



**FINAL REPORT**  
**“GYNECOLOGICALLY TESTED**  
**CLINICALLY TESTED UNDER GYNECOLOGICAL AND DERMATOLOGICAL CONTROL”**  
**ASCE PLUS IRLV**

PROTOCOL N°: 0058-25A-04SGMOD1

COSMETIC TO BE TESTED: COSMETIC FOR INTIMATE CARE VULVAR AREA

IMPORTER: PHARMABAX S.R.L.

MANUFACTURER: ExoCoBio Inc. Seoul, Korea

SCIENTIFIC DIRECTOR: PHD SILVIA H. PÉREZ DAMONTE



GYNECOLOGIC AND DERMATOLOGIC SAFETY STUDIES  
Protocol N° 0058-25A-04SGMOD1

**DATE OF FINAL REPORT**

May 2nd, 2025

**CONTRACT RESEARCH ORGANIZATION**

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## 1.0 Objective

The purpose of this study is to evaluate, with a single application of a cosmetic, the possible primary irritation of the vulvovaginal mucosa, as well as to verify the appearance of the discharge, odor and whether it causes itching in the area in healthy individuals. To support the claim “**Gynecologically tested**” “**Clinically tested under gynecological and dermatological control**”, the guidelines of ISO 10993-10 Biological evaluation of medical devices - Part 10: Test for irritation and skin sensitization and ISO 14155:2020 Clinical investigation of medical devices for human subjects, as well as the Good Clinical Practices (GCP) are followed.

The test is performed for the product called “**ASCE plus IRLV**”, identified by its quantitative formula. It is also complemented by the measurement of vulvovaginal pH.

## 2.0 Sponsor

PHARMABAX SRL  
Susana Pintos 3040  
Montevideo  
URUGUAY

## 2.1 Sponsor Representative

Q.F Alinne Galbarini

## 3.0 Testing Facility

CLAIM®  
José Bonifacio 717- CABA.  
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## 4.0 Study investigators

**Scientific Director CLAIM®:** Silvia H. Pérez Damonte Ph.D. Pharmacist specializing in the production of cosmetics MN 11332.

**Medical Researcher Dermatologist:** Patricia N. López MD, MN 91915.

**Gynecologist Medical Researcher:** Rita P. García, MD MN 89500.

## 5.0 Study Dates

**Start of study:** April 14<sup>th</sup>, 2025

**Final evaluation:** April 28<sup>th</sup>, 2025

## 6.0 Quality Assurance

### 6.1 Ethical Conduct of the Study

The study protocol complies with the following international standards for research involving human subjects: **Good Clinical Practice (ICH-GCP)** and the **Declaration of Helsinki** of the **World Medical Association** (1964), including its amendments in **Tokyo (1975)**, **Venice (1983)**, **Hong Kong (1989)**, **Seoul (2008)**, and **Fortaleza (2013)**.

The following ISO standards are also observed:

- **ISO 10993-10:** "Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization"
- **ISO 14155:2020:** "Clinical investigation of medical devices for human subjects – Good clinical practice"

At the national level, the study adheres to **Resolution 1480/11 – “Guidelines for Research Involving Human Subjects”**.

Finally, the study follows the **Standard Operating Procedures (SOPs)** described in the **CLAIM® Quality Manual**, in compliance with **ISO 17025:2005**.

### 6.2 Subject information and Consent

Prior to the beginning of the testing procedure all participating subjects were duly informed about the purpose of the study. Thereafter, they signed and issued their written consent. (Appendix A).

## 7.0 Test Product

The product used in this study was supplied by **Laboratorio Oxapharma S.A.** It was delivered in March/April 2025 and entered into CLAIM with the identification shown in the table:

COMPONENT	AMOUNT	LOT	PACKAGE	DATE
Diluent	3 boxes	VGAC24001	1 vial of 2.5ml per box	3/25/2025
Freeze-dried powder in a vial	3 boxes	VGBC24001	1 vial of 20mg per box	3/25/2025
Diluent	2 boxes	VGBC24002	1 vial of 2.5ml per box	3/25/2025
Freeze-dried powder in a vial	2 boxes	VGAC24002	1 vial of 20mg per box	3/25/2025
Freeze-dried powder in a vial	20 boxes	VGAC24002	1 vial of 20mg per box	4/1/2025
Diluent	20 boxes	VGBC24002	1 vial of 2.5ml per box	4/1/2025

It was stored at 2° to 8°C.









**Product identification:** lots VGAC24002/ VGBC24002 y VGAC24001/ VGBC24001

**Physical description:** lyophilized powder plus diluent..












## 8.0 Subject Selection

Twenty gynecologically fit panelists were selected. Ages ranged from 23 to 62 years. Each panelist read, understood, and signed the informed consent form (Appendix A).

### 8.1 Inclusion Criteria

-  Ages will be between 20 and over.
-  No gynecological problems.
-  Panelists will be notified by CLAIM® and will receive an explanation of the study requirements, sign a written informed consent form.
-  Users who habitually use cosmetics, willing and able to adhere to the study requirements.
-  Must bring the last gynecological control or gynecological visit.
-  Users should not have sexual intercourse 72 hours prior to the study.
-  Panelist may not use intimate products such as lubricants, deodorant, tampons, intimate wipes 72 hours prior to and throughout the study.
-  Under the same conditions panelist will not be able to wax or shave.

### 8.2 Exclusion Criteria

-  Panelists with a medical condition.
-  Panelists using any medication that may increase the risk of participation or confound or influence the results of this study (example: anti-inflammatory steroid and non-steroid medication).
-  Panelists undergoing an organ transplant that requires the use of immunosuppressive medications (with the exception of corneal transplants).
-  Panelists who have diabetes and are taking insulin.
-  Panelists with asthma or respiratory allergy.
-  Having any gynecological disease.
-  Panelists who have a dermatological condition such as psoriasis, eczema, atopic dermatitis, folliculitis or vitiligo.
-  Panelists who are pregnant, breastfeeding or planning a pregnancy.
-  Panelists who present thyroid disorders.
-  Panelists who have a history of skin reactions to the application of topical products.
-  If they have been under medical treatment in the area 6 months prior to the convening of this study.

## 9.0 Test Procedure

CLAIM® technical staff selected qualified women to participate in the study. During the first visit, prior to the start of the study, the dermatologist and gynecologist physicians evaluated the panelists to ensure compliance with the inclusion criteria and health conditions in the study area, while at the same time completing the medical histories. In addition, they performed the instrumental measurement of vulvovaginal pH with Universal Test Paper Merck®.

Subsequently, the doctors applied the product according to the instructions provided by the client as follows.

*Directions for use: "Mix carefully Vial 1 (lyophilized powder) and Vial 2 (diluent). Gently apply the appropriate amount to the intimate area. Apply 2-3 times and allow to absorb. \*Mix and use immediately after opening.*

*\*Single use product.topical use."*

The panelists were instructed to use the usual hygiene products in the area (bidet shower, etc.). They returned after 1 week for the same gynecologic and dermatologic clinical control and then again the following week for the final gynecologic and dermatologic clinical evaluation.

In addition, the panelists completed a daily log.

## 10.0 Results

The following parameters and variants were evaluated in the different citations with the following tables:

Presentó	BASAL	+	SHOWED	9 DAYS	SHOWED	14 DAYS
<b>Eritema</b>	Ninguna Leve Moderado Severa		<u>Erythema</u>	None Slight Moderate Severe	<u>Erythema</u>	None Slight Moderate Severe
<b>Edema</b>	Ninguna Leve Moderado Severa		<u>Oedema</u>	None Slight Moderate Severe	<u>Oedema</u>	None Slight Moderate Severe
<b>Descamación</b>	Ninguna Leve Moderado Severa		<u>Desquamation</u>	None Slight Moderate Severe	<u>Desquamation</u>	None Slight Moderate Severe
<b>Flujo vaginal</b>	<u>Cantidad:</u> Ausente Escasa Moderada Abundante <u>Color:</u> Transparente Blanco Amarillento Marrón/Hemático Otro: observaciones		<u>Vaginal discharge</u>	<u>Amount:</u> Absent Scarce Moderate Abundant <u>Color:</u> Transparent White Yellowish Brown/Hematic Other: remarks	<u>Vaginal discharge</u>	<u>Amount:</u> Absent Scarce Moderate Abundant <u>Color:</u> Transparent White Yellowish Brown/Hematic Other: remarks
<b>Olor</b>	Inodoro Leve Maloliente		<u>Odor</u>	Odorless Slight Smelly	<u>Odor</u>	Odorless Slight Smelly

For the **clinical dermatological aspects**: The clinical observation scale for erythema, edema and desquamation, according to Frosch & Kligman, 1979, was used.

### Dermatological clinical observation scale

	Score	Description
<b>ERYTHEMA</b>	0	None
	1	Slight
	2	Moderate
	3	Severe
<b>OEDEMA</b>	0	None
	1	Slight
	2	Moderate
	3	Severe
<b>DESQUAMATION</b>	0	None
	1	Slight
	2	Moderate
	3	Severe

The following criteria were used for the combined **dermatologic and gynecologic** clinical evaluation:

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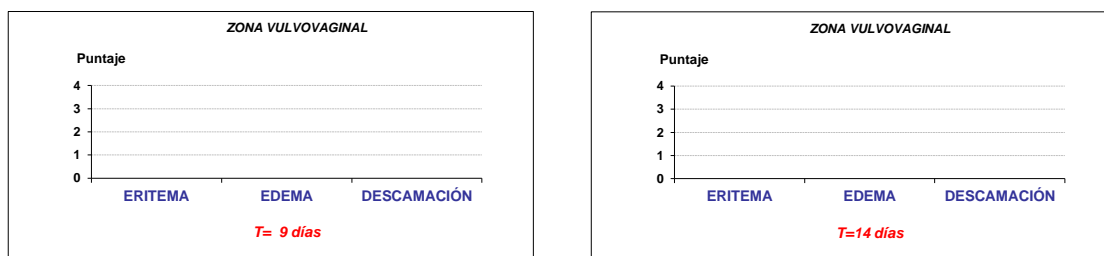
**Response criteria**

Score	Description
Good	All values correspond to zero (0;0;0;0;0)
Fair	At least one non-zero value (0;1;0;0;0)
Poor	Two non-zero values (1;1;0;0;0)

**Table - Clinical dermatological and gynecological evaluation VULVOVAGINAL ZONE**

Panelist	Initials	Age	9 days	14 days	Gynecological and dermatological evaluation
1	RFL	38	0;0;0;0;0	0;0;0;0;0	Good
2	AGC	58	0;0;0;0;0	0;0;0;0;0	Good
3	EAQ	47	0;0;0;0;0	0;0;0;0;0	Good
4	NMA	45	0;0;0;0;0	0;0;0;0;0	Good
5	MCA	61	0;0;0;0;0	0;0;0;0;0	Good
6	GLB	60	0;0;0;0;0	0;0;0;0;0	Good
7	DHV	53	0;0;0;0;0	0;0;0;0;0	Good
8	AAM	60	0;0;0;0;0	0;0;0;0;0	Good
9	MNE	54	0;0;0;0;0	0;0;0;0;0	Good
10	NDR	31	0;0;0;0;0	0;0;0;0;0	Good
11	MAG	59	0;0;0;0;0	0;0;0;0;0	Good
12	KNI	39	0;0;0;0;0	0;0;0;0;0	Good
13	MFG	51	0;0;0;0;0	0;0;0;0;0	Good
14	AFE	52	0;0;0;0;0	0;0;0;0;0	Good
15	JB	24	0;0;0;0;0	0;0;0;0;0	Good
16	PCK	47	0;0;0;0;0	0;0;0;0;0	Good
17	AMG	62	0;0;0;0;0	0;0;0;0;0	Good
18	SR	59	0;0;0;0;0	0;0;0;0;0	Good
19	MLS	49	0;0;0;0;0	0;0;0;0;0	Good
20	OV	23	0;0;0;0;0	0;0;0;0;0	Good

Below are graphs according to - Values corresponding to the cutaneous clinical response as a function of time.



20 panelists involved (100% of the total population).

## 10.1 Statistical results

### Vulvovaginal pH assessment

Instrumental measurements were made to determine the stability of the vulvovaginal pH, comparing the initial pH obtained at 9 days and 14 days after application.

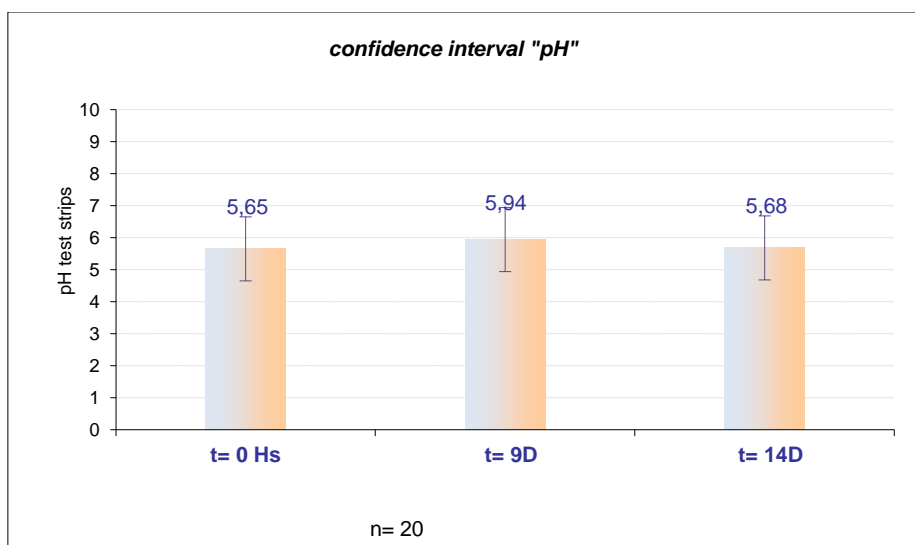
Measurements were performed at the beginning of treatment, at 9 days and 14 days of use, where a study of the variation of the mean value of the measurements was applied using a WILCOXON T-TEST OF PAIRED SAMPLES, with an  $\alpha$ -risk of 0.05 and a  $\beta$ -risk of 0.2.

The quantitative and statistical information can be summarized in the following table:

Factor	Time	Mean	SD	Min	Max	Sample size (n)
PH	Basal	5.65	0.83	4.00	7.00	20
	9 days	5.94	0.82	4.00	7.00	20
	14 days	5.68	0.82	4.00	7.00	20

Gráficamente, puede observarse que en general los valores de "PH" no se alteran:

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The Wilcoxon T-TEST FOR PAIRED SAMPLES revealed that there is statistical evidence to infer no alteration of PH for the evaluation instances comparing the initial time with 9 and 14 days.  
 - For the "PH" parameter, a summary of the test results between t=0 and t=9 days evidenced no change in the mean: Wilcoxon T-Test with Paired Samples

-----  
 Null Hypothesis: Sample drawn from populations with difference of means equal to 0.  
 Alt. Hypothesis: Sample drawn from population with difference of means not equal to 0.  
 Sample size: 20.  
 Difference in means: 0  
 Difference std. dev.: 0  
 Distribution: StudentT(19)  
 Computed statistic: 1  
 Computed pvalue: 1  
 Confidence interval: [0 , 0] (difference of population means)

-----  
 Result: [Accepted]  
 There is no statistical evidence against the null hypothesis = false.

- For the "PH" parameter, a summary of the test results between t=0 and t=14 days shows no change in the mean:

Wilcoxon T-Test with Paired Samples

-----  
 Null Hypothesis: Sample drawn from populations with difference of means equal to 0.  
 Alt. Hypothesis: Sample drawn from population with difference of means not equal to 0.  
 Sample size: 20.  
 Difference in means: 0  
 Difference std. dev.: 0  
 Distribution: StudentT(19)  
 Computed statistic: 1  
 Computed pvalue: 1  
 Confidence interval: [0 , 0] (difference of population means)

-----  
 Result: [Accepted]  
 There is no statistical evidence against the null hypothesis = false.

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The non-alteration of the vaginal pH can be evidenced in the following table:

<b>Comparison pH - after 9 days - after 14 days</b>		
Initial	9 days	14 days
<b>% Variation:</b>	0%	0%
<b>% Panelists sin variación:</b>	100%	100%

Parameters with \* correspond to those in which the treatment produced significant changes with an  $\alpha$ -risk of 0.05 and a  $\beta$ -risk of 0.2, according to the WILCOXON T-TEST FOR PAIRED SAMPLES. Mean values with different letters correspond to significant differences according to the test. In the parameters without \* % Variation and % Panelists without variation are included for information purposes, since in those instances the test does not evidence changes in the PH values..

The evidence observed in the graphs, statistical tests and quantitative data showed that the product called **“ASCE plus IRLV” does not produce alterations in vulvovaginal pH.**

## 11.0 Conclusions

- Based on gynecological and dermatological evaluation, self-perception and instrumental measurement by non-invasive bioengineering carried out in the area in a single application during two weeks, we can affirm that in this population and under the conditions of the study, the product **“ASCE plus IRLV”**:
- Demonstrated no potential for vulvar irritation, vaginal discharge changes or odor throughout the study.
- Verified good tolerance in the vulvovaginal area throughout the trial without manifestation of pruritus.
- No alteration in the vulvovaginal pH.
- Found safe for intended use, thus considered approved for topical use.

Therefore, **“ASCE plus IRLV”** has been **“Gynecological and Dermatologically Tested”**, demonstrating **“clinically gynecological and dermatological safety”**.

Dr. PATRICIA NOEMÍ LÓPEZ  
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Patricia Noemí López  
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RITA P. GARCÍA  
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**Appedix A –****CONSENTIMIENTO INFORMADO**

Presupuesto N° 0058-25-SG- Rev.A

**CONSENTIMIENTO INFORMADO**

Me han invitado a participar en un estudio de investigación clínica para evaluar la seguridad ginecológica y dermatológica de un producto cosmético de única aplicación. Este producto ha sido estudiado en cuanto a su tolerancia por medio de otros procedimientos de testeo, siendo sus resultados satisfactorios. El laboratorio patrocinante quiere comprobar su seguridad en la zona vulvovaginal.

**Me han informado que, si estoy embarazada o en periodo de lactancia, no podré participar de este estudio.**

¿Cuánto tiempo durará el estudio?

Me han informado que la duración del estudio será de dos semanas, requiriendo de tres visitas a la sede encargada del testeo, en la cual el primer día será el día 0, luego tendré que asistir a la semana para hacer el mismo control que el primer día y regresaré nuevamente transcurrida la segunda semana para el último control y finalización del estudio. Me han informado que recibiré por escrito las fechas y horarios en que debo presentarme para las siguientes visitas.

**Me han informado que mi participación es voluntaria y puedo retirarme del estudio en cualquier momento.**

¿Qué sucederá mientras participo del Estudio?

Me han informado que el primer día del estudio una médica ginecóloga examinará la zona vulvovaginal y me medirá el pH con una cinta de pH, así mismo una médica dermatóloga también examinará la piel de la zona vulvovaginal para asegurar que no existen condiciones previas que me impidan participar del estudio, confirmando así que cumpla con todos los criterios de inclusión.

Me han informado que la doctora me aplicará el producto en CLAIM. Transcurrida 1 semana, deberé concurrir nuevamente a la sede de en donde se me realizará el mismo control clínico ginecológico y dermatológico que el primer día. Seguidamente, transcurridas las dos semanas regresaré nuevamente a CLAIM® para la evaluación clínica ginecológica y dermatológica final.

Me han informado que tengo que completar un registro diario que me será entregado

¿Qué debo hacer si tengo reacciones inesperadas?

Me han informado que, si padeciera cualquier reacción adversa o problema no deseado como ser irritación, enrojecimiento, picazón o alguna otra molestia en la zona vulvovaginal tengo que llamar a CLAIM. Si es posible me pedirán que registre, y documente lo que le sucede.

El patrocinador del estudio se hará cargo de cualquier tratamiento médico y / o los gastos que la solución del problema demandare. "Tratamiento médico" significa: la consulta con un médico o servicio hospitalario y los medicamentos que fueran necesarios para curarlo o aliviarlo de los efectos producidos por los artículos testeados o dentro del procedimiento de testeo.



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¿Quién tendrá acceso a mis datos personales?

Me han informado que mis datos personales sólo se utilizarán a los fines de este estudio. Por lo tanto, solo serán conocidos por la sede examinadora y su personal técnico y de ser necesario por el Comité de Ética y las autoridades regulatorias, sin violar la confidencialidad de los datos, y no se harán de conocimiento público.

Como indica la ley N° 25.326, me han informado que tengo el derecho de acceder a mis datos en forma gratuita y la posibilidad de rectificarlos. En caso de no poder acceder a los mismos me han informado que tengo el derecho a hacer la denuncia correspondiente en la Dirección Nacional de Protección de Datos Personales. Esta dirección certifica que la Dra. Silvia Haydee Pérez Damonte se encuentra inscripta en el Registro Nacional de Bases de Datos alcanzadas por la Ley N° 25.326 con el Número de Registro: 1953

¿Con quién me puedo comunicar si tengo dudas?

Ante cualquier reacción adversa, por favor comuníquese con las investigadoras principales: Dra. Rita García y la Dra. Patricia Noemí López; y por cualquier pregunta sobre este estudio contactar a la Dra. Silvia H. Pérez Damonte.

**Teléfono de línea: 4433 - 2732 / 2148 - 6633 / Teléfono celular: 11 6838 7190**

¿Me pagarán por participar?

Me han informado que recibiré un pago por participar de este estudio por única vez de **\$25.000** si cumpla con todas las visitas. Si no pudiera cumplir con las mismas se me pagará un proporcional, una vez finalizado el estudio.

Recibiré una copia de este formulario de aceptación.

He **LEÍDO, COMPRENDIDO Y ACEPTO** participar de este estudio, por lo cual firmo 2 copias de este Consentimiento Informado, una de ellas quedará en CLAIM y la otra la llevaré conmigo.

**Firma y Aclaración del participante:** \_\_\_\_\_

**DNI:** \_\_\_\_\_

**Fecha:** \_\_\_\_\_

**Investigadora Principal:** \_\_\_Dra. Rita García MN 89500 y Dra. Patricia Noemí López MN 91915/ MP 447465\_\_\_\_\_

**GRACIAS POR SU PARTICIPACION**

**CLAIM**

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## **Appendix C - Bibliography**

- European Commission Directorate General for Health and Consumers. Dec. 2010. Guidelines on Medical Devices. Guidelines on Clinical Investigation: A Guide for Manufacturers and Notified Bodies.
- ISO 10993-10 Biological evaluation of medical devices. Part 10 Test for irritation and skin sensitization.
- ISO 14155-1 Clinical investigation of medical devices for human subjects. Part1: General requirements.
- ISO 14155-2 Clinical investigation of medical devices for human subjects. Part 2: Clinical investigation plans.
- The SCCS notes of guidance for the testing of cosmetic ingredients and their safety evaluation. 12<sup>th</sup> revision (2023).