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TESTING
CNAS L2954

Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH-M201501556-2

Skin Sensitization Test of
Kinesiology Tape
using ISO 10993-10:2010 Test Methods
Guinea Pig Maximization Test
0.9% Sodium Chloride Injection Extract

Sponsor
Hangzhou Gspmed Medical Appliances Co., Ltd

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SUPPLEMENTARY EXPLANATION

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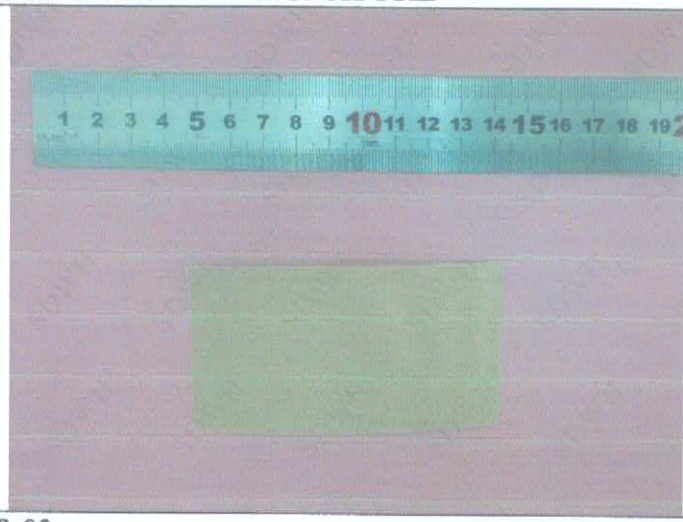
STUDY VERIFICATION AND SIGNATURE

Test Article	
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Study Director
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Date

Approved by : [signature]
Authorized signatory
Date

苏州大学卫生与环境技术研究所 检测专用章 (2)

Sanitation & Environment Technology Institute, Soochow University

1.0 Study Summary

The extract of the test article Kinesiology Tape (extraction in 0.9% Sodium Chloride for Injection) was evaluated for its potential to induce skin sensitization in the Guinea Pig Maximization Test.
The test article extract was intradermally injected and applied topically for induction to ten guinea pigs. Five control animals were treated accordingly but with the solvent alone. The topical challenge with the test article extract elicited no skin reaction in the test and in the control animals. The skin sensitization rate was determined with 0%.
As defined by the scoring system of Magnusson and Kligman the test article extract showed no signification evidence of causing skin sensitization in the guinea pig under the conditions of this study.

2.0Purpose

The test was designed to evaluate the potential of a test article to cause skin sensitization. The test is used as a procedure for screening of contact allergens in guinea pigs and extrapolating the results to humans, but it does not establish the actual risk of sensitization.

3.0Reference

Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)
Biological evaluation of medical devices-Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

4.0Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS-CL01 Accreditation Criteria for the competence of testing and calibration laboratories)
China National Accreditation Service for Conformity Assessment
Laboratory Accreditation Certificate No. CNAS L2954
Accreditation Criteria for the competence of the laboratories (Quality and Technical Bureau of Jiangsu Province Metrology Accreditation Certificate CMA 2013100106S)

5.0Identification of test and control articles

5.1 Test article name: Kinesiology Tape
Test article initial state: Not Sterilized
CAS/Code#: Not Supplied by Sponsor (N/S)
Size: 5cm*5m

Lot/ Batch#: 201507-1093
Test article materials: cotton
Package materials: Shrink Film
Physical State: Solid
Color: Skin
Density: N/S
Stability: N/S
Solubility: N/S
Storage Condition: Room Temperature
The information about the test article was supplied by the sponsor wherever applicable.

5.2 Control article

5.2.1Negative Control

Article Name: 0.9% Sodium Chloride Injection (SC)
Manufacturer: Anhui Double-Crane Pharmaceutical Co., Ltd.
Size: 500ml
Lot/ Batch#: 141230 5C
Physical State: Liquid
Color: Colourless
Storage Condition: Room Temperature

5.2.2Positive Control

Article Name: 2, 4-Dinitrochlorobenzene (DNCB)
Manufacturer: Xiya Reagent^{R}
Size: 100g
Lot/ Batch#: W5656
Induction Concentration: 0.5%
Challenge Concentration: 0.1%
Solvent: 95% Ethanol
Date prepared: 2015-08-03
Physical State: Liquid
Color: light yellow
Storage Condition: Room Temperature

6.0Identification of test system

Species: Hartley Guinea Pig (Cavia Porcellus)
Number: 15 (10 Test +5 Negative Control)
Sex: males
Initial body weight: 307～358g
Health status: Healthy, not previously used in other experimental procedures
Housing: Animals were housed in groups in cages identified by a card indicating the lab number, test code and first treatment date, etc
Animal identification: Stain with picric acid
Cages: Plastic cage

Acclimation Period: 7 days under the same conditions as for the actual test

7.0Animal Care and Maintenance

Animal purchase: Wuxi Huishan Jiangnan Experimental Animal Center; Permit Code: SCXK (SU) 2015-0004
Bedding: Corncob, Suzhou shuangshi laboratory animal feed science Co.,Ltd
Feed: Guinea Pig Diet, Wuxi Huishan Jiangnan Experimental Animal Center
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26℃
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full-spectrum lighting
Personnel: Associates involved were appropriately qualified and trained
Selection: Only healthy, previously unused animals were selected
There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data

8.0Justification of the test system

The albino guinea pig has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study .The susceptibility of the guinea pig to a known sensitizing agent, 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at SDWH.

9.0Route of administration

The test article was extracted and administered in vivo through a medium compatible with the test system. Dermal application corresponds to the likely route of human exposure.

10.0Experiment design

10.1 Sample and Control Preparation

Intradermal induction phase Ⅰ:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2:1ml	20.0ml	37℃,72h	6.0	Clear

Topical induction phase II :

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2:1ml	20.0ml	37℃,72h	6.0	Clear

Challenge phase:

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract	
Sampling Manner	Actually sampling	Ratio	SC	Condition	pH	Clear or Not
Random	Surface area 120cm^2	6cm^2:1ml	20.0ml	37℃,72h	6.0	Clear

The extract was stored at 4℃ and tested within 24h after extraction.

The vehicle (without the test article) was similarly prepared to serve as the control.

10.2 Equipment

Constant Temperature Vibrator（SDWH-217）,Calibration Expire（2015-11-18）

Cylindrical pressure steam sterilizer (SDWH-030), Calibration Expire (2016-05-26)

Steel Straight Scale (SDWH-463) ,Calibration Expire（2015-10-14）

Electronic scale (SDWH-442) ,Calibration Expire（2015-10-22）

10.3 Reagents

Freund's Adjuvant,Complete liquid

Manufacturer: SIGMA

Lot No: SLBL3699V

Sodium dodecyl sulfate (SDS)

Manufacturer: Sinopharm Chemical Reagent Co.Ltd

Lot No: F20090922

Concentration: 10%

Solvent: Distilled water

Date prepared: 2015-02-09

10.4 Intradermal induction phase I

A pair of 0.1ml intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) as shown in Figure 1 in the clipped intrascapular region.

Site A: A 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen solvent.

Site B: The test sample (undiluted extract); the control animals were injected with the solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%); the control animals were injected with an emulsion of the blank liquid with adjuvant.

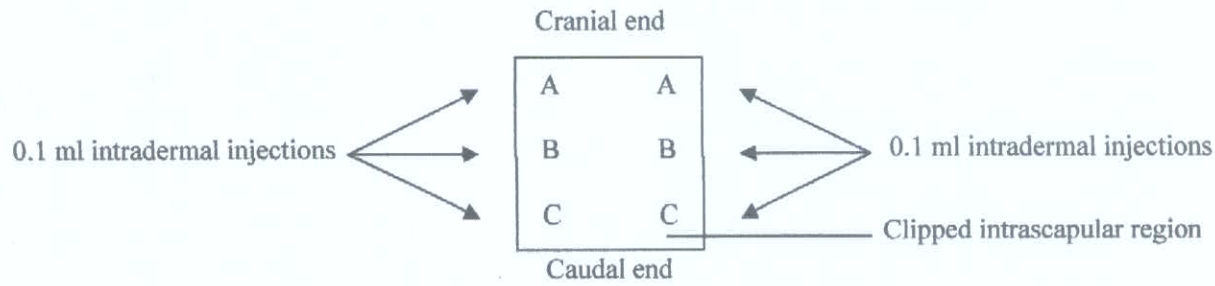

Figure 1 Location of intradermal injection sites

10.5 Topical induction phase Ⅱ

The maximum concentration that can be achieved in Intradermal induction phase Ⅰ did not produce irritation, animals are pretreated with 10% sodium dodecyl sulfate 24(±2) hours before the topical induction application.

At 7 d after completion of the intradermal induction phase, administer the test sample by topical application to the intrascapular region of each animal, using a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Use the concentration selected in Intradermal induction phase Ⅰ for site B. Secure the patches with an occlusive dressing. Remove the dressings and patches after (48±2) h.

Treat the control animals similarly, using the blank liquid alone.

10.6 Challenge phase

At 14 d after completion of the topical induction phase, challenge all test and control animals with the test sample. Administer the test sample and a blank by topical application to sites that were not treated during the induction stage, using absorbent gauze (2.5cm×2.5cm) soaked in the test sample at the concentration selected in the intradermal induction phase Ⅰ for site C. Secure with an occlusive dressing. Remove the dressings and patches after (24±2) h.

10.7 Observation of animal

Observe the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Full-spectrum lighting was used to visualize the skin reactions. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading given in Table 1 for each challenge site and at each time interval.

10.8 Evaluation of results

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.

If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.

If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.

The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

10.9 Results

Individual results of dermal scoring for the challenge appear in Table 2.

10.10 Conclusion

Under the conditions of this study, the test article Kinesiology Tape extract showed no significant evidence of causing skin sensitization in the guinea pig.

11.0 Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated SDWH archive.

12.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

Table 2 Guinea pig Sensitization Dermal Reactions

Group	Animal Number	24±2h before phase II patch application		Hours following Challenge phase		Positive rate after challenge phase
		Left	Right	24±2 h	48±2 h	
Test Group	1	0	0	0	0	0%
	2	0	0	0	0	
	3	0	0	0	0	
	4	0	0	0	0	
	5	0	0	0	0	
	6	0	0	0	0	
	7	0	0	0	0	
	8	0	0	0	0	
	9	0	0	0	0	
	10	0	0	0	0	
Negative control	11	0	0	0	0	—
	12	0	0	0	0	
	13	0	0	0	0	
	14	0	0	0	0	
	15	0	0	0	0	

Table 3 Weigh change and Clinical observation

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Test Group	1	355	404	Normal
	2	316	369	Normal
	3	325	377	Normal
	4	333	388	Normal
	5	332	401	Normal
	6	323	408	Normal
	7	354	396	Normal
	8	330	399	Normal
	9	326	388	Normal
	10	307	361	Normal
Negative control	11	351	410	Normal
	12	316	367	Normal
	13	358	436	Normal
	14	329	406	Normal
	15	331	414	Normal

Table 4 Guinea pig Sensitization Dermal Reactions of Positive Group

Group	Animal Number	24±2h before phase II		Hours following Challenge phase		Positive rate after challenge phase
		Left	Right	24±2 h	48±2 h	
Positive Group	1	3	3	3	3	100%
	2	3	3	2	2	
	3	3	3	2	2	
	4	3	3	2	2	
	5	3	3	2	2	
Negative control	6	0	0	0	0	—
	7	0	0	0	0	
	8	0	0	0	0	
	9	0	0	0	0	
	10	0	0	0	0	

Note: The data of positive control come from SDWH-M201501558-1 (Completed Date: 2015-08-27)

Table 5 Weigh change and Clinical observation of Positive Group

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Before injection	After experiment	
Positive Group	1	324	398	Normal
	2	311	388	Normal
	3	329	409	Normal
	4	343	417	Normal
	5	330	410	Normal
Negative control	6	320	405	Normal
	7	335	420	Normal
	8	306	391	Normal
	9	327	406	Normal
	10	310	392	Normal

Note: The data of positive control come from SDWH-M201501558-1 (Completed Date: 2015-08-27)