CLINICAL STUDY OF A TOPIC PRODUCT COMPARATIVE EFFICACY PERCEIVED IN REAL CONDITIONS OF USE

FINAL REPORT

PRODUCT'S NAME: Lubrinat / Colpotrofine

PRODUCT CODE: 052818-01 / 02
STUDY CODE: All-E-EP-052818-01 / 02.10.15
REPORT CODE: All-E-EP-052818-01 / 10.15.02-RFV01-Rev01

DATE OF REPORT: November 17.2015

SPONSOR: MASTER INDUSTRIAL PROD TRADE AND PHARMACIST ODONTO LTDA
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CLINICAL STUDY TOPIC OF A PRODUCT COMPARATIVE EFFICACY PERCEIVED IN REAL CONDITIONS OF USE

ABSTRACT
PRODUCT'S NAME: Lubrinat / Colpotrofine

PRODUCT CODE	052818-01 / 02
STUDY CODE	All-E-EP-052818-01 / 02.10.15
REPORT CODE:	All-E-EP-052818-01 / 10.15.02-RFV01-Rev01
PURPOSE OF THE STUDY	Verify the Efficacy through the subjective perception of the research participant through evaluations of efficacy Perceived in real conditions of use.
METHODOLOGY	Participants were instructed to use the product at home according to the instructions provided for 21 days (+/- 2 days). They were held evaluations of perceived Efficacy were held, through questionnaires, on the first day of the study, prior to the use of the product (T0) and after 21 days (+ /- 2 days) of use (T21).
PRINCIPLE INVESTIGATOR	Vivian Pessoto Rosa.
PERIOD OF TEST	21 days (+ /- 2 days).
APPLICATION FREQUENCY	Every 3 days / Daily.
TEST AREA	Vagina
NUMBER OF PARTICIPANTS	70
POPULATION DESCRIPTION	Female, ages of 42-67 postmenopausal participants and presenting complaint of dryness at the vaginal region.
ETHICS	This study was conducted in accordance with principles of the Declaration of Helsinki, the applicable regulatory requirements, including CNS Resolution No. 466/12, and the Good Clinical Practices (Document of Americas and ICH E6: Good Clinical Practice).
RESULTS/ CONCLUSIONS	**Evaluation of efficacy perceived by study participants after 21 (+ /- 2) days of use of product 052818-01:** • 94.3% of participating strongly agree or agree with the

assertion "The product has moisturizing properties to the intimate mucosa."

- 97.1% of the assessed participants reported reduction of skin Dryness .
- 88.6% of the assessed participants reported increased comfort sensation in the skin.
- 88.6% of the assessed participants reported liking the Fragrance Product in the skin.
- 100% of participating mentioned ease Product Application in the skin.

Evaluation of efficacy perceived by study participants after 21 (+ /- 2) days of use of product 052818-02:

- 97.0% of the assessed participants strongly agreed or agreed with the affirmation "The product has moisturizing properties to the intimate mucosa."
- 100% of the evaluated participants reported reduction of dryness in the skin.
- 90.9% of the assessed participants reported increased *comfort sensation* in the skin.
- 78.8% of the assessed participants reported liking the *Fragrance Product* in the skin.
- 84.8% of participating mentioned ease *Product Application* in the skin.

Evaluation of Comparative Efficacy of Products 052818-01 and 052818-02.

- No significant difference was observed between both products regarding the attribute "0 product has moisturizing properties to the intimate mucosa" (p = 0.142).
- No significant difference was observed between both regarding products to the dryness of the intimate mucosa (p-value = 0.786).
- No significant difference was observed between both products regarding sensation comfort in intimate mucosa (p-value = 0.528).
- No significant difference was observed between both products regarding fragrance of the product (p-value = 0.088)
- No significant difference was observed between both products regarding ease of application (p-value = 0.123).

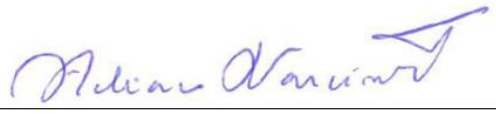
QUALITY ASSURANCE

The study was performed in accordance to CNS Resolution No. 466/2012, in the spirit of the Good Clinical Practice and in accordance with the Allergisa Standard Operating Procedures.

Our quality Data are assured considering that our employees are trained and qualified according the research to be conducted, our equipment are maintained calibrated, and were used recognized and / or validated methods.

The Quality Assurance Area performs audit of the Management System; and is available to receive our customers for specific tutoring of their research.

Representative signature of Quality Assurance System means that the research was conducted as described above.



Quality Manager
Heliara Nascimento Lopes
11/17/2015

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LIST OF ABBREVIATIONS

ANVISA	Agencia Nacional de Vigilância Sanitária (Brazilian Health Surveillance Agency)
ASTM	American Society for Testing and Materials
GCP / ICH	Good Clinical Practice / International Conference on Harmonization.
COLIPA	Cosmetics Europe - The Personal Care Association.
CNS	Conselho Nacional de Saúde (Brazilian National Health Council)
ICH E6:.	Good Clinical Practice.
TO	Start time, before the use of product-testing.
T21	Time Apps 21 days of product use test.
IC	Informed Consent

2. INTRODUCTION

In the last years, the cosmetic industry has grown considerably as well as its interest in developing effective and safe products. The creation of the Consumer Protection Code, the requirements of the Department of Health Surveillance from the Ministry of Health and the competition itself led to more cautious attitudes from the Industries regarding the action and benefits of their products, seeking to associate their affirmations to the scientific work.

The awareness of industry and consumer demands resulted in adoption of new procedures by the cosmetics manufacturers: Currently, companies are concerned about, prior to the commercialization, clinical tests of allergenicity and efficacy, which are coordinated by medical dermatologists. This procedure offers more safety, credibility and trust toward consumers. (ANVISA, 2003).

Research conducted with human beings regulated according to laws very rigid, in order to protect and safeguard the individuals. These laws vary depending on the country. In Brazil, these studies are allowed, provided they follow the precepts of Declaration of Helsinki and CNS Resolution No. 466/12 (NATIONAL COUNCIL OF HEALTH, 2013).

Sensory analysis is the scientific discipline used to evoke, measure, analyze and interpret sensations caused by food and materials as they are perceived by the senses of vision, smell, taste, touch and hearing (ANVISA, 2003). Sensory analysis was structured from the decade of 40, with the works done by the US Army Quartermaster Food and Container Institute in the food area, spreading by other segments in the most recent decades (Stone and Sidel, 1993).

The methods that comprise the sensory evaluation are classified into: discriminative, descriptive and affective. Affective methods are used to evaluate the preference or acceptability of a given product with the consumer market. Thus, when used properly, is an excellent tool for comparing products, market orientation, corrections of the desired attributes for the product and the real perception from the consumer regarding expectations. (ASTM E 1958-06).

With the advance of the statistics techniques used, sensory analysis has started to be used as a product development tool, quality control and quality assured, analysis of competitors and claims support (what the product offers). Regarding support claims in cosmetic products, the following guidelines have been described by COLIPA (2001):

The benefits provided by a cosmetic product should be consistent with the consumer expectations generated by the claims;

To assess whether a claim is appropriate, it is necessary to take into account the general impression of consumers regarding product presentation or advertisement. The claims must be supported by solid, clear and relevant evidences. Such evidences can be in

experimental studies (methods biochemical / instrumental, sensory evaluations, technical evaluations and evaluations without participation of research participants - *in vitro* tests in cell culture, use of hair strands, etc.), and consumer evaluations . (ASTM E 1958-06).

Currently a large progress on sensory Evaluation associated with instrumentals and clinical techniques have been carried out, looking for a more complete product evaluation on consumer benefit. (ASTM E 1958-06).

3. OBJECTIVE

The objective of this study was to verify the efficacy through the subjective perception of the research participants through evaluations of Perceived Efficacy in actual use conditions.

4. investigational product

The product Information, as declared by the sponsor, is described in Annex 5. A sample of the product was cataloged and is on our files, which will be maintained four a period of one month.

4.1. Identification

Table 1. Product test Identification

Product Name	**Product code**
Lubrinat	052818-01
Promestriene	052818-02

4.2. How to use

Product 052818-01

Separate urn applicator and open the lid of the tube. To attach the applicator nozzle on the tube screw slowly. After fitting the applicator at horizontal position, gently squeeze the base of the tube with the fingers forcing the gel to enter the applicator, filling it up to the recommended limit. Remove the applicator and close the tube.

The vaginal gel application must be done while lying on your back deeply introducing the applicator gently into the vagina, Slowly press the plunger until it stops gently pushing the plunger, until completely empty applicator. Apply the product every three days. The gynecological applicator is disposable after use discard.

Product 052818-02

Separate urn applicator and open the lid of the tube. To attach the applicator nozzle on the tube screw slowly. After fitting the applicator at horizontal position, gently squeeze the base of the tube with the fingers forcing the gel to enter the applicator, filling it up to the recommended limit. Remove the applicator and close the tube.

The vaginal gel application must be done while lying on your back deeply introducing the applicator gently into the vagina, Slowly press the plunger until it stops gently pushing the plunger, until completely empty applicator. Apply the product once a day.

Although it is rarely necessary to use a sanitary napkin can be advisable, especially if there is discharge associated.

4.2.1. Compliance check of the Product Use

The compliance check of the product use by the participants was verified through the diary of product use by the participants.

4.3 - Storage

The products supplied by the sponsor were initially stored in the Research Center sample room with temperature controlled and restricted access. The product release was controlled by the principal investigator or designated technicians responsible for it.

Upon receiving the product, the participants were instructed about their storage conditions, highlighting the importance to keep them in places out of reach of children and / or animals.

5. ETHICAL CONSIDERATIONS APPLICABLE

The study was conducted in compliance of the principles of Declaration of Helsinki, the applicable regulatory requirements including CNS Resolution No. 466/12, and in the spirit of the Good Clinical Practice (Document of the Americas and ICH E6: Good Clinical Practice).

Participants were informed of the purpose of the study, its methodology and time, and the benefits expected and possible restrictions related to the study and those who have confirmed their interest in participating signed an informed consent form (Appendix 1).

All the technical documentation of the research is found in the archives of Allergisa, where will be kept for a period of 5 years.

6. STUDY DATES

The total search time was 21 days (+ /- 2 days).

- **Start:** 10/19/2015;
- **End:** 11/10/2015.

7. RESEARCH PARTICIPANTS

7.1. Recruitment of Research Participants

The recruitment of the research participants was conducted by the recruitment Section at the Research Center, which has a computerized system and updated records. The participants that have an interest in participating in this research are registered in this system who were contacted to participate in the selection and having all the necessary criteria, were included in the study.

7.2. Selection and Admission of Research Participants

During selection of the participants to this research, Allergisa made sure that they had no conditions that could interfere at the results of the study. Allergisa is still responsible for the information present in the participant's Evaluation form, checking all the criteria of inclusion and exclusion for its admission to the research.

7.3. Description of the Population

For this study, 74 participants were recruited to the research **(Error! Reference source not found.).** Of these, 04 (participants 019, 026, 044 and 066) did not meet the criteria for inclusion or had some criteria of exclusion.

The study was initiated with 70 female participants, between 42 and 67 years old.

The study aimed to obtain to its end at least 60 answers, according to Evaluation Guide to Cosmetic Safety the National Sanitary Surveillance Agency Products - ANVISA.

7.4. Inclusion criteria

- healthy participants;
- Skin and mucosa Integra in the test region;
- Concordance to adhere the procedures and requirements of the test and attend to the Office at the day(s) and hour (s) set for evaluations;
- Capacity to consent participation in the study;
- females
- Ages of 40 to 70;
- Menopausal participants;
- Dryness complaint in the vaginal region.

7.5. No Inclusion Criteria

- Cutaneous pathology in the area of product application;
- Diabetes Mellitus Type 1; insulin dependent diabetes; presence of complications due to diabetes (retinopathy, nephropathy, neuropathy); presence dermatosis related to diabetes (ulcer plant, necrobiosis lipoidica, granuloma annular, opportunistic infections); episodes or history of hypoglycemia, diabetic ketoacidosis and / or hyperosmolar coma;
- Immunological deficiency;
- Current use of the following rnedications use of topical or systemic: corticosteroids, immunosuppressant drugs and antihistamines;
- Skin disorders: vitiligo, psoriasis, atopic dermatitis;
- history of Reaction to the category of the product tested;
- Other disorders or medication that may interfere directly in the study or even endanger the health of the research participant.

7.6. Interdiction and restriction

- Do not apply any product in the experimental region to interfere in the study Evaluation;
- Do not change cosmetic habits, including hygiene.

001.8 Methodology

8.1. Study Design

Open clinical study.

8.2. Study area

Participants were instructed to use the product in the vagina.

8.3. Evaluation Perceived Efficacy of the Research Participants

The evaluation of Perceived Efficacy was carried out based on "Standard Guide for Sensory Claim substantiation" (ASTM E 1958-06, 2006) through the application of questionnaires. ASTM (American Society for Testing and Materials) was formed over one century ago and is one of the largest voluntary standards development organizations of the world, being a trusted source for technical standards materials, products, systems and services. Known for their high technical quality and market relevancy, ASTM plays an important role in the information infrastructure that guides design, manufacture and trade at global economy. The "Standard Guide for Sensory Claim substantiation" is an ASTM standard which ASTM which aims to disseminate good practices in sensory testing and addresses reasonable practices of execution of sensory tests that validate the claims regarding the product attributes.

Participants were asked to evaluate the skin through the Questionnaire of Perceived Efficacy (Annex 3) at the following times:

T0: On the first day of the study, before application of the product test (Profile of Participant Research);

T21: After 21 + /- 2 days of product use (Perceived Efficacy).

The attributes evaluated by the research participants at T0 time were: *"Dryness" and "Comfort Sensation."*

The affirmation assessed by research participants at the time T21 was: "The *product has moisturizing properties to the intimate mucosa."*

The attributes evaluated by research participants in T21 time were: *"Dryness", "Comfort Sensation," "fragrance Product", "Ease of Application".*

8.4. Procedure schedule

Table 2. Study schedule

		T0	T21
STEPS	Signature of IC	X	-
	Questionnaire Profile of Research Participants	X	-
	Efficacy Perceived Evaluation by the Participant	-	X
	acceptability and compliance Evaluation of the product through the conference of the diaries of use of product test	-	X
	Distribution of the product test	X	-
	Adverse Events Evaluation (if applicable)	-	X

8.5. Criteria and Procedures for Research Participants Withdrawal

The exclusion of research participant by the investigator could be due to the following reasons:

- Research participants not included: participants that signed the informed consent form, but that would not meet the criteria for inclusion and exclusion of the research;
- Participants presenting, at the vision of the investigator, any problem that prevent continuity of product applications at any period of the study;
- Withdrawal of consent by the research participant, regardless of the reason;
- Lack of adherence of the research participant to the study. Shall be considered significant lack of adhesion when the participant does not attend the center for evaluations,
- Adverse Event Severe,
- Disorder or concurrent treatment any disease process or treatment that occurs during the course of the study and may interfere with the study product as drug interaction or could mask the results.

Participants withdrawn from the study by the investigator will be accompanied if they present any possibly event related to study, even after its withdrawal. Participants will be taken by presenting adverse event will be followed up till the overall solution.

In case of withdrawal after the inclusion phase of the study, there was not reposition of these participants.

9. STATISTICAL ANALYSIS

Exploratory analysis data (summary tables, graphs, frequencies and percentages)was carried out. The comparison between treatments was carried out through the non-parametric test Mann-Whitney. The number of research participants was equal to 35 for the treatment with 052818-01 and 33 for treatment with 052818-02 33.

The level of confidence considered at the comparative analysis was 95%.

Software: XLSTAT 2015 STATA 10 and MINITAB 14.

Note: The percentages of the results of perceived efficacy are inserted into the table with one decimal place after comma. Owing to this rounding, some percentages when added manually by the rounded data from the tables may be equal to 100.1% or 99.9%.

RESULTS

10.1. Adherence to Study

68 participants completed the study. Of these, 01 had an adverse event (participant 029). The event is described in item 10.2

01 participant (participant 032) dropped out of the study for personal reasons not related to the study

It was withdrawn from the study 01 participant (participant 074) due to adverse events according to item 10.2.

10.2. Occurrences during the study

Participant 029

On 11.10.2015, the end date of the research, the participant 029 attended the institute referring mild "abdominal discomfort" in the hypogastric region, about ten hours after application of product-test, with duration of minutes and spontaneous remission from 10/21/2015 day, third day of the study.

The participant kept using the product-test until the end of the research, with recurrence of complaint only at 10/22/2015 only the fourth day of the study.

In clinical gynecological evaluation showed normal gynecological examination without clinical signs.

Considering the context the case was closed corn negative connection.

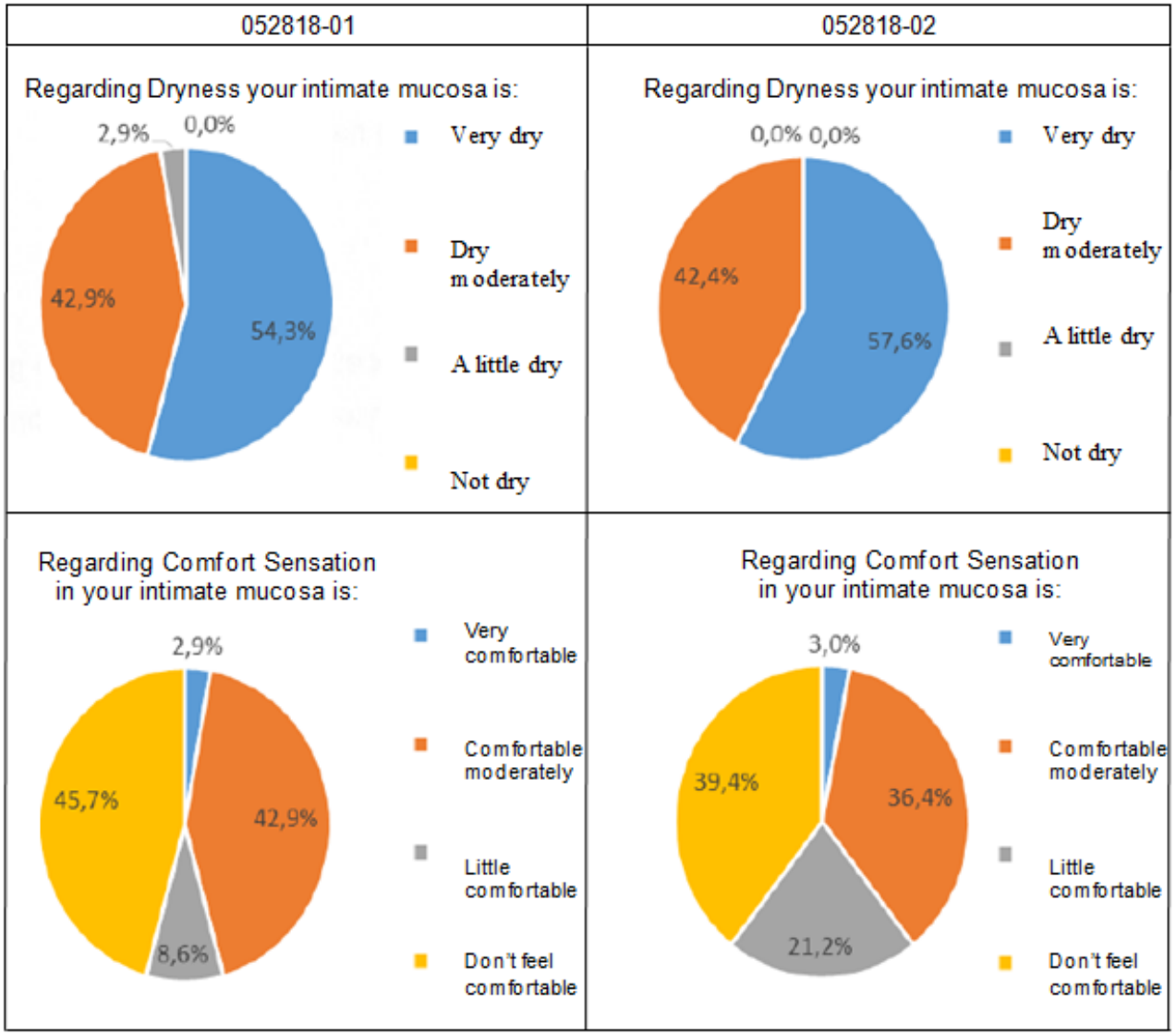
The participant's data were considered in the research.

Participant 074

On 11.10.2015, the end date of the research, the participant attended the institute referring intense gastritis an hour after application of product-test, with five-day duration and spontaneous remission, on 10.27.2015, the ninth day of research.
The participant started using the product test from the day 10.27.2015.
The participant stopped using the product test after the application which referred the symptom.
The gynecological examination showed a normal one without clinical signs. The participant was questioned about the possible ingestion of the product test and denied any ingestion.
Considering the context the case was closed with no causal connection. This was an adverse events possibly related to gastritis.
The participant data were not considered in the research.

10.3. **Profile of Research Participants**

The following figures (pizza Graphics) present the evaluation of the participants before the use of the product (Profile of Search Participants).



10.4. Evaluation Perceived Efficacy by the Research Participants

The tables below show the percentage of participants who reported acceptance and affirmation for the attributes evaluated after 21 + /- 2 days of product use(T21).

Table 3. Perceived Efficacy results

Affirmations	T21 (%) 052818-01	T21 (%) 052818-02
The product has moisturizing properties for the intimate mucosa.	94.3	97

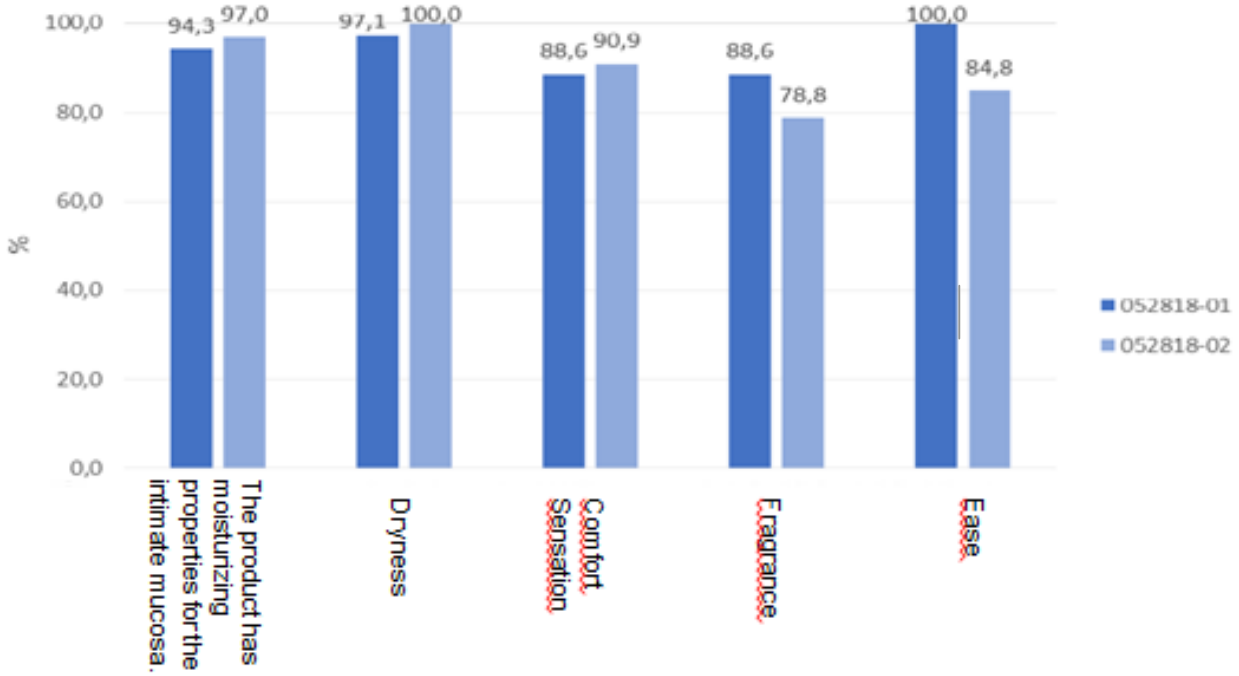
For the affirmation above it was considered as the sum of categories "totally agree" and "agree".

Table 4. Perceived Efficacy results

ATTRIBUTES	T21 (%) 052818-01	T21 (%) 052818-02
Dryness	97.1	100
Comfort Sensation	88.6	90.9
Fragrance Product	88.6	78.8
Ease of Product Application	100	84.8

For the attribute Dryness, it was considered as the sum of categories " slightly decreased ", "decreased moderately" and "decreased a lot".
For the attribute Comfort Sensation It was considered as the sum of categories "slightly increased." , "moderately increased" and "increased a lot"
For the attribute Fragrance of the product, It was considered as the sum of categories "Liked it slightly", "liked moderately", "I liked a lot" and “loved”
For the attribute Ease of Application Product, It was considered as the sum of categories "a little easy ',' 'easy" and very easy

The figure below shows a summary of the percentage of acceptance and affirmation of the attributes of Perceived Efficacy evaluated by research participants at the time T21.



PERCEIVED EFFICACY: AFTER 21 DAYS OF PRODUCT USE

Table 5. Media and standard deviation

Attribute	052818-01		052818-02	
	Media	SD.	Media	SD
The product has moisturizing properties to intimate mucosa "	4,2	0,5	4.4	0,6
Dryness of intimate mucosa	6,2	8.0	1 5/16	0,8
Comfort Sensation in intimate mucosa	5,9	1,1	6.1	1,1
Fragrance product	7,4	1,6	0-7	1,2
Ease of application.	6,3	0,5	5/9	1,1

Table 6. Comparison of results between treatments

Attribute	052818-01 vs 052818-02	
	P-value	Results
The product has moisturizing properties to intimate mucosa "	0,142	-
Dryness of intimate mucosa	0,786	-
Comfort Sensation in intimate mucosa	0,528	-
Fragrance product	0.088	-
Ease of application.	0,123	-

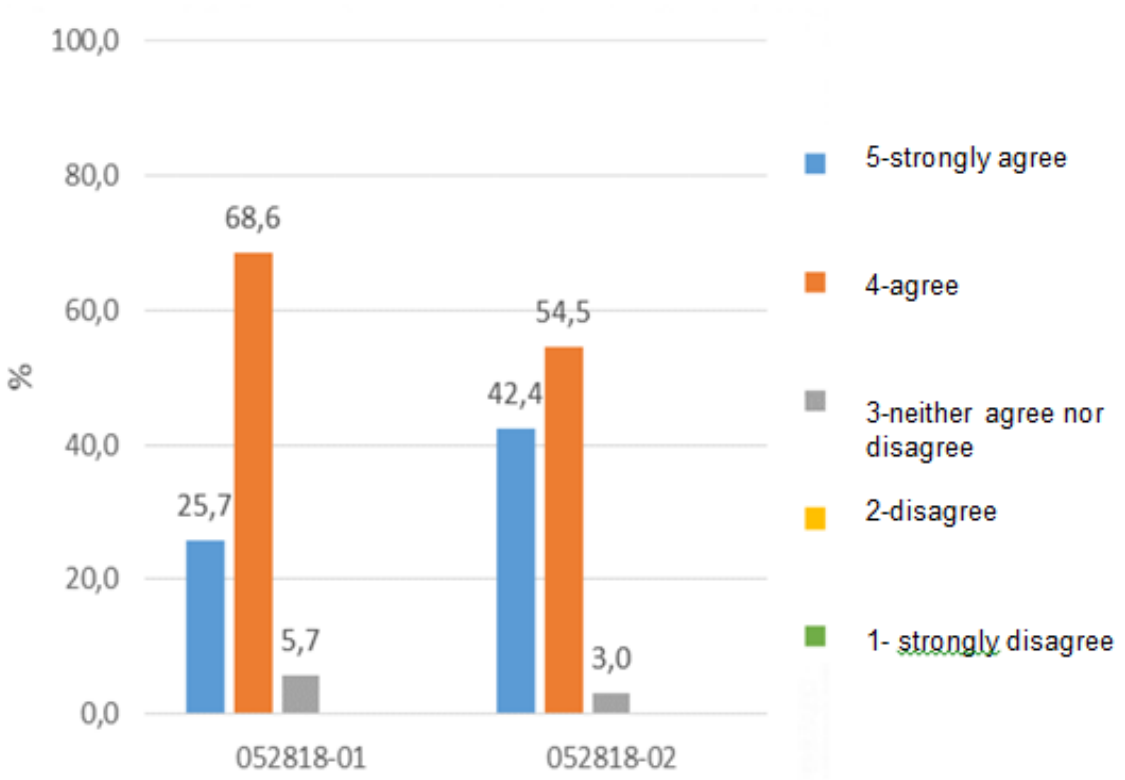
*** significant at the level of 0,1 %; ** significant at the level of 1% ; significant at the level of 5%- Mann-Whitney test)

No significant difference was observed between the products regarding the attribute "The product has moisturizing properties to the intimate mucosa" (p = 0.142).
No significant difference was observed between the products regarding dryness of the intimate mucosa (p-value = 0.786).

No significant difference was observed between the products regarding comfort sensation in intimate mucosa (p-value = 0.528).
No significant difference was observed between the products regarding the fragrance of the product (p-value = 0.088).
No significant difference was observed between the products regarding ease of application (p-value = 0.123).

"The product has moisturizing properties to the intimate mucosa"
Table 7. Frequency and percentage

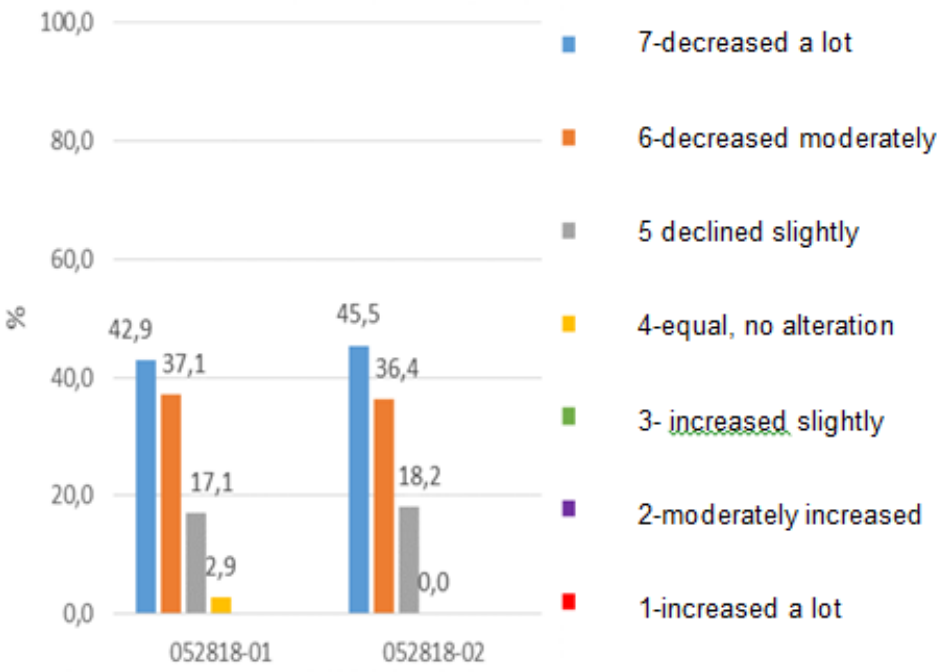
About the affirmation: "The product has moisturizing properties to the intimate mucosa" You'd say:	052818-01		052818-02	
	n	%	n	%
5-strongly agree	9	25.7	14	42.4
4-agree	24	68.6	18	54.5
3-neither agree nor disagree	2	5/7	1	1.08
2-disagree	0	0	0	0
1- strongly disagree	0	0	0	0
Top two	33	94.3	32	97
Bottom two	0	0	0	0



Dryness

Table 8. Frequency and percentage

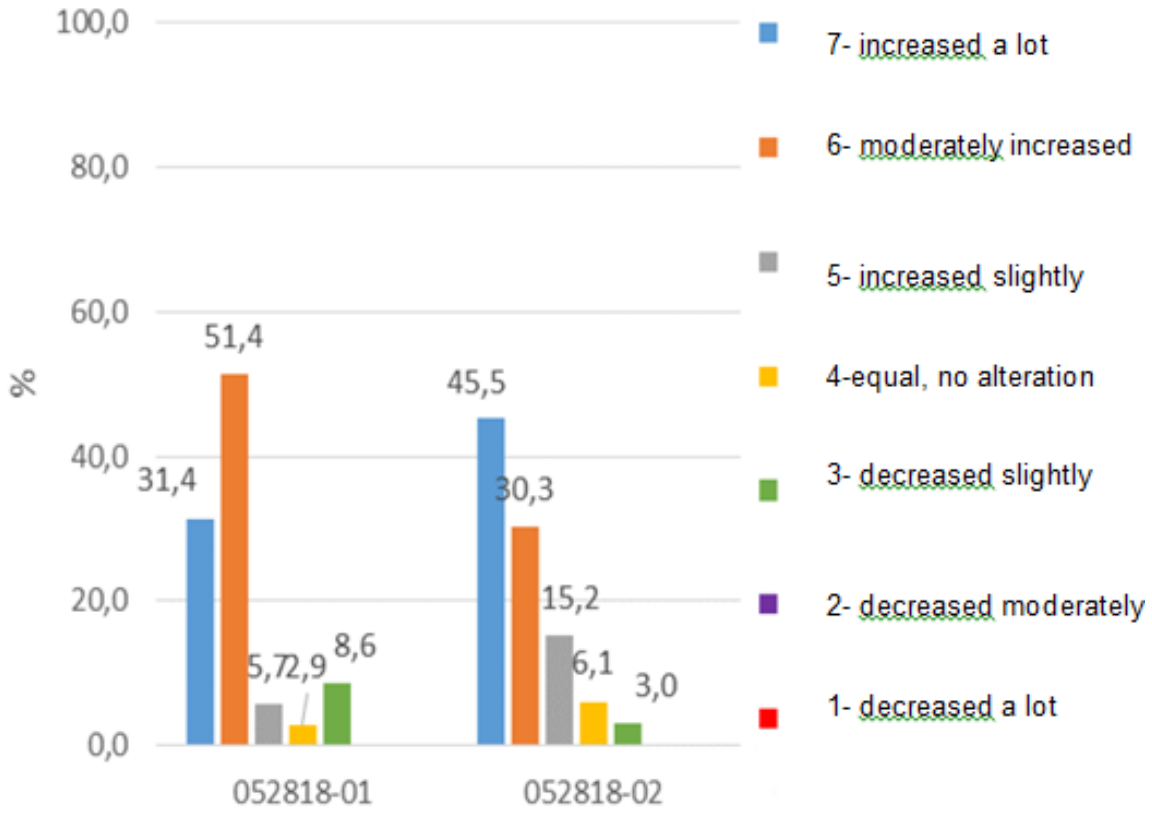
With the use of the product, the dryness of your intimate mucosa:	052818-01		052818-02	
	n	%	n	%
7-decreased a lot	15	42.9	15	45.5
6-decreased moderately	13	37.1	12	16.5
5 slightly decreased	6	17.1	6	18.2
4-equal, no alteration	1	2-9	0	0
3- slightly increased	0	0	0	0
2-moderately increased	0	0	0	0
1-increased a lot	0	0	0	0
Top three	**34**	**97.1**	**33**	**99.5**
bottom three	**0**	**0**	**0**	**0**



Comfort Sensation

Table 9 Frequency and percentage

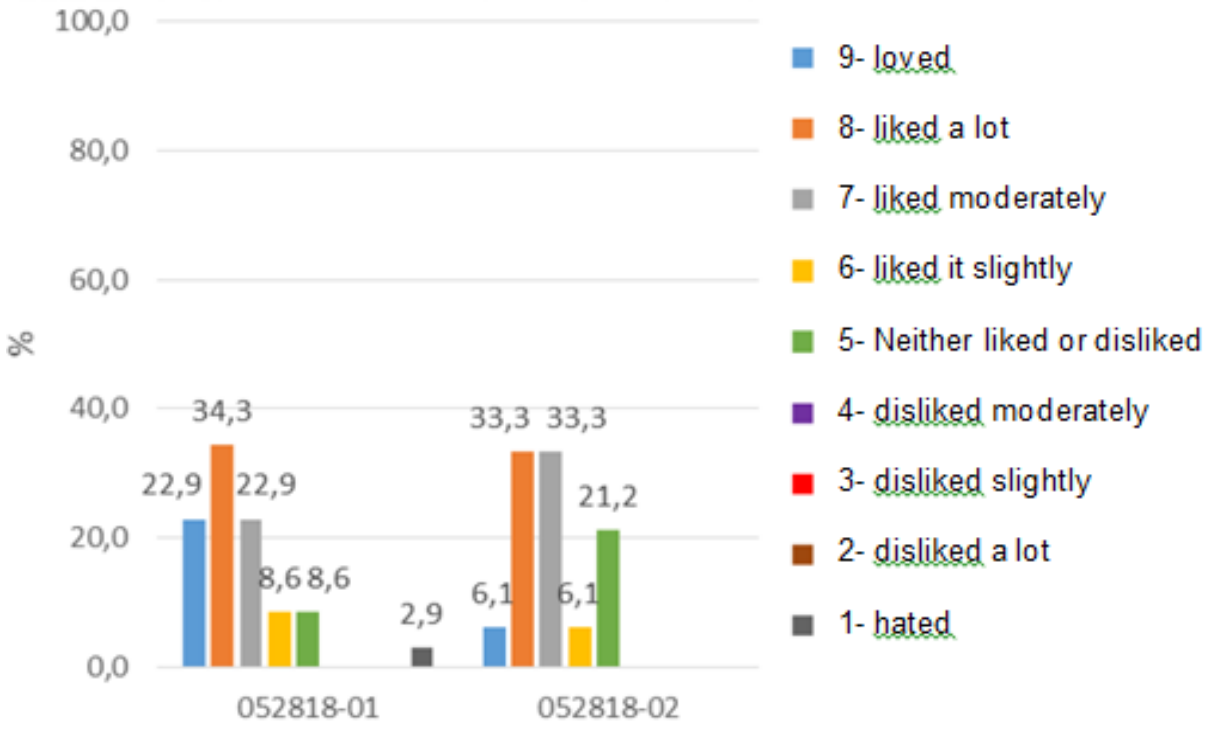
With the use of the product, the comfort sensation in the intimate mucosa:	052818-01		052818-02	
	n	%	n	%
7- increased a lot	11	31.4	15	45,5
6- moderately increased	18	51,4	10	30,3
5 slightly increased	2	5,7	5	15,2
4-equal, no alteration	1	2,9	2	6,1
3- slightly decreased	3	8,6	1	3,0
2- decreased moderately	0	0,0	0	0,0
1- decreased a lot	0	0,0	0	0,0
Top three	**31**	**88,6**	**30**	**90.9**
bottom three	**3**	**8,6**	**1**	**3,0**



Product Fragrance

Table 10:Frequence and Percentage

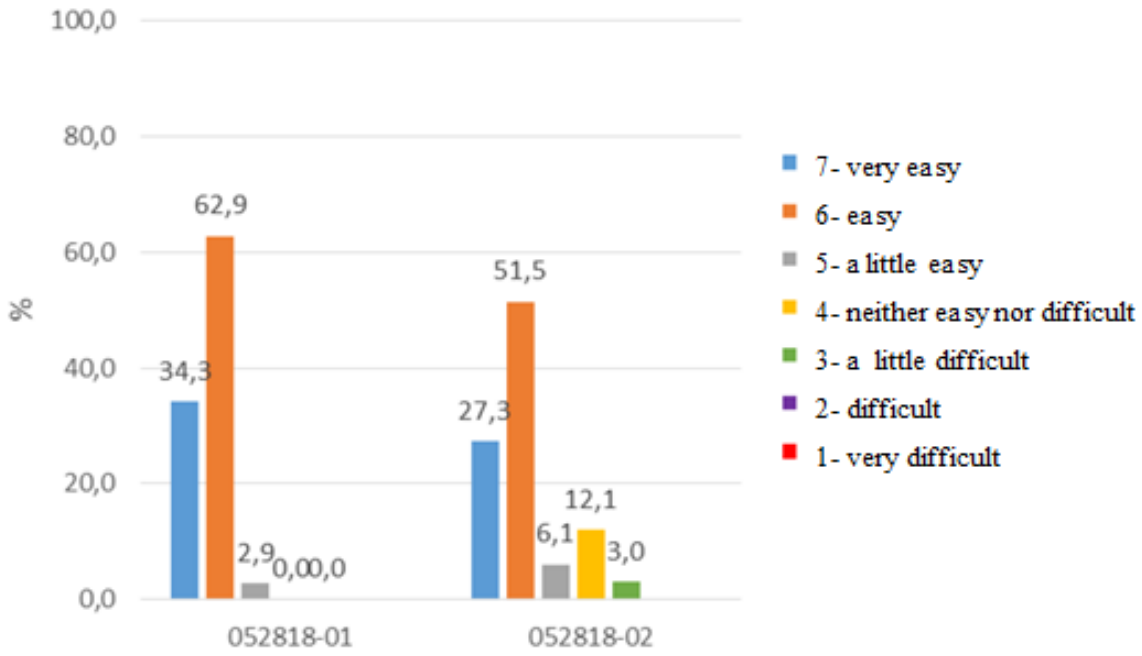
At the time of application, how much you liked or disliked the **Fragrance of the product:**	052818-01		052818-02	
	n	%	n	%
9-loved	8	22.9	2	6.1
8- liked a lot	12	34.3	11	33.3
7- liked moderately	8	22.9	11	33.3
6- slightly liked it	3	8,6	2	6.1
5-Neither liked or disliked	3	8,6	7	21.2
4-disliked moderately	0	0,0	0	0,0
3- disliked slightly	0	0,0	0	0,0
2-disliked a lot	0	0,0	0	0,0
1-hated	1	2-9	0	0,0
Top four	**31**	**88.6**	**26**	**78.8**
Bottom four	**1**	**2,9**	**0**	**0,0**



Ease of application

Table 11. Frequency and percentage

Regarding ease of product application you would say it is :	052818-01		052818-02	
	n	%	n	%
7-very easy	12	34,3	9	27,3
6-easy	22	62,9	17	51,5
5-a little easy	1	2,9	2	6,1
4-neither easy nor difficult	0	0,0	4	12,1
3-a little difficult	0	0,0	1	3,0
2-difficult	0	0,0	0	0,0
1- very difficult	0	0,0	0	0,0
Top three	**35**	**100,0**	**28**	**84,8**
bottom three	**0**	**0.0**	**1**	**3,0**



11. CONCLUSION

According to the methodology used to assess the perceived efficacy of the products Lubrinat / Colpotrofine, forwarded by the company MASTER OF INDUSTRIAL AND PHARMACIST ODONTO PROD LTD., It can be concluded:

Evaluation of perceived efficacy by study participants after 21 (+/- 2) days of product use 052818-01:

94.3% of the assessed participants strongly agreed or agreed to the affirmation "The product has moisturizing properties to the intimate mucosa."

97.1% of the assessed participants reported dryness reduction in the skin.

88.6% of the assessed participants reported increased comfort sensation in the skin.

88.6% of the assessed participants reported liking the fragrance Product in the skin.

100% of participating mentioned easy product application in the skin.

Evaluation of perceived efficacy by study participants after 21 (+ /- 2) days of product use 052818-02:

97.0% of the assessed participants strongly agreed or agreed to the affirmation "The product has moisturizing properties to the intimate mucosa"

100% of the assessed participants reported dryness reduction in the skin.

90.9% of the assessed participants reported increased comfort sensation in the skin.

78.8% of the assessed participants reported liking the Product Fragrance in the skin.

84.8% of participating mentioned ease of Product Application in the skin.

Evaluation of the Comparative Products 052818-01 and 052818-02 Efficacy:

No significant difference was observed between the products regarding the attribute "The product has moisturizing properties to the intimate mucosa" (p = 0.142).

No significant difference was observed between the products regarding the dryness of the intimate mucosa (p-value = 0.786).

No significant difference was observed between the products regarding comfort sensation in intimate mucosa (p-value = 0.528).

No significant difference was observed between the products regarding the fragrance of the products (p-value = 0.088).

No significant difference was observed between the products regarding ease of application (p-value = 0.123).

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11/17/20158

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Study Coordinator
11/17/2015

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ANNEX 5 Product information

Lubrinat

Components
Hyaluronate sodium
Propylene glycol
Natrosol 250 HHX
Sodium lactate, 50% in solution
Sodium benzoate
Lactic acid
Methyl paraben
Cremophor EL
Deionized Water

Colpotrofine
Each gram of the vaginal cream contains promestriene ……10 mg
Excipients: methyl paraben, propyl paraben, glycerol, mono and diglycerides of saturated fatty acids , poliglycol eter of saturated fatty alcohols " decyl ester of oleic acid, triglycerides of capric and caprylic acids, purified water