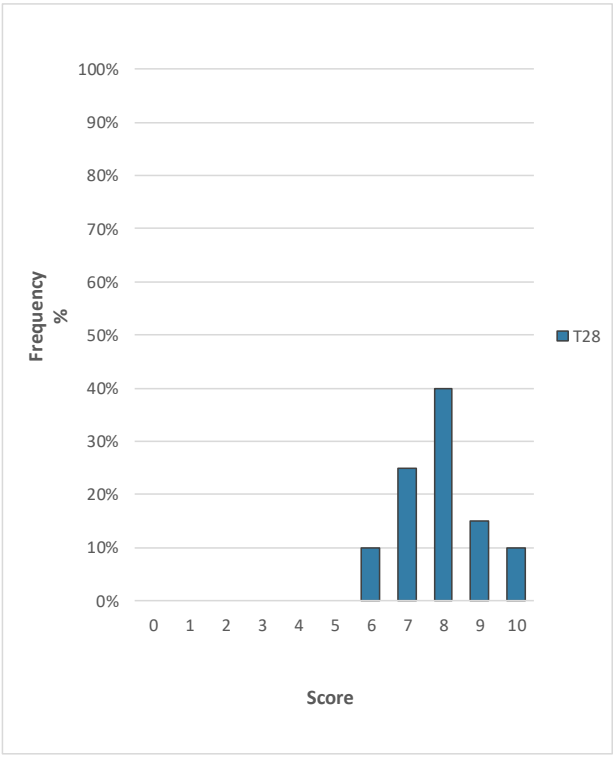
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	15%
5	10%
6	15%
7	10%
8	30%
9	5%
10	15%



Have you noticed an improvement in the general condition of your skin?

Vol. n°	Judgement T28
01	8
02	7
03	8
04	8
05	7
06	10
07	9
08	7
09	8
10	7
11	9
12	9
13	6
14	7
15	8
16	8
17	8
18	10
19	6
20	8
Median	8,0

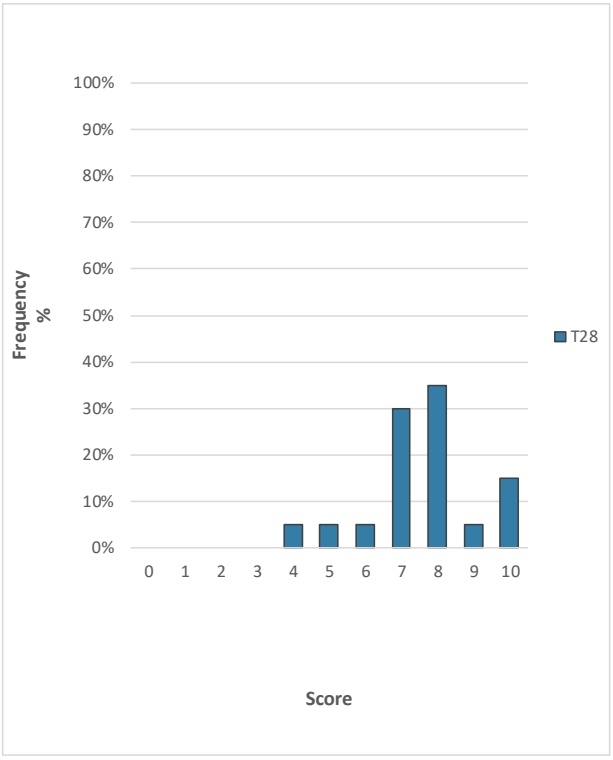
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	0%
6	10%
7	25%
8	40%
9	15%
10	10%



Do you find the gel texture of the product pleasant?

Vol. n°	Judgement T28
01	7
02	10
03	8
04	7
05	7
06	10
07	7
08	6
09	8
10	8
11	8
12	9
13	4
14	7
15	8
16	5
17	8
18	10
19	7
20	8
Median	8,0

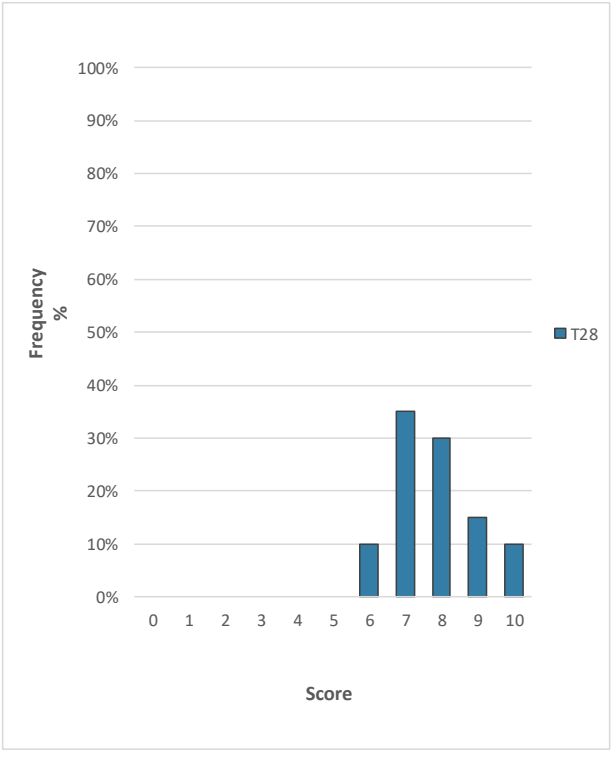
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	5%
5	5%
6	5%
7	30%
8	35%
9	5%
10	15%



Overall product assessment

Vol. n°	Judgement T28
01	7
02	7
03	8
04	7
05	7
06	10
07	9
08	6
09	8
10	8
11	9
12	9
13	7
14	7
15	8
16	7
17	8
18	10
19	6
20	8
Median	8,0

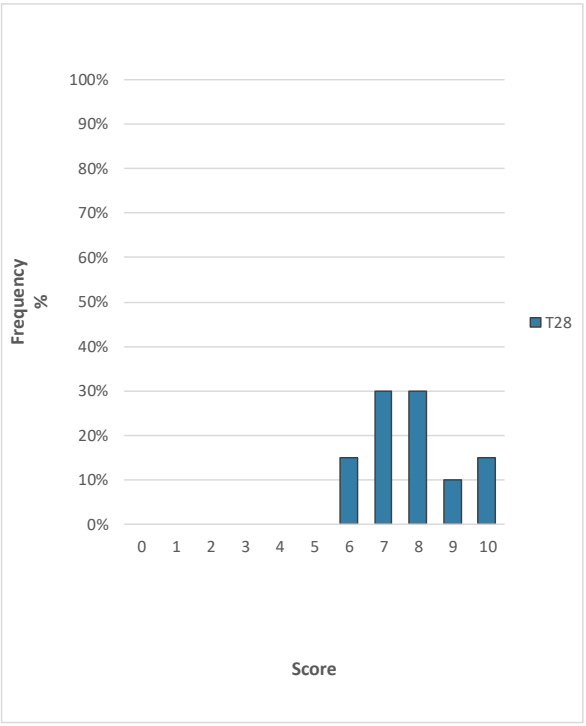
Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	0%
6	10%
7	35%
8	30%
9	15%
10	10%



Would you buy the product?

Vol. n°	Judgement T28
01	7
02	7
03	8
04	8
05	7
06	10
07	10
08	6
09	8
10	9
11	8
12	9
13	6
14	7
15	7
16	7
17	8
18	10
19	6
20	8
Median	8,0

Score	Frequency %
0	0%
1	0%
2	0%
3	0%
4	0%
5	0%
6	15%
7	30%
8	30%
9	10%
10	15%



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Annex C

TECHNICAL SCIENTIFIC COMMITTEE STATUTE – REGULATION

ART. 1 INTRODUCTION

The Technical Scientific Committee of "Bio Basic Europe S.r.l." is an independent and impartial work group, constituted in accordance with interdisciplinarity criteria and with autonomous decision-making powers, whose task and responsibility is to ascertain the compliance of the methodologies and validate scientific and clinical research protocols. The TSC is called upon to formulate operating proposals and opinions on Bio Basic Europe S.r.l. research projects at the CDC Dermo Clinical Research Institute of Milan, at the microbiological, chemical/physical and in vitro analysis laboratories of the Technical Scientific Park of the University of Pavia, or at laboratories, medical clinics and Hospital Institutes that collaborate with the company. The TSC acts in compliance with the ethical principles contained in the Helsinki declaration, with the Clinical and Laboratory Best Practice Standards and with all applicable national and European related regulatory frameworks, as well as with the recommendations and guidelines of the main competent international organizations and institutions.

ART.2 INDEPENDENCE OF THE TECHNICAL SCIENTIFIC COMMITTEE

The independence of the TSC is guaranteed:

- by the lack of hierarchical subordination of the TSC to the principal;
- by the presence of experts who are not employed by the principal;
- by the absence of conflicts of interest of TSC members with regard to the trials proposed.

ART.3 FUNCTIONS OF THE TECHNICAL SCIENTIFIC COMMITTEE

In brief, the TSC performs the following functions:

- It assesses the clinical trial protocols and the scientific protocols, ascertaining the conformity of the procedures and the compliance with all mandatory regulatory frameworks, expressing its opinion and validating in particular:
    - clinical trials and laboratory analyses that assess cosmetic products, nutraceutical products, medical and diagnostic devices, medical/surgical aids, detergents, hazardous substances, biocides, and chemical substances, in general.
    - protocols that assess the adoption of new clinical and scientific operating procedures.
    - observational studies and monitoring.
- It may propose information/training/refresher initiatives for the operators involved in the trials, as well as workshops on pertinent scientific topics.

ART. 4 COMPOSITION OF THE TECHNICAL SCIENTIFIC COMMITTEE

The TSC is composed of members who are internal and external to Bio Basic Europe S.r.l., with multidisciplinary skills, so that it may guarantee the qualifications and experience required to assess the scientific, methodological and ethical aspects of the protocols presented. The members of the TSC have proven skills and qualifying experience in the sector covered by the study.

For this purpose, at least the following persons participate in all TSC meetings:

a. The Chairman and /or the Vice Chairman to the TSC
b. The University of Pavia Director of Research
c. The Investigator/Medical Director of the CDC Dermo Clinical Research Institute*
d. The expert of Bio Basic Europe S.r.l. depending on the issue on which the opinion is formulated

*In the specific case of in vitro, microbiological and chemical/physical tests, member c. will be replaced by member d., or by one of the members who specialise in topics pertinent to Bio Basic Europe.

In general, the TSC work group comprises at least:

e. one chemist/cosmetic chemist
f. one toxicologist
g. one pharmacist/pharmacologist
h. one physician
i. one biologist
j. one biostatistician
k. one microbiologist/virologist/expert in genetics
l. one clinician

MANAGING MEMBERS OF THE TECHNICAL SCIENTIFIC COMMITTEE

- Prof. **ORNELLA PASTORIS**
  TSC Chair and Scientific Director, "Lazzaro Spallanzani" Faculty of Biology and Biotechnologies, University of Pavia
- Dr. **CLAUDIO ANGELINETTA**
  TSC Vice Chair, Chemist/Cosmetic chemist

- Dr. **FERNANDO MARCO BIANCHI**, M.D.
  Medical Director of the CDC Dermo Clinical Research Institute, specialising in dermatology and venereology

MEMBERS AFFILIATED WITH THE UNIVERSITY INSTITUTES AND RESEARCH CENTRES

- Prof. **GIULIANO MAZZINI**
  National Research Council, Pavia Institute of Molecular Genetics, expert in genetics
- Prof. **FIORENZO PEVERALI**
  National Research Council, Pavia Institute of Molecular Genetics, expert in genetics

MEMBERS AFFILIATED WITH BIO BASIC EUROPE S.R.L..

Clinical research experts:

- Dr. **DANIELA GANDINI**
  Bio Basic Europe Safety Clinical Test Reporting Contact Person, expert in in vivo safety tests
- Dr. **ANTONELLA PRATICO'**
  Bio Basic Europe Clinical Test Reporting Coordinator, expert in clinical research
- Dr. **GAETANA RIZZI**
  Bio Basic Europe Medical Device and Food Supplement Clinical Tests Reporting Contact Person, expert in clinical research
- Dr. **ROBERTA VILLA**
  Bio Basic Europe Statistical Analysis Coordinator and Efficacy Clinical Test Reporting Contact Person, expert in clinical statistics

Other experts:

- Dr. **MARA FOPPIANI**
  Head of Bio Basic Europe Microbiology Laboratory, expert in microbiology and virology
- Dr. **ELIANA REGOLA**, PhD
  Bio Basic Europe Laboratory Test Coordinator, expert in microbiology and virology
- Dr. **FRANCESCA VALLOTTO**
  Coordinator of the Regulatory Department of Bio Basic Europe, expert in cosmetic chemistry and toxicology
- Dr. **RICCARDO VICINI**, PhD
  Head of Bio Basic Europe Vitro Laboratory, expert in pharmacology and toxicology

CLINICAL INVESTIGATORS

- Dr. **MAURIZIO BARBIERI CARONES**, M.D., specialising in gynaecology
- Dr. **ANTONELLA COLOMBO**, M.D., specialising in dermatology and venereology
- Dr. **ALESSANDRA DI BENEDETTO**, M.D., specialising in dermatology and venereology
- Dr. **TIZIANA DIVINO**, M.D., specialising in aesthetic medicine and dermosurgery
- Dr. **EVELYN FALCONI KLEIN**, M.D., specialising in dermatology and venereology
- Dr. **GIORGIO GRASSI**, M.D., specialising in ophthalmology
- Dr. **ANDREA RAMONI**, M.D., specialising in ophthalmology
- Dr. **LUCA VETTORUZZO**, M.D., specialising in dentistry and dental prosthesis

In the case of evaluations pertaining to areas not covered by its members, the Chairman of the TSC may convoke, for specific consultations, experts who are not members of the TSC. In the case of resignation or of the exit on any grounds of one of the mandatory members of the TSC, the Chairman of the TSC ensures that they are promptly replaced.

ART. 5 FUNCTIONS OF THE CHAIRMAN

The Chairman exercises the following functions:

- he/she is the official representative and spokesperson of the TSC
- he/she is the contact person for any critical issues of a clinical/scientific nature that arise during the activity of the TSC
- he/she decides on the possible supplementation of the TSC's composition and on the replacement of members who have been deprived of their office and/or have resigned
- he/she convokes, moderates and conducts the meetings of the TSC
- he/she supervises the decisions adopted by the TSC

The Vice Chairman replaces the Chairman in all his/her functions in case of absence or temporary impediment. He/she assists the Chairman who may confer specific assignments thereto. The Chairman uses the services of a Scientific Secretary for the performance of activities of an administrative/scientific nature. The Secretary participates in the meetings with advisory, supporting functions and takes the minutes.

ART.6 DUTIES OF THE MEMBERS

The Members of the TSC:

- are personally responsible for the activities under their remit carried out in the TSC
- are bound to secrecy with regard to the actions related to their activity in the TSC
- must communicate any bias and lack of impartiality that may have an impact on their participation in the TSC

ART. 7 VALIDATION OF THE PROJECTS

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The TSC is called upon to express opinions on and ascertain the completeness of scientific and clinical protocols by Bio Basic Europe S.r.l. TSC certifies the adequacy of the documentation and the conformity of the procedures and methodologies followed in designing and developing the research project, in compliance with the applicable rules and regulations. Each protocol, once confirmed by the mandatory members of the TSC, as indicated in Art. 4, is signed by the Investigator/Medical Director of the CDC Dermo Clinical Research Institute, or by the Head of the Laboratory in case of test reports, and thereafter by the Safety Assessor/Vice Chairman to the TSC, who attests the validity of the document with digital signature. Each protocol approved by the TSC will be archived and be available to all members of the TSC.

TSC Chairman and Scientific Director, University of Pavia	TSC Vice Chairman	The Investigator and Medical Director of the CDC Dermo Clinical Research Institute