Study Report

Intracutaneous reactivity test of „Walletmor Payment Implant with Vivokey biopolymer”

Study code: 21-45-2

Report Index: 21-45-2-SP.01

Study Director Statement

I the undersigned declare that the studies described in this report have been conducted under my supervision and in compliance with the following documents and standards:

- ISO 10993-1:2018(E), Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,
- ISO 10993-10:2010(E), Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization,
- ISO 10993-12:2012(E), Biological evaluation of medical devices – Part 12: Sample preparation and reference materials,
- Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.

There were no circumstances that may affected the quality or integrity of the study.

Study Director	Quality Assurance
Monika Dropik Acting Study Director 2021-12-02 10:16:00	Konrad Jankowski 2021-12-01 09:22:11

1. TYPE AND PURPOSE OF THE TEST

The scope of the study included testing of the skin irritation potential of the test item carried out in accordance with the principles of ISO 10993-10:2010(E) standard. The aim of the study was to determine the intracutaneous reactivity properties of the test item provided by the Customer.

2. CONSENT OF THE LOCAL ETHICS COMMITEE

1188/2021 I Ethics Committee in Warsaw

3. DATES

Experimental starting date: 16.07.2021

Experimental completion date: 22.07.2021

4. ADDRESSES

Customer

Name: Walletmor LTD

Address: 85 Great Portland St, W1W 7LT London, United Kingdom

Test Facility

Name: Konmex sp. z o.o.

Address: ul. Nałkowskiej 5, 05-410 Józefów, Poland

5. PERSONNEL

Study Director

Anna Wiatrowska

Address: Konmex sp. z o.o., ul. Nałkowskiej 5, 05-410 Józefów, Poland

Study Personnel

Monika Dropik

Address: Konmex sp. z o.o., ul. Nałkowskiej 5, 05-410 Józefów, Poland

6. TEST ITEM

a. Test Item

Table 1. Information on test item.

Name: Walletmor Payment Implant with Vivokey biopolymer		
REF: N/A	**LOT:** N/A	**Item code:** 21-45-A
Mfg date: 01.01.2021	**Exp date:** 01.01.2029	**Sterile:** EO
Storage conditions: Temperature: normal, Humidity: N/A		
Intended use: Contactless payments in NFC technology		

Information above were submitted by the Customer. Responsibility for assuring proper conditions during transportation of the test items lied with the Customer. Results apply to the samples as received.

Receiving date: 06.05.2021

Storage conditions: Test item were stored at temperature 18-25ºC

b. Reliability check

Table 2. Information on reliability check.

Negative (K-)	Sodium Chloride Injection, Cottonseed Oil
Positive (K+)	Not applicable
Blank (B)	Not applicable

c. Extraction

Table 3. Information on extracts.

No	Extract	Vehicle	Ratio	Time [h]	Temperature [ºC]
1.	16 x 21-45-A	Sodium Chloride Injection	6 cm²/ml	72±2	50±2
2.	16 x 21-45-A	Cottonseed Oil	6 cm²/ml	72±2	50±2

7. TEST SYSTEM

Description of the test system

Species: White Rabbit
Strain: New Zealand
Sex: Males 2/Female 1
Weight: 4210-4470 g at the beginning of the test
Quantity: 3
Age: Adult, Young
Temperature: 19.0 – 19.7ºC daily monitored
Humidity: 55% daily monitored
Lighting: 12 h light/dark cycle
Water: Reverse osmosis, *ad libitum*

Diet: Agropol, LSK gr. LOT: 2/059
Housing: Individually. During the test animals were daily observed.
Re-use: Animals were reused. Before test used animals are clinical examined by veterinarian.

Justification of assay system

The evaluation of the skin irritation potential was conducted with use albino rabbit, recommended by the International Organization for Standardization, described in ISO: 10993-10:2010(E).

Animal identification

Animals used in the study were identified by of an individual animal number (by indelible marker) placed through the edge of the right ear and individual number on the animal cage.

Quarantine

The animals were kept in quarantine in days: 19.01.2021-11.02.2021 (rabbit 3/K), 03.11.2020-23.11.2020 (rabbit 17/K, 18/K). During this period, they were daily observed. The temperature during quarantine in animal room was between 19.0 – 19.7ºC, humidity was 55%. There no recorded dissent from recommend environmental conditions in animal housing room. At the end of the quarantine and before start of the study animals were carefully examined in order to evaluate their suitability for the study.

8. SAMPLE PREPARATION

According to ISO 10993-12:2012(E), two extracts of the test item, in polar vehicle and in non-polar vehicle, was prepared. The extraction parameters are shown in Table 3 "Information on extracts". No abnormalities were observed in extract appearance: no signs of particles, clouding, discoloring or chemical precipitation were recorded; the extracts were not filtered before use.

9. DESCRIPTION OF TEST METHOD

In the test used 1 group of 3 rabbits. Before start this test was conducted cytotoxicity test of the test item (no cytotoxicity reveal, study code: 21-45-1). For this reason skin irritation is not anticipated. The left side of each rabbit has been treated with the test item extracts and the right side has been treated with the relative control solvent (Sodium Chloride Injection and Cottonseed Oil) as reported below:

Table 4. Arrangement of injection sites.

Injection site	Right side	Left side	Dose/site
Cranial	Sodium Chloride Injection (5 sites)	Sodium Chloride Injection extract (5 sites)	200µl
Caudal	Cottonseed Oil (5 sites)	Cottonseed Oil extract (5 sites)	200µl

Treatment

Skin preparation

6.5 hours before animal treatment, the fur on the animal's back on both sides of the spinal column was closely clipped over a sufficiently large test area, avoiding mechanical irritation and trauma.

Application

0.2 ml of the extract obtained with polar (Sodium Chloride) and non-polar (Cottonseed Oil) solvent at five sites on one side of each rabbit have been injected intracutaneously. Similarly, 0.2 ml of the polar and non-polar solvent control on five sites of the contralateral side of each rabbit have been injected intracutaneously.

Observations

All animals has been immediately observed after injection and 24±2, 48±2 and 72±2 hours after the treatment, to evaluate for local signs of local reaction. Injection sites were examined for evidence of any tissue reaction such as erythema, oedema and eschar. Tested and control sites were scored according to the Table 5.

Table 5. Grading system for intracutaneous (intradermal) reactions.

Reaction	Numerical grading
Erythema and eschar formation	
No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well defined oedema (edges of area well defined by define raising)	2
Moderate oedema (edges raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extended beyond exposure area)	4

Interpretation of results

After the 72±2 h grading, all erythema grades plus oedema grades (at 24±2 h, 48±2 h and 72±2 h) are separately totalled for each test sample or blank for each individual animal. To calculate the score of a test sample or blank on each individual animal, divide each of the totals by 15 (3 scoring time points x 5 test or blank sample injection sites). To determine the overall mean score for each test sample and each corresponding blank, add the scores for the tree animals and divide by three. The final test sample score can be obtained by subtracting the score of the blank from the test sample score. The requirements to the test are met if the final test score is 1.0 or less. If at any observation period the average reaction to the test sample is questionably greater than the average reaction to the blank, repeat the test using three additional rabbits.

10. EQUIPMENT

Table 6. Equipment used in the study.

No.	Name	Evidence No.
1.	Scale	WL35
2.	Pipettor	WL03
3.	Laminar Flow hood	WL47
4.	Water bath	WL11
5.	Anestesia apparatus	WL32
6.	Temperature recorder	WL55

11. MATERIALS

Table 7. Materials used in the study.

No.	Name	Manufacturer	REF	LOT
1.	Sodium Chloride Injection	Braun	3547043	211258141
2.	Cottonseed Oil	Pol-Aura	PA-03-3259-L	686XAR
3.	Single-use syringe (1 ml)	dicoNEX	001ML-3CZ-BL	662101012E
4.	Injection needle (25G)	BD Microlance	300400	190321
5..	Isoflurin	Vetpharma Animal Health	N/A	I067-01

12. RESULTS

Table 8. Polar vehicle results.

EXTRACT IN SODIUM CHLORIDE INJECTION									
Rabbit No.	Site No.	24 hour after injection		48 hour after injection		72 hour after injection		PIS	PIS total
		E	O	E	O	E	O		
18/K	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
17/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
3/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
SOLVENT CONTROL: SODIUM CHLORIDE INJECTION									
Rabbit No.	Site No.	24 hour after injection		48 hour after injection		72 hour after injection		PIS	PIS total
		E	O	E	O	E	O		
18/K	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
17/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
3/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		

E = Erythema O = Oedema PIS = Primary Irritation Score

No abnormalities immediately after intradermal injection of test sample extract and solvent control in Sodium Chloride Injection were observed. During the study, all treated sites with test sample extract in Sodium Chloride Injection showed no signs of erythema, eschar and no signs of oedema. During the study, all the control sites, treated with solvent control, showed no signs of erythema, eschar and no signs of oedema 24±2h, 48±2h and 72±2h hours after injections.

PRIMARY IRRITATION INDEX in sodium chloride injection (TREATED – CONTROL): 0.00

Table 9. Non-polar vehicle results.

EXTRACT IN COTTONSEED OIL									
Rabbit No.	Site No.	24 hour after injection		48 hour after injection		72 hour after injection		PIS	PIS total
		E	O	E	O	E	O		
18/K	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
17/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
3/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
SOLVENT CONTROL: COTTONSEED OIL									
Rabbit No.	Site No.	24 hour after injection		48 hour after injection		72 hour after injection		PIS	PIS total
		E	O	E	O	E	O		
18/K	1	0	0	0	0	0	0	0	0
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
17/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		
3/K	1	0	0	0	0	0	0	0	
	2	0	0	0	0	0	0		
	3	0	0	0	0	0	0		
	4	0	0	0	0	0	0		
	5	0	0	0	0	0	0		

E = Erythema O = Oedema PIS = Primary Irritation Score

No abnormalities immediately after intradermal injection of test sample extract and control solvent in Cottonseed Oil were observed. During the study, treated sites with test sample extract in Cottonseed Oil showed no signs of erythema, eschar and no signs of oedema. All the control sites, treated with solvent control (Cottonseed Oil), showed no signs of erythema, eschar and oedema.

PRIMARY IRRITATION INDEX in cottonseed oil (TREATED - CONTROL): 0.00

13. CONCLUSIONS

On the basis of the results, interpreted according to ISO 10993-10:2010(E), the test item “Walletmor Payment Implant with Vivokey biopolymer (REF: N/A, LOT: N/A)” MEET the requirements of the test.

14. LIST OF RECORDS AND MATERIALS SUBMITTED TO THE ARCHIVE

- Raw data,
- Study report,
- Laboratory journal,
- Data on monitoring the testing environment - temperature and humidity records at the time of testing.

All the above-mentioned records and documents are to be filed to the archives of the research facility for 10 years after issuing the study report. The Test Facility does not store test items in the archive.