CONFIDENTIAL

REPORT: ACCEPTABILITY STUDY (IEC BULGARIA)

IN-USE TEST UNDER ODONTOLOGICAL CONTROL

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

Investigational product	:	**SMOKETREE HYDROLINA BY INA ESSENTIALS** (ref.: 3220901 - Batch n° Lot 6 - 2021)
Standard Study Protocol	:	PEG-TUDRSTD-3.0-GB-of 17 February 2020
Specific Study Protocol	:	N° B220449PE - Version 1, of 29 April 2022
Report	:	N° B220449RD – Version 2, of 02 August 2022
Sponsor	:	**"Ina Trade" Ltd.** 13, Rayna Knyaginya Street 4500 Panagiurishte, Bulgaria
Study monitor	:	Mrs Maria RALCHEVA
Beginning of observations	:	04 May 2022
End of observations	:	01 June 2022
Address of investigation	:	**I.E.C. Bulgaria** -17, Henrik Ibsen Street, Hladilnika, Lozenetz, 1407 Sofia – BULGARIA
Investigator	:	Mr Svilen MITEV, D.D.S. – Dental Surgeon
Responsible for study	:	Mr Valeri KRASTEV

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AUTHENTICATION

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(R2): EMA/CHMP/ICH/135/1995).

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

Svilen MITEV, D.D.S
Dental Surgeon Investigator

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

Valeri KRASTEV
Responsible for study

PERSONNEL INVOLVED IN THE STUDY

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- **President**
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- **General Director**
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  Ph.D in Cellular Biology and Microbiology

- **Head of Clinical Safety Studies**
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  Post-Graduate in Dental Surgery

- **Technician**
  MARIA VALCHANOVA
  Nurse

- **Responsible for the Study**
  VALERI KRASTEV
  Bachelor's degree in Molecular Biology

QUALITY CONTROL

This study is performed in compliance 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(R2): EMA/CHMP/ICH/135/1995).

Audits of clinical studies are conducted every 6 months on each type of study. They are intended to verify the good compliance with the procedures during the study. The results of these audits are reported to the investigator(s) and to the responsible of the laboratories.

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

Sofia,
On 02 August 2022

Evgeniya RUSEVA
Quality Auditor

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6. RESULTS

6.1. Amendment and protocol compliance

6.1.1. Amendment

No amendment to the protocol was issued during the course of this study.

6.1.2. Protocol Compliance

Criterion(a)	Deviation(s) noted	Criterion(a) indicated in the protocol
Number of subjects	22 subjects on D0 21 subjects on D28	25 subjects
Inclusion criteria . Bleeding Index score	. between 1 and 1.5 for 7 subjects (n° 02, 08, 10, 13, 14, 18, 22)	. at least a score of 2

These deviations did not affect, in a notable way, the quality or the interpretation of the results obtained.

6.1.3. Studied population

Number of subjects recruited	26
Number of subjects who came to I.E.C.	22
Number of subjects included in the study	22
Number of subjects discontinued from the study - Consent withdrawal by the subject	1 1 (n° 01)
Number of subjects for the analysis of the results	21

6.1.4. Subjects' characteristics

The characteristics of the subjects are summarized in the following table

Subjects	Sensitivity	Healthy subjects with history of atopy	Users of this type of product°
Number : 21 Females : 11 (52 %) Males : 10 (48 %) Mean age : 43.8 Age min : 22 Age max : 57	Gums : 21 (100 %)	1 (5 %)	21 (100%) *Regular users* 18 (86 %)

°mouthwash

All these subjects also presented with at least 20 natural teeth and a mean Modified Gingival Index (MGI) ≥ 2.

6.2. Appraisal of the oral and dental acceptability of the investigational product

No abnormal clinical sign was noted, by the Dental Surgeon Investigator, after the 4 weeks of use. All the subjects also indicated not having felt and/or observed any discomfort and/or irritation signs during the study.

These results allow to conclude to a very good tolerance at the oral and dental levels for this type of product studied in these conditions.

6.3. Clinical evaluation by the investigator

		Means and standard deviations (Sd)		Probability p: Wilcoxon test	Variation percentage #	Delta on the mean
	n	**D0 Initial value**	**D28**			
Modified Gingival Index-mean score	**21**	2.06 ± 0.23	1.93 ± 0.23	***0.004***	**-6%**	-0.13
Bleeding Index-mean score*	**21**	1.72 ± 0.42	1.21 ± 0.38	***<0.001***	**-30%**	-0.51

 # Variation with regard to the initial values; ***bold type %: variation ≥ 5% (statistically and clinically significant)***

Delta: difference(s) between the means on the considered time point(s) and the initial values

Statistically significant probability: p < 0.05
Probability close to significativity: 0.05 ≦ p < 0.10
Not significant probability: p ≥ 0.10.

6.4. Appraisal by the subject of the cosmetic acceptability and efficacy of the investigational product

6.4.1. Appraisal in the presence of the Odontologist Investigator

Cosmetic acceptability	→	good to very good	:	**100%**
Efficacy	→	good to very good	:	**100%**

6.4.2. Questionnaire

APPRAISAL *(2 or 4 point scale - answers given by "somewhat agree" to "agree" or by "yes")*	**D28** *(n = 21)*
The product is suitable for the subject's gums*	**95%**
From a cosmetic point of view, the investigational product was considered as "good" to "very good"	**90%**
On the whole, the product is pleasant (*"Agree to Somewhat Agree")*	**90%**
Product rating by the subjects (on a scale of 0 to 10)	Mean 7.5
The subject would like to continue using the product *	**71%**
Purchase intention (regardless of its price)*	**52%**

Bold type : % ≥ 50%

**regular users of this type of product*

IN COMPARISON WITH THE USUAL PRODUCT	**D28** *(n = 18)*
By comparing with the product generally used, the subject found his gums "just as good" to "better"	**94%** *(17/18*)*
Preferred product: . the usual product . the investigational product . no preference	 17% *(3/18*)* 22% *(4/18*)* **61%** *(11/18*)*
Comparison of the efficiency of the investigational product with the one normally used: . the usual product was more efficient . the investigational product was more efficient . no preference	 17% *(3/18*)* 22% *(4/18*)* **61%** *(11/18*)*

Bold type : % ≥ 50%

**regular users of this type of product*

7. CONCLUSION

The ORAL AND DENTAL ACCEPTABILITY of the investigational product designated as "SMOKETREE HYDROLINA BY INA ESSENTIALS (ref.: 3220901 - Batch n° Lot 6 - 2021)" can be judged VERY GOOD, after repeated applications under normal conditions of use, twice a day for 4 consecutive weeks, to the oral cavity, by 21 adult subjects, of both genders, from 22 to 57 years old and all with "sensitive" gums.

Moreover, the repeated applications of this investigational product by these subjects led to:

A STATISTICALLY SIGNIFICANT DECREASE of mean BLEEDING INDEX and MODIFIED GINGIVAL INDEX, after 4 weeks of application, in comparison with the initial values, on the basis of a clinical scoring performed by the Dental Surgeon Investigator.

The claims such as "TOLERANCE TESTED UNDER ODONTOLOGICAL CONTROL" and "SUITABLE FOR SENSITIVE GUMS" can thus be justified.

Sofia,
On 02 August 2022

Svilen MITEV, D.D.S
Dental Surgeon Investigator

Valeri KRASTEV
Responsible for study

This study was conducted by INSTITUT D'EXPERTISE CLINIQUE - BULGARIE,
registered by the Bulgarian Health Authorities
Professor Rumyana YANKOVA, MD., Ph. D., Head, Dermatology and Allergy Center,
PULMED University Hospital of Plovdiv, Bulgaria

APPENDICES

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APPENDIX 1

SUMMARY OF THE REPORT

INSTITUT D'EXPERTISE CLINIQUE

17, Henrik Ibsen street, Hladilnika, Lozenetz, 1407 Sofia – BULGARIA

SUMMARY OF THE REPORT: ACCEPTABILITY AND OBJECTIVATION STUDY IN-USE TEST UNDER ODONTOLOGICAL CONTROL (IEC BULGARIA)

Clinical Study	:	Clinical study for the appraisal of the oral and dental acceptability and for the evaluation of the efficacy of an investigational product, after repeated use under normal conditions, in the adult subject
Investigational Product	:	**SMOKETREE HYDROLINA BY INA ESSENTIALS** (ref.: 3220901 - Batch n° Lot 6 - 2021)
Standard Study Protocol	:	PEG-TUDRSTD-3.0-GB-of 17 February 2020
Specific Study Protocol	:	N° B220449PE - Version 1, of 29 April 2022
Report	:	N° B220449RD – Version 2, of 2 August 2022
Beginning of observations	:	04 May 2022
End of observations	:	01 June 2022
Address of investigation	:	**I.E.C. Bulgaria** 17, Henrik Ibsen Street, Hladilnika, Lozenetz, 1407 Sofia – BULGARIA

Protocol

Specific inclusion criteria :

. Number of subjects: 25
. Origin: Indifferent
. Gender: Indifferent
. Age: 18 to 70 years old

. Other:
. Subject presenting with a mean Bleeding Index (BI) of at least 2
. Subject presenting with a mean Modified Gingival Index (MGI) of at least 2
. At least 20 natural teeth

Methodology :

. Application modalities of the investigational product:
. area: oral cavity
. frequency and duration: at least twice a day (in the morning and evening) for 4 consecutive weeks
. conditions of application: by the subject, at home, under the normal conditions of use.

. Modalities of evaluations:
. oral and dental acceptability: clinical examinations by the Dental Surgeon Investigator (D0 and D28) and questionnaire filled in by the subject
. clinical evaluation (scoring) by the Dental Surgeon investigator: clinical evaluation of the MODIFIED GINGIVAL INDEX and BLEEDING INDEX on D0 and D28.
. cosmetic qualities and efficacy: questionnaire filled in by the subject.

Results and conclusion

The claims such as "TOLERANCE TESTED UNDER ODONTOLOGICAL CONTROL" and "SUITABLE FOR SENSITIVE GUMS" can thus be justified.

Sofia,
On 02 August 2022

Svilen MITEV, D.D.S
Dental Surgeon Investigator

Valeri KRASTEV
Responsible for study

This study was conducted by INSTITUT D'EXPERTISE CLINIQUE - BULGARIE,
registered by the Bulgarian Health Authorities
Professor Rumyana YANKOVA, MD., Ph. D., Head, Dermatology and Allergy Center,
PULMED University Hospital of Plovdiv, Bulgaria

APPENDIX 2
PANEL DATA

Code	Subject	Gender	Age	Origin	Healthy subject with history of atopy	Past history of reactions to cosmetics	Past history of reactions to this kind of product	sensitive gums	Subject presenting a good oral heaith with at least 20 natural teeth	bleeding to brushing presently	bleeding to brushing in the past	anterior gingival treatment	Subejct having brushed his/her teeths before the visit (D0 morning)	Subject presenting with a mean Modified Gingival Index(MGI) at least 2	Subject presenting with a mean Bleeding Index (BI) of 1 to 2	Subject who is not a smoker	Subject committing to follow the specific instructions related to the Covid-19 outbreak	Subject who doesn't present or has not presented within the last 15 days symptoms
ARAVA02	01	M	43	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
KOSST06	02	F	38	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
KANEL03	03	F	35	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
MILST06	04	F	57	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
GRIZD	05	M	42	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
DANSA	06	M	42	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
IVAIV02	07	M	22	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
HRIDO04	08	F	25	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
LOZNI	09	M	54	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
CHAAN05	10	F	33	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
MITHR02	11	M	51	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
MARNI06	12	F	45	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
HRIBO09	13	F	49	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
YOVMA	14	F	57	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
GEOYA06	15	M	49	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
STAIV	16	M	38	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
NIKDI11	17	F	42	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
TOTIR	18	F	52	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
TROIV	19	M	47	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
ILINI02	20	M	47	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
DIMPL	21	M	52	Caucasian	-	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes
MITBO07	22	F	44	Caucasian	yes	-	-	yes	yes	-	-	-	yes	yes	yes	yes	yes	yes

APPENDIX 3
APPRAISAL OF THE INDIVIDUAL ACCEPTABILITY BY THE INVESTIGATOR

Nothing to report.

APPENDIX 4
APPRAISAL OF THE ACCEPTABILITY BY THE SUBJECT

Nothing to report.

APPENDIX 5
APPRAISAL OF THE COSMETIC ACCEPTABILITY AND EFFICACY BY THE SUBJECT

COSMETIC ACCEPTABILITY

04	very good	17	good
0	rather good	0	mediocre
0	bad		

EFFICACY as a "MOUTHWASH"

4	very good	17	good
0	rather good	0	mediocre
0	bad		

APPENDIX 6
ADVERSE EVENTS

Subject number	Adverse Event	Serious	Intensity	Action taken	Outcome
/	/	/	/	/	/

APPENDIX 7
INDIVIDUAL DATA and RESULTS OF STATISTICAL ANALYSIS: CLINICAL EVALUATION by a trained assessor

NOMENCLATURE:

Time point 0	:	D0 *(baseline)*
Time point 1	:	D28
Product 0	:	Investigational product
Measure 1	:	MGI-mean score
Measure 2	:	BI-mean score
PC	:	*Variation percentage (with regard to the initial values)*
DMα Tx or Px	:	*Difference on time point(s) or product(s) for measure α*

Individual Data

vol	temps	m1p0	m1pcp0	m2p0	m2pcp0
2	0	2,00		1,50	
	1	1,83	-8,50%	1,33	-11,33%
3	0	2,00		2,00	
	1	2,00	0,00%	2,00	0,00%
4	0	3,00		2,00	
	1	2,67	-11,00%	1,67	-16,50%
5	0	2,00		2,00	
	1	2,00	0,00%	1,30	-35,00%
6	0	2,00		2,00	
	1	1,67	-16,50%	1,17	-41,50%
7	0	2,00		2,00	
	1	1,67	-16,50%	0,67	-66,50%
8	0	2,00		1,33	
	1	1,83	-8,50%	1,33	0,00%
9	0	2,00		2,00	
	1	1,67	-16,50%	1,50	-25,00%
10	0	2,00		1,33	
	1	2,00	0,00%	1,00	-24,81%
11	0	2,00		2,00	
	1	1,67	-16,50%	1,67	-16,50%
12	0	2,33		2,00	
	1	2,00	-14,16%	1,50	-25,00%
13	0	2,00		1,00	
	1	2,00	0,00%	0,67	-33,00%
14	0	2,00		1,00	
	1	2,00	0,00%	1,00	0,00%
15	0	2,00		2,00	

vol	temps	m1p0	m1pcp0	m2p0	m2pcp0
	1	2,00	0,00%	1,00	-50,00%
16	0	2,00		2,00	
	1	2,00	0,00%	1,67	-16,50%
17	0	2,00		2,00	
	1	2,00	0,00%	1,50	-25,00%
18	0	2,00		1,00	
	1	1,50	-25,00%	0,50	-50,00%
19	0	2,00		2,00	
	1	2,00	0,00%	1,00	-50,00%
20	0	2,00		2,00	
	1	2,00	0,00%	1,00	-50,00%
21	0	2,00		2,00	
	1	2,00	0,00%	1,00	-50,00%
22	0	2,00		1,00	
	1	2,00	0,00%	1,00	0,00%

Measure 1 Product 0 Time 1

Shapiro-Wilk Test

	Statistic	ddl	Signification
Product 0 dm1t0t1	0.733	21	0

Wilcoxon Test

Descriptive statistics

	N	Mean	Std deviation	SEM	Minimum	Maximum
Product 0 m1t0	21	2.063	0.226	0.049	2	3
Product 0 m1t1	21	1.929	0.233	0.051	1.5	2.67

Ranks

	N	Mean ranks	Sum of ranks
m1t1p0 - m1t0p0 : Negative ranks	9	5	45
m1t1p0 - m1t0p0 : Positive ranks	0	0	0
m1t1p0 - m1t0p0 : Ex aequo ranks	12		
m1t1p0 - m1t0p0 : Total	21		

Test paired samples

	Z	Sig asympt (bilaterale)	Sig exact (bilaterale)	Sig exact (unilaterale)
m1t1p0 - m1t0p0	-2.754	0.006	0.004	0.002

Measure 2 Product 0 Time 1

Shapiro-Wilk Test

	Statistic	ddl	Signification
Product 0 dm2t0t1	0.92	21	0.086

Wilcoxon Test

Descriptive statistics

	N	Mean	Std deviation	SEM	Minimum	Maximum
Product 0 m2t0	21	1.722	0.42	0.092	1	2
Product 0 m2t1	21	1.213	0.384	0.084	0.5	2

Ranks

	N	Mean ranks	Sum of ranks
m2t1p0 - m2t0p0 : Negative ranks	17	9	153
m2t1p0 - m2t0p0 : Positive ranks	0	0	0
m2t1p0 - m2t0p0 : Ex aequo ranks	4		
m2t1p0 - m2t0p0 : Total	21		

Test paired samples

	Z	Sig asympt (bilaterale)	Sig exact (bilaterale)	Sig exact (unilaterale)
m2t1p0 - m2t0p0	-3.642	0.000	0	0.000