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PHARMACEUTICAL RESEARCH
AND DEVELOPMENT

Final Report FR15A/P017C14/EN

IN VIVO SAFETY ASSESSMENT OF FORMULATIONS CONTAINING PARTICLES: ACUTE CUTANEOUS IRRITATION TEST (PATCH TEST) - SI BAC-PURE® TEXTILE FINISH

Promoter:

Smart Inovation Lda

August, 2019

UPTEC, Parque de Ciências e Tecnologia da Universidade do Porto · Edifício Inovar e Crescer, Salas 23/39 · Rua Alfredo Allen, n.º 455/461 · 4200-0135 Porto · Portugal
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SPONSOR (if applicable)

Name of the sponsor's representative

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Yogeeta Rocha, Quality Manager

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HISTORY OF THE DOCUMENT

Revision	Amendment/Deviation	Date
A	First issue	22/08/2019

Table of contents

1 – Study Identification

Proposition n.	P017C14
Report n.	FR15A/P017C14/EN
Title	*In vivo* Safety Assessment of formulations containing particles: Acute cutaneous irritation test (patch test) - Si Bac-Pure® TEXTILE FINISH
Study beginning date	17/07/2014 (products received on 03/07/2014)
Test beginning date (if applicable)	21/07/2014
Test conclusion date (if applicable)	24/07/2014
Study conclusion date	28/08/2014
Report Date	22/08/2019

Identification of Test items and Reference items (if applicable)

Commercial name of the Test Product(s)	Dosage form	Active Principle Ingredient (if applicable)	Comments
Si Bac-Pure® TEXTILE FINISH	Liquid	-	The tested product was provided by the promotor in the exact concentration in which it is previewed that it will be in contact with skin

Name of the Test Substance(s)	IUPAC name	CAS Number	Biological Parameters
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Name of the Reference Substance(s)	IUPAC name	CAS Number	Biological Parameters

Sodium Lauryl Sulfate (SLS), 99% purity (in aqueous solution at 2%)	Sodium dodecyl sulphate	151-21-3	---
Water	Aqua	7732-18-5	---

2 – Identification of the Study Personal

Sponsor	Smart Inovation Lda
	Parque Industrial ACIB, lote 7, 4755-539 Várzea, Barcelos
Proponent	INOVAPOTEK, Pharmaceutical Research and Development Lda
	UPTEC, Parque de Ciência e Tecnologia da Universidade do Porto Edifício Inovar e Crescer, Salas 23 e 39, Rua Alfredo Allen, n.º 455/461 4200-135 Porto – PORTUGAL
Study Director	Marta Ferreira
Researcher(s)	Filipa Oliveira
	Responsible for Study Phase(s) n. 4.1 – Recruitment, Study implementation, Final Report
Laboratory Technician(s)	Tânia Martins
	Responsible for Study Phase(s) n. 4.1 – Data analysis
	Liliana Rodrigues
	Responsible for report elaboration
Administrative Assistant	Fátima Ribeiro
	Responsible for Study Phase(s) n. 4.1 –Scheduling of volunteers
Test Facility(ies)	INOVAPOTEK, Pharmaceutical Research and Development Lda
	UPTEC, Parque de Ciência e Tecnologia da Universidade do Porto Edifício Inovar e Crescer, Salas 23 e 39, Rua Alfredo Allen, n.º 455/461 4200-135 Porto – PORTUGAL

3 – Study Report

3.1 Introduction

The goal of this study was to evaluate the safety of a formulation containing particles - **Si Bac-Pure® TEXTILE FINISH**, by assessment of its acute irritant potential in human volunteers after a single application under occlusion (patch test).

3.2 Methods

3.2.1 Volunteers recruitment

33 volunteers complying with the following inclusion and exclusion criteria, verified through a recruitment questionnaire (Annex I) were recruited to this study:

Inclusion criteria:

- Gender: female/male;
- Age: from 18 to 60 years old;
- Caucasian;
- Good general health condition.
- Do not use any topic product in the test site since 12 hours before the beginning of the study and until the end of the study.

Exclusion criteria:

- Skin diseases that may interfere with the study;
- Cutaneous alterations in tested body region like scars, tattoos or others;
- Pharmacological treatment that could influence the study;
- Pregnancy;
- Breast-feeding.

Volunteers signed an informed consent form before the beginning of the study.

3.2.2 Products preparation and codification

The products were numerically coded before the beginning of the study:

5. Si Bac-Pure® TEXTILE FINISH
13. Negative control (water type II)
14. Positive control (Sodium Lauryl Sulfate, 99% purity, at 2% concentration in aqueous solution)

The tested product was given by the promotor in the exact concentration in which it will be in contact with skin, so it was applied on the skin without any dilution.

The positive control was prepared as follows:
0.1 grams of Sodium Lauryl Sulfate (SLS) were accurately weight and diluted in 4.90 grams of water up to a final concentration of 2% of SLS.

3.2.3 Mode of application

Liquid products were dispensed with a micropipette over filter paper discs, placed onto the Finn chamber.
Every product was added to the Finn Chambers right before patch application on volunteers.

The patch was applied on the back/forearm of volunteers, promoting complete occlusion over 48 h.

3.2.4 Measurements

Clinical evaluations

The acute cutaneous irritation potential was evaluated by clinical scorage 30 minutes and 24 hours after patch removal.

Erythema and oedema were scored in a 4-point scale according to table 1 and other clinical signs and symptoms felt by the volunteers during the study were recorded according to the coding presented on table 2.

Table 1. Clinical Scoring of erythema and oedema

Clinical Scoring	CRITERIA: description	
	ERYTHEMA	OEDEMA
0	No erythema	No edema
1	Slight erythema (quiet pinked coloration of the complete tested area or rather visible on one part of the tested area)	Slight edema (palpable and visible)
2	Obvious erythema (clear erythema covering all the tested area)	Obvious edema with or without papule(s) or vesicle(s)
3	Important erythema (severe erythema covering all the tested area or erythema diffusing outside the tested area)	Important edema (extended area outside the tested area) with or without papule(s) or vesicle(s)

Table 2. Clinical coding of skin signs and symptoms.

Code	Description
D	Desquamation
S	Dryness
P	Papule
V	Vesicle
PRU	Itching
PIC	Tingling
ARD	Burning
ADE	Marked reaction to the adhesive

The evaluation of the skin reactions was performed for the tested product and negative and positive controls. However, for the analysis and interpretation of the results, the scoring of negative control was deducted to the scoring of the test product and positive control. Based on those results, the calculation of the acute irritation index (M.I.I.) for the test product was performed. The M.I.I. is an index calculated according to the following formula:

M.I.I. = ∑ of the grade (erythema + oedema)/ Number of subjects

This obtained index was used to classify the studied product according to the following scale:

M.I.I.	CLASS
M.I.I. ≤ 0.20	Non irritating
0.20 < M.I.I. ≤ 0.50	Slightly irritating
0.50 < M.I.I. ≤ 1	Moderately irritating
M.I.I. > 1	Irritating

3.2.5 General Procedure

Recruitment

- Volunteers were informed by oral and written communication about the study protocol and measures to adopt in case of occurrence of adverse reactions;
- Inclusion and exclusion criteria were verified (Annex I);
- Volunteers signed the informed consent form (Annex II);
- Volunteers were alerted about necessary cautions: not to apply any cosmetic products on the test area on the 12 h preceding the beginning of the study and until it was completed; to avoid direct water contact with the adhesive in bath and not to submerge it;
- Volunteers were instructed to address to the study facilities at the scheduled date and time.

1st Visit

- Volunteers were accommodated on the acclimatized trial room for 5 minutes with the skin test area exposed;
- Volunteers were questioned if any change on medication/health condition occurred since last visit;
- The area of application was selected – the tested area should have no skin alterations like scars, tattoos, burnings, etc. Generally, the upper area of the back was chosen. The area was cleaned with purified water and then dried with absorbent paper.
- Finn chambers on Scanpor with the products were prepared right before patch application (the products shall not be exposed to the air for a long period) and applied to each volunteer on the back/forearm under occlusion;
- Volunteers were instructed to keep the patch in the skin during 48h, taking out the patch 30 minutes before the next visit.
- Volunteers were alerted not to apply any other topic application product on the test area during the study; not to be exposed to UV light during the study; to inform the researchers in case of any change in their health status or medication; to avoid direct water contact to the adhesive in bath and not to submerge the adhesive

(drying it well if it gets wet, without rubbing); to address to the study facilities at the scheduled date and time.

2nd Visit

- 48 h after application the patch was removed;
- Volunteers were accommodated on the acclimatized trial room for 5 minutes with the skin test area exposed;
- Volunteers were questioned if any change on medication/health condition occurred since last visit;
- The conditions of the room (temperature and relative humidity) were registered;
- 30 minutes after patch removal the clinical evaluation was performed by the researcher. Results were considered valid only when a circle indicating total occlusion of the patch was observed.
- To perform this evaluation a reading ruler was used.

3rd Visit

- Volunteers were accommodated on the acclimatized trial room for 5 minutes with the skin test area exposed;
- Volunteers were questioned if any change on medication/health condition occurred since last visit;
- The conditions of the room (temperature and relative humidity) were registered.
- 24 hours after patch removal the clinical evaluation was performed by the researcher.
- To perform this evaluation a reading ruler was used.

3.3 Results and Discussion

After the recruitment process 33 volunteers were included, but only 30 completed the trial until the end. The 3 volunteers that dropped-out did not appear for the first visit due to personal reasons.

The mean age of the volunteers enrolled on the study was 34.3 ± 10.02 years old. The study was performed on an acclimatized room with mean Temperature of 24.5ºC ± 0.33ºC and mean Relative Humidity of 61.6% ± 1.33% on the first measurement´s day and with mean Temperature of 24.6ºC ± 0.33ºC and mean Relative Humidity of 65.6% ± 1.09% on the second measurement´s day.

Results of skin reaction recording and acute irritation index for the test product and positive control at 30min and 24h after patch removal are presented on the following tables.

Table 3. Skin reaction recording for the tested product and positive control 30 min and 24h after patch removal (negative control deducted)

Vol. nr.	5 - Si Bac-Pure® TEXTILE FINISH					
	30 MIN AFTER PATCH REMOVAL			24H AFTER PATCH REMOVAL		
	Erythema	Oedema	Other symptons/signs	Erythema	Oedema	Other symptons/signs
1	0	0	-	1	0	-
2	0	0	-	0	0	-
3	0	0	-	0	0	-
4	0	0	-	0	0	-
7	0	0	-	0	0	-
8	0	0	S	0	0	-
10	1	0	-	0	0	-
11	1	0	-	0	0	-
12	0	0	-	0	0	-
13	0	0	-	0	0	-
14	0	0	-	0	0	-
15	0	0	-	0	0	-
16	0	0	-	0	0	-

17	1	0	-	1	0	-
18	0	0	-	0	0	-
19	0	0	-	0	0	-
20	0	0	-	0	0	-
21	0	0	-	0	0	-
22	0	0	-	0	0	-
23	0	0	-	0	0	-
24	0	0	-	0	0	-
25	0	0	-	0	0	-
26	0	0	-	0	0	-
27	0	0	-	0	0	-
28	0	0	-	0	0	-
29	0	0	-	0	0	-
30	0	0	-	1	0	-
31	0	0	-	0	0	-
32	0	0	-	0	0	-
33	0	0	-	0	0	-

Vol. nr.	**Positive Control (SLS 2%)**					
	30 MIN AFTER PATCH REMOVAL			**24H AFTER PATCH REMOVAL**		
	Erythema	**Oedema**	**Other symptons/signs**	**Erythema**	**Oedema**	**Other symptons/signs**
1	1	0	-	2	0	-
2	1	0	-	2	0	-
3	0	0	-	1	0	-
4	1	0	-	2	0	-
7	1	0	-	1	0	-
8	1	0	-	1	0	-
10	1	0	-	2	0	-
11	0	0	-	0	0	-
12	0	0	-	1	0	-
13	0	0	-	2	0	-
14	1	0	-	2	0	-
15	0	0	-	1	0	-

16	1	0	-	1	0	-
17	1	1	-	2	0	-
18	1	0	-	2	0	-
19	1	0	-	1	0	-
20	1	0	-	2	0	-
21	2	0	-	1	0	-
22	0	0	-	0	0	S
23	2	0	-	2	0	-
24	1	0	-	2	0	-
25	0	0	-	1	0	-
26	0	0	-	1	0	-
27	1	0	-	1	0	-
28	1	1	-	2	0	-
29	1	0	-	2	0	-
30	1	0	-	2	0	-
31	1	1	-	1	0	-
32	0	0	-	0	0	-
33	1	0	-	2	0	-

Table 4. Acute irritation index for the tested product and positive control

Product	M.I.I. (after 30 min)	M.I.I.(after 24h)
Si Bac-Pure® TEXTILE FINISH	0.10	0.10
Positive Control (SLS 2%)	0.87	1.40

Analyzing the M.I.I. calculated (table 4) 30 minutes after patch removal, and according to the scale adopted, it can be concluded that the test product was non-irritating.

Besides the clinical evaluation 30 minutes after patch removal, an evaluation at 24h after patch removal was also performed. Once it is known that the skin irritation reaction reaches its maximum 24h after the patch removal, the results at this time (24h) show better the real reactions and are more meaningful than at 30 minutes, and

therefore M.I.I. calculations at 24h will be considered over the M.I.I. calculations at 30 minutes.

So, analyzing the M.I.I. calculated (table 4) after 24 hours of patch removal, and according to the scale adopted, it can be concluded that the test product Si Bac-Pure® TEXTILE FINISH was non-irritating.

3.4 Conclusion

After a 48h patch test performed in 30 volunteers and subsequent clinical evaluation of acute irritant reactions, it can be concluded that the test product Si Bac-Pure® TEXTILE FINISH was non-irritating.

4 – Archiving

The study plan, laboratory technical books, signed consent forms, raw data records, and the final report will be stored for 10 years at inovapotek's facilities.

Annexes

Annex I – Recruitment Questionnaire

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Study nr. : P017C14, 4.1

Date : / /2014 **Volunteer nr. :**

Recruitment questionnaire

(Record nr. 1_version 00)

Mark with a (√) if the following criteria are accomplished:

VERIFICATION OF INCLUSION CRITERIA

1 Age between 18 and 60 years old: ☐ *Specify age:* _____*years old*

2 Female/Male: ☐, specify gender:_____

3 Do not use any topic product in the test site since 12 hours before the beginning of the test and until the end of the study ☐

4 Caucasian ☐

5 Good general health condition ☐

VERIFICATION OF EXCLUSION CRITERIA

6 Does not have skin diseases that can interfere with the study ☐

7 Does not have cutaneous alterations in tested body region like scars, tattoos or others ☐

8 It is not under pharmacological treatment that can influence the study ☐

9 *In case of female volunteers:* is not pregnant ☐

10 *In case of female volunteers:* is not breast-feeding ☐

Comments:

Page 1/2

Date : / /2014

GENERAL DATA ON VOLUNTEERS

11 Have you had any allergy to cosmetic products before?

Yes ☐ No ☐

12 Do you consider to have sensitive skin?

Yes ☐ No ☐

13 Is your skin intolerant to the use of detergents?

Yes ☐ No ☐

Annex II - Informed Consent Form

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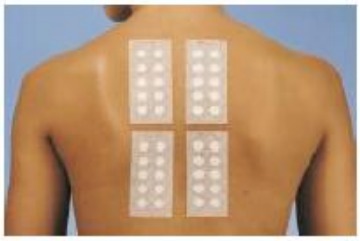
IN VIVO EVALUATION OF THE SKIN COMPATIBILITY OF PRODUCTS OF HYGIENE AND SANITIZERS

Informed Consent Form - Study number: P017C14, 4.1

(Record nr. 2_version 00)

Information about the trial	
Summary description	**The main objective of this study is to evaluate the skin compatibility of products of Hygiene and Sanitizers in healthy humans through an unique application test, under occlusion for 48h.**
Area of application	Back
Application of the products	The products tested and respective controls will be applied on the skin under occlusion, using a hypoallergenic adhesive containing occlusion chambers, as illustrated on the following image:   The adhesives should be kept on the skin for 48h until the next visit.
Methodology	In the first visit the adhesives will be applied in the back of each volunteer. Second and third visits will be scheduled 48h and 72h after. 30 minutes before the second visit the volunteer should remove the adhesive.
Measurements	The skin compatibility will be evaluated by clinical classification 30 minutes and 24h after the patch removal.
Risk	Being a study to evaluate the skin compatibility of products, the occurrence of irritation skin reactions is possible. A dermatologist will provide all the medical support needed, in case any relevant adverse reaction is observed.
Benefits	The foreseen benefit to the volunteers is the possibility of knowing substance(s) that causes them cutaneous irritation and the possibility of avoiding the use of the substance(s) in the future. The foreseen benefit to the society is a better knowledge of the cutaneous compatibility of the products tested.

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Observations	- Volunteers must not apply any other topic application product on the test area on the 12 h preceding the beginning of the study and during the study; - Volunteers must not be exposed to sun or go to tanning bed/booth during the study; - Volunteers must inform the researchers in case of any change in their health status or medication; - Volunteers must address to the study facilities at the scheduled date and time; - During the period of the study while the volunteers have the adhesives on the back, the volunteers may bathe as usual, avoiding to direct water to the adhesive and not to submerge the adhesive, drying it well if wet, without rubbing.
Benefit	Each volunteer will received at the end of the study a gift card SONAE of 20 euros.
Conflict of interest	Inovapotek is subcontracted to perform this study.

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Consent agreement

I hereby consent to take part in the clinical study which has been described to me (clinical study nr. P017C14, 4.1), which will be performed by Dr. Filipa Oliveira and supervised by Dr. Marta de Oliveira Ferreira. I declare that the purpose, the conditions, the proceedings and the duration of the trial have been fully explained to me, as well as the possibility of intolerance/allergy reactions or skin irritation and I have had complete freedom to ask any questions about the trial.

I agree to follow the previously described protocol, and to address at Inovapotek at the scheduled day and time. I understand that I am free to withdraw my consent to be part of the trial and discontinue participation at any time, without any further notice to Inovapotek.

I will be able to ask for further information concerning the trial, or report adverse effects, at any time by telephone on 91 647 59 55 or 22 030 15 31. I agree to inform the supervisor of any changes in my health status or medication during the course of the trial.

I also agree with the promoter's access to the data recorded during the trial and with its computerized treatment. I understand that any information which can be identified with me will be kept confidential with the trial records.

I have read and signed this consent statement in duplicate with full knowledge of the facts.

Volunteer:

First and last name_____

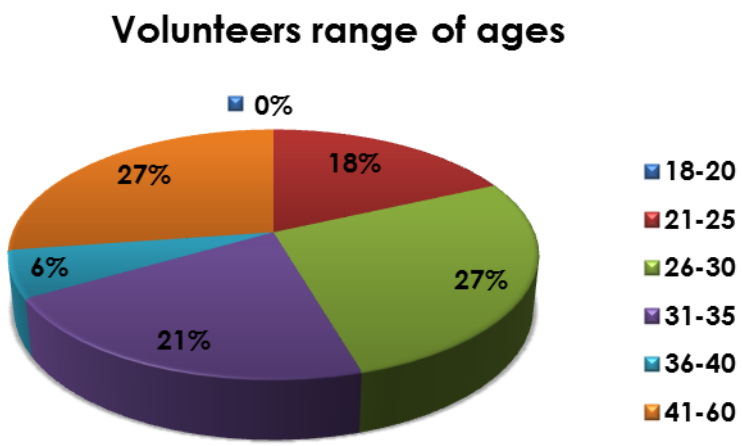
Signature _____ Date: _____

Researcher:

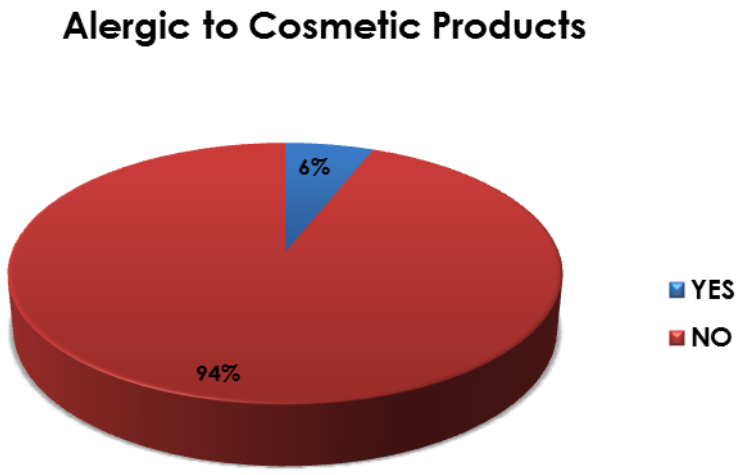
First and last name: Filipa Oliveira

Signature _____ Date: _____

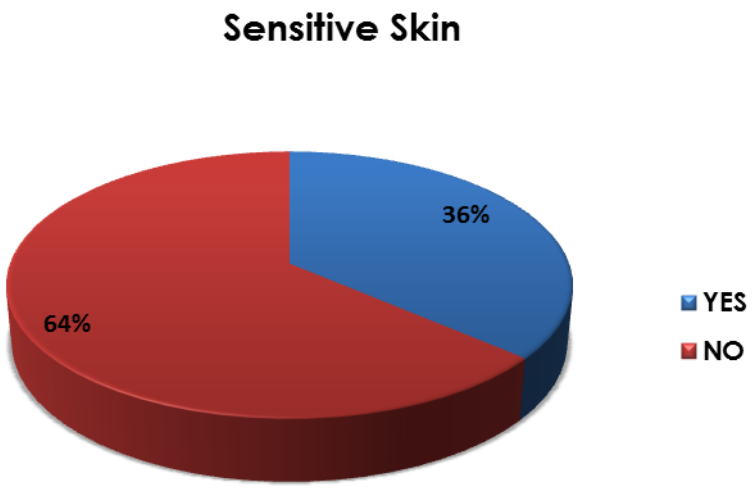
Annex III – General Information



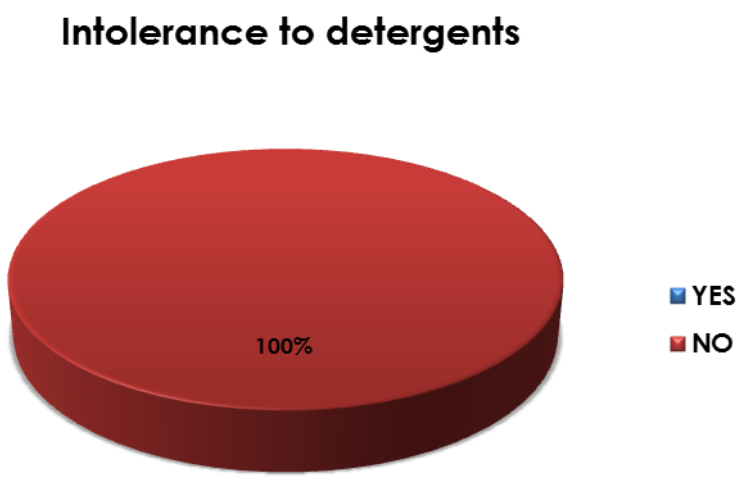
Graphic 1. % of range of ages of volunteers



Graphic 2. % of volunteers allergic to a cosmetic product



Graphic 3. % of volunteers with sensitive skin



Graphic 4. % of volunteers intolerant to detergents

Annex IV – Raw Data record

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Trial n.º: P017C14, 4.1

Date : / /2014 Volunteer n.º :

Raw Data Record

(Record nr. 3_version 00)

1st VISIT

1 Therapeutic changes since last visit:

YES: ☐ NO: ☐

If yes, describe drug name, posology, beginning date and reason:

2 Disease episodes since last visit:

YES: ☐ NO: ☐

If yes, describe disease and period of occurrence:

3 Application site:

LEFT FOREARM: ☐ LEFT SIDE OF THE BACK: ☐

RIGHT FOREARM: ☐ RIGHT SIDE OF THE BACK: ☐

4 Time of patch application: ____h ___min

Comments:

2ND VISIT

1 Therapeutic changes since last visit:

YES: ☐ NO: ☐

If yes, describe drug name, posology, beginning date and reason:

2 Disease episodes since last visit:

YES: ☐ NO: ☐

If yes, describe disease and period of occurrence:

3 Patch removed 30 minutes before measurement:

YES: ☐ NO: ☐

If not, wait the 30 minutes before proceed for the measurements.

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Trial n.º: P017C14, 4.1

Date : / /2014 Volunteer n.º :

4 Room Conditions:

Temperature (ºC):_____ Relative Humidity (%)_____

5 Time of evaluation:___h___min

6 Skin reactions evaluation:

Product nr.	Score of the erythema evaluation	Score of the edema evaluation	Other signs and symptoms
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			

Comments:

3rd VISIT

1 Therapeutic changes since last visit:

YES: ☐ NO: ☐

If yes, describe drug name, posology, beginning date and reason:

2 Disease episodes since last visit:

YES: ☐ NO: ☐

If yes, describe disease and period of occurrence:

3 Room Conditions:

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Trial n.º: P017C14, 4.1

Date : / /2014 Volunteer n.º :

Temperature (ºC):_____ Relative Humidity (%)_____

4 Time of evaluation:___h___min

5 Skin reactions evaluation:

Product nr.	Score of the erythema evaluation	Score of the edema evaluation	Other signs and symptoms
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			

Comments:

Annex V – Complete Raw Data

Table 5. Record of acute irritant reactions for the tested product and controls (30 minutes and 24h after patch removal)

Vol. nr.	Erythema – Tested products							Oedema – Tested products							Other symptons/signs – Tested products						
	30 min				24h			30 min				24h			30 min				24h		
	5	13	14		5	13	14	5	13	14		5	13	14	5	13	14		5	13	14
1	1	1	2		1	0	2	0	0	0		0	0	0	-	-	-		-	-	-
2	1	1	2		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
3	1	1	1		0	0	1	0	0	0		0	0	0	-	-	-		-	-	-
4	1	1	2		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
7	1	1	2		0	0	1	0	0	0		0	0	0	-	-	-		-	-	-
8	1	1	2		0	0	1	0	0	0		0	0	0	S	-	-		-	-	-
10	1	0	1		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
11	1	0	0		0	0	0	0	0	0		0	0	0	-	-	-		-	-	-
12	1	2	2		0	1	2	0	0	0		0	0	0	-	-	-		-	-	-
13	1	1	1		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
14	0	1	2		0	0	2	0	0	0		0	0	0	-	S	-		-	-	-
15	1	1	1		0	1	2	0	0	0		0	0	0	-	-	-		-	-	-
16	1	1	2		0	1	2	0	0	0		0	0	0	-	S	-		-	-	-
17	2	1	2		1	0	2	0	0	1		0	0	0	-	-	-		-	-	-
18	1	1	2		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
19	1	1	2		0	0	1	0	0	0		0	0	0	-	-	-		-	-	-
20	1	1	2		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
21	0	0	2		0	1	2	0	0	0		0	0	0	-	-	-		-	-	-
22	1	1	1		1	1	1	0	0	0		0	0	0	-	-	-		-	-	S
23	0	0	2		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
24	1	1	2		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
25	1	1	1		0	0	1	0	0	0		0	0	0	-	-	-		-	-	-
26	1	1	1		0	0	1	0	0	0		0	0	0	-	S	-		-	-	-
27	1	1	2		0	0	1	0	0	0		0	0	0	-	-	-		-	-	-
28	0	1	2		0	0	2	0	0	1		0	0	0	-	-	-		-	-	-
29	1	1	2		0	0	2	0	0	0		0	0	0	-	-	-		-	-	-
30	1	1	2		1	0	2	0	0	0		0	0	0	-	-	-		-	-	-
31	1	1	2		1	1	2	0	0	1		0	0	0	-	-	-		-	-	-
32	0	1	1		1	1	1	0	0	0		0	0	0	-	-	-		-	-	-
33	1	1	2		0	0	2	0	0	0		0	0	0	S	S	-		-	-	-

- 5 - Si Bac-Pure® TEXTILE FINISH; 13 – Negative control; 14 – Positive control