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## REPORT: ACCEPTABILITY STUDY (IEC BULGARIE)

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### IN-USE TEST UNDER DERMATOLOGICAL CONTROL

Clinical study for the appraisal of the cutaneous acceptability of a cosmetic investigational product, after repeated applications under normal conditions of use, in the adult subject

<u>Investigational product(s):</u>	:	<b>GEL CONFIDENCE BOOSTER №5</b> (formula n° 01022016, N of batch : L 08 exp 07.2019.)
<u>Protocol</u>	:	N° B171686PE-Version 1, of 19 September 2017
<u>Report</u>	:	N° B171686RD – Version 1, of 3 <sup>rd</sup> November 2017
<u>Sponsor</u>	:	ASTROLOGOS LTD 2-6 TSAR IVAN ASEN II STR 6300 HASKOVO - BULGARIA
<u>Study monitor</u>	:	D. GIUROVA
<u>Beginning of observations</u>	:	25 September 2017
<u>End of observations</u>	:	16 October 2017
<u>Address of investigations</u>	:	<b>I.E.C. Bulgarie</b> Lozenetz - 17, Henrik Ibsen Street 1407 SOFIA - BULGARIA
<u>Investigator</u>	:	N. LOZEV, M.D. - Dermatologist
<u>Responsible for study</u>	:	Mrs. N. ATANASOVA

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## AUTHENTICATION

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The study subject of the present report was conducted under my responsibility, in compliance with the study protocol, in accordance with the standard operating procedures of I.E.C., and in the spirit of the general principles of the Good Clinical Practice published by I.C.H. (Topic E6: CPMP/ICH/135/95).

I assume the responsibility of the validity of all raw data obtained during this study and mentioned in the present report.



**Nikolay LOZEV, M.D.**  
**Dermatologist Investigator**

I have read this report, I certify that these data are accurate reflection of the results obtained and I agree with its content.



**Nevena ATANASOVA**  
**Responsible for study**

## 1 STUDY OBJECTIVE

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. Appraise the cutaneous acceptability of a cosmetic investigational product.

## 2 STUDY TYPE

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Acceptability study ("in-use test"), under dermatological control, in "open".

## 3 STUDY RELEVANCE

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Cutaneous irritation can be defined as an attack of skin integrity, with lesions to the epidermis and coming from an inflammatory reaction of the dermis, expressed by macroscopically visible phenomena, mainly redness (erythema) up to oedema.

In man, the "in-use" ("acceptability") test performed under Dermatological control (subjects individually examined by a Dermatologist Investigator) enables to check the absence of discomfort and/or irritation reactions (functional and physical signs) linked to the investigational product.

A directed and adapted questionnaire also enables to appreciate the cosmetic acceptability and the efficacy of the investigational product on the basis of answers given by the subjects.

## 4 STUDY PRINCIPLE

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ACTIONS	D0	D21
Admission by the Dermatologist Investigator (checking of inclusion and non-inclusion criteria)		
Individual clinical examination by the Dermatologist Investigator (checking of functional and physical signs)		
Applications of the investigational product by the subject		
Subject filling in a questionnaire concerning the safety of the investigational product		
Subject filling in a questionnaire concerning the cosmetic acceptability and efficacy of the investigational product		

*Grey boxes = actions done*

## 5 GENERAL INCLUSION AND NON INCLUSION CRITERIA

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These criteria are defined in I.E.C. procedures and the computerized database of I.E.C.

## 6 INCLUSION CRITERIA SPECIFIC TO THE STUDY

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- Number of subjects: 20
- Origin: Caucasian
- Gender: female
- Age: 18 to 70 years old
- Body skin nature: all types
- Other: Subjects presenting with skin laxity.

## 7 METHODOLOGY

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### MODE OF APPLICATION

The applications of the investigational product are performed by the subject herself (from D0 to D20), in replacement of the one she generally uses and according to the following indications:

Application area	Body (hips, thighs)
Quantity	as much as necessary
Frequency	twice a day (in the morning and in the evening)
Duration	From D0 to D20
Application Conditions	By the subject herself, according to the sponsor's recommendations, at home : Apply on clean and dry skin.

### APPRAISAL OF THE CUTANEOUS ACCEPTABILITY

- Clinical examinations by the Dermatologist Investigator (on D0 and on D21) to appreciate the physical and functional signs linked to the applications of the investigational product
- Questionnaire filled in by the subject during the study, precising the nature, location, intensity, duration, period of appearance and emergence after application of the reactions, if any.

### APPRAISAL OF THE COSMETIC QUALITIES AND EFFICACY

Questionnaire prepared in collaboration with the Study Monitor, filled in by the subject, at home, before his/her last visit to I.E.C..

## 8 DATA ANALYSIS

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Descriptive analysis of:

- . reactions noted during the study
- . reactions observed by the Dermatologist Investigator
- . reactions reported by the subjects (discomfort, irritation ...)
- . reactions that needed to modify significantly the application modalities
- . reactions which can be considered as "relevant"
- . reactions considered as adverse events linked to the investigational product
- . reactions considered as serious adverse events linked to the investigational product

## 9 RESULTS INTERPRETATION

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Interpretation of the results obtained, under the experimental conditions used, based on:

- . the effects searched by the Study Monitor
- . the type of investigational product
- . analysis of reactions

## 10 RESULTS

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### Studied population

Number of subjects recruited	26
Number of subjects who came to I.E.C.	21
Number of subjects included in the study	21
Number of subjects discontinued from the study	0
Number of subjects for the analysis of the results	21

The characteristics of the subjects are summarized in the following table:

Subjects	Body skin nature	Sensitivity	Healthy subjects with history of	Users of this type of product <sup>o</sup>
Number : 21	Normal : 9 (43 %)	Body skin : 4 (19 %)	0 (0 %)	15 (71 %)
Females : 21 (100 %)	Dry : 8 (38 %)			<i>regular users:</i>
Males : 0 (0 %)	Very Dry : 4 (19 %)			10 (48 %)
Mean age : 40				
Age min : 23				
Age max : 58				

<sup>o</sup> *body moisturiser*

All these subjects presented with skin laxity.

## Discussion

### Cutaneous acceptability

Analysis of the results obtained revealed a very good acceptability of the investigational product in the 21 subjects who took part in the whole study.

No abnormal clinical sign was noted, by the Dermatologist Investigator, after the 3 weeks of use. All the subjects also indicated not having felt and / or observed discomfort and / or irritation signs during the study.

### Questionnaire

<b>EFFICACY AND COSMETIC QUALITIES</b> (4 point scale - answers given by "somewhat agree" to "agree")	<b>D21</b> (n = 21)
The product does not heat the skin	<b>100%</b>
The product does not provoke itching	<b>90%</b>
The product does not provoke redness	<b>95%</b>
The aroma is pleasant	<b>85%</b>
The consistency is pleasant	<b>90%</b>
The product penetrates fast into the skin	<b>87%</b>
The product smooths the problem areas	<b>96%</b>

<b>APPRAISAL</b> (answers given by "somewhat agree" to "agree" or by "yes*")	<b>D21</b> (n = 21)
The product is suitable for subject's skin type*	<b>100%</b>
On the whole, the product is pleasant	<b>95%</b>
From a cosmetic point of view, the investigational product was considered as « good » to « very good »	<b>100%</b>
The subject would like to continue using the product*	<b>100%</b>
Purchase intention*	<b>87%</b>

<b>IN COMPARISON WITH THE USUAL PRODUCT</b>	<b>D21</b> (n = 10) •
By comparing with the product generally used, the subject found her skin "just as good" to "better"	<b>100%</b>
Preferred product: <ul style="list-style-type: none"> <li>. the usual product</li> <li>. the investigational product</li> <li>. no preference</li> </ul>	10% <b>70%</b> 20%
Most efficient product: <ul style="list-style-type: none"> <li>. the usual product</li> <li>. the investigational product</li> <li>. no difference</li> </ul>	10% <b>70%</b> 20%

• regular users of this type of product

## 11 CONCLUSION

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The CUTANEOUS ACCEPTABILITY of the investigational product designated as "GEL CONFIDENCE BOOSTER №5 (formula n° 01022016, N of batch : L 08 exp. 07.2019)" can be judged, VERY GOOD, after repeated applications under normal conditions of use, twice a day for 3 consecutive weeks, to the body skin, by 21 female adult subjects, from 23 to 58 years old.

The claim such as "Tolerance tested under Dermatological control" can thus be justified

Sofia,  
On 3/11/2017



**N. LOZEV, M.D.**  
Dermatologist Investigator



**N. ATANASOVA**  
Responsible for study

## CONTROLE QUALITE

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This study was performed in conformity with the Standard Operating Procedures of the Institut d'Expertise Clinique, the protocol signed with the sponsor and "in the spirit" of the general principles of the Good Clinical Practices published by I.C.H. (Topic E6 : CPMP/ICH/135/95).

Audits of clinical studies are conducted every 6 months on each type of study. They are intended to verify the correct respect of the procedures during the study. The results of these audits are subject to reporting to the Investigator(s) and the Head of Laboratories.

I.E.C. Bulgaria Quality Unit confirms the compliance of this report with the data generated during the study.

Sofia,  
On 03/11/2017



**ELENA GANCHEVA**  
Quality Manager

## COMPLIANCE

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No incident, which could have affected the quality or the interpretation of the results obtained, was observed.

## STORAGE OF THE INVESTIGATIONAL PRODUCT

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The investigational product was kept under lock and key, from heat (between + 5°C and + 25°C).

A sample of the investigational product will be kept in our facilities for 4 months as of the date of despatch of the final report. From this date on, and with no contrary advice of the Sponsor, the investigational product will be destroyed.

## DATA RECORDING AND ARCHIVING

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Raw data are defined as original records and certified copies of original records of clinical / instrumental findings and observations (hand-written data, printing tickets, pictures, digital recordings, samples...) directly input in the case report form (constituted, paginated and stapled before the start of the study) or in another specific software / folder / file. Raw data are then synthesised in compilation documents, which are mainly computer files and enable either direct analysis of the data, or transfer to a more specific software (video/image analysis, statistical analysis...). If corrections of the raw data or of the compilation are required, the person in charge of the correction should state the reason, date and sign, according to the investigator's procedure (the original entry must remain legible).

All raw data (case report forms, questionnaires if any), as well as the original documents of the compilation and a copy of the final protocol (amendments if any) and of the final report (all different versions and/or amendments if any, are kept in the archives of I.E.C. Bulgarie for 10 years, at the following addresses:

- . For the 2 to 6 months following despatch of report:  
I.E.C. Bulgarie - Hladilnika, Lozenetz - 17, Henrik Ibsen Street  
1407 Sofia - Bulgaria
- . For the following years:  
"Reisswolf-Bulgaria S.A." Logistics Park Bozhurishte, 10 Evropa Blvd  
2227 Bozhurishte - Bulgaria.

One copy of the compilation and the original documents (statistics, final protocol (protocol amendments if any), final report (all different versions and/or report amendments if any) and summaries) are kept for 10 years at the following addresses :

- For the 2 to 6 months following despatch of report:  
I.E.C., 88, boulevard des Belges, 69006 Lyon - France
- For the following years: in the premises of EVERIAL  
Head office: 27, rue de la Villette, 69003 Lyon - France.

Once this period is over, the Sponsor is contacted regarding its archives. No archive destruction is done without the written agreement from the Sponsor.