Report No: BP-A-2335541EN

Test Report

Sample Name:	FEP Heat Shrink Tube
Client Name:	Forbest Manufacturing Co Ltd.
Client Address:	Fulian industrial Longhua Town Shenzhen City Guangdong Province China
Test item:	Skin sensitization test
Date of Issue:	2024.01.09

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DECLARE

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Task No.	BP-A-2335541	Detection category	Commission test
Sample No.	BP-S-23093130	Sample source	Sent by client
Sample name	FEP Heat Shrink Tube	Batch number	/
Model	4.9mm*0.25mm*100mm	Sample number	16
Specification	/		
Manufacturer	/		
Manufacturer address	/		
Client	Forbest Manufacturing Co Ltd.		
Client address	Fulian industrial Longhua Town Shenzhen City Guangdong Province China		
Receiving date	2023.11.21		
Test location	3 Floor, Building 7,166-1, Fengjin Road, Fengxian District, Shanghai.		
Test period	2023.11.21 to 2023.12.24		
Test item	Skin sensitization test		
Test criterion	GB/T 16886.10-2017/ISO 10993-10:2010		
Test conclusion	Under the conditions of this experiment, the skin reaction grading of all animals in each period was grade 0, and the positive activation rate of the experimental group was 0%, indicating that the extract of the sample did not produce allergic reaction. Date of issue 2024.01.09		
Implementation standard	ISO/IEC 17025:2017; RB/T214—2017		
Remarks	"N/A" in the report indicates that this item is not applicable, and "/" in the report indicates that this item is blank.		

Edited by	Checked by	Approved by (Authorized signatory)
郭桂芳 Date: 2024.01.09	王菲 Date: 2024.01.09	江衡 Date: 2024.01.09

Catalogue

1 Objective

The test was designed to evaluate the potential of a test article to cause skin sensitization using Guinea Pig Maximization Test.

2 Test method

Guinea Pig Maximization Test.

3 Test conclusion

Under the conditions of this experiment, the skin reaction grading of all animals in each period was grade 0, and the positive activation rate of the experimental group was 0%, indicating that the extract of the sample did not produce allergic reaction.

4 Test and control samples

4.1 Test samples

(The information in the form is provided by the client)

Sample name	FEP Heat Shrink Tube
Sterilization state	Unsterilized
Sterilization methods	/
Sample material	/
Physical condition	Solid
Color	See photo page of inspection report for details
Preservation conditions	Room temperature, dry
Application	/

4.2 Control samples

Polar negative control sample: 0.9%NaCl injection	
Manufacturer	Shandong Qidu Pharmaceutical Co., Ltd.
Specification	500mL/bottle
Batch No.	15B23032602
Characteristics	Liquid
Color	Colorless
Preservation condition	Room temperature
Non-Polar negative control sample: Cotton oil	
Manufacturer	Shanghai Macklin Biochemical Co., Ltd.
Specification	13kg

Batch No.	C14894162	
Characteristics	oil	
Color	Light yellow	
Preservation condition	Room temperature	
Positive control sample：2,4-Dichloronitrobenzene		
Manufacturer	TCI	
Specification	25g/bottle	
Batch No.	WT6CA-LZ	
Characteristics	Light yellow crystal	
Color	Light yellow	
Preservation condition	Room temperature	
Concentration	Intradermal induction phase	0.8%
	Topical induction phase	0.8%
	Challenge phase	0.2%

5 Reagents and Instrument

5.1 Reagents

Name	Supplier
0.9%sodium chloride injection	Shandong Qidu Pharmaceutical Co., Ltd.
Cotton oil	Shanghai Macklin Biochemical Co., Ltd.
Complete Freund's Adjuvant	Sigma-Aldrich
Sodium dodecyl sulfate	Adamas-beta®
2, 4-dinitrochlorobenzene	TCI
Anhydrous ethanol	Chinasun Specialty Products Co., Ltd.

5.2 Instrument

Name	Instrument ID
Clean bench	WPE-TL0127
Constant temperature incubator	WPE-TL0081
pH meter	WPE-TL0079
Electronic balance	WPE-TL055

6 Test system

6.1 Test animal selection

The guinea pig is believed to be the most sensitive animal model for this type of study.

6.2 Test animal information

Species	guinea pig
Number	30
Sex	Male
Weight	300g~500g
Age	Early adulthood
Health condition	Healthy
Adaptation	5 days
Source	Shanghai Songjiang Chedundongwu Breeding Farm Co., Ltd., License number:SCXK（Shanghai）2022-0001，Quality Qualification Certificate number: 20220001001245

6.3 Feeding and management

Fodder	Shanghai Zhouyu Biotechnology Co., LTD., License number: Shanghai Feed Certificate (2021) 04027
Water	Tap water, free drinking water.
Environment	Common animal room 325, the temperature range of 18~29℃, humidity range of 40~70%.
Light	Control cycle light (12 hours on, 12 hours dark)
Veterinary	Give necessary veterinary attention
Raise	The animals were raised in accordance with the "Feeding and management procedures of the experimental animal guinea pig" in our Toxicology laboratory.
Pollutant	The feed provided and the possible contaminants in the water will not have a potential impact on the results of this experiment.
Certification body	The animal laboratory of this institution shall be certified by Shanghai Laboratory Animal Center, and the certifying authority: Shanghai Municipal Department of Science and Technology. Experimental animal use License No.: SYXK (Shanghai) 2021-0023, applicable to ordinary grade rabbits in general environment.
Welfare	The IACUC established by the Institute confirmed that the experiment used a minimum number of animals without affecting the test results, and relevant documents were developed to safeguard animal welfare.

7 Test procedure

7.1 Sample preparation

The extracts were prepared according to the method in the table below. After the extraction, the changes of the extracts were checked. The extracts were not centrifuged and etc. The pH was not adjusted. Blank control, negative control and positive control samples were prepared by the same method.

Table 7-1 Preparation of extracts

Extraction solvent	experimental stage	Actually sample	Sampling ratio	Solvent volume	Sampling condition	Whether the extract is clear	pH
0.9%NaCl injection	Intradermal induction phase	129.368 cm^2	6cm^2:1 mL	21.56mL	37±1℃ 72±2h 60rpm	Yes	7.79
	Topical induction phase	97.026c m^2		16.17mL		Yes	7.66
	Challenge phase	64.684c m^2		10.78mL		Yes	7.69
Cotton oil	Intradermal induction phase	129.368 cm^2	6cm^2:1 mL	21.56mL	37±1℃ 72±2h 60rpm	Yes	6.32
	Topical induction phase	97.026c m^2		16.17mL		Yes	6.28
	Challenge phase	64.684c m^2		10.78mL		Yes	6.26

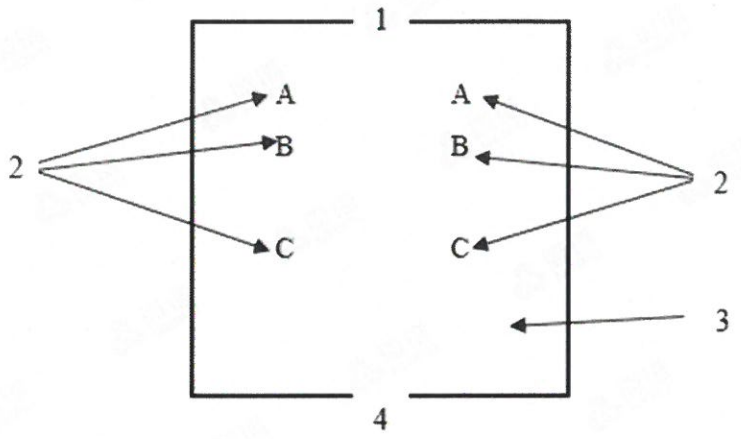
7.2 Test procedure

Before the experiment, the guinea pigs are marked and weighed. They are randomly divided into 0.9%NaCl injection test groups and control groups, Cottonseed oil test groups and control groups.

The skin reactions of guinea pigs are observed after 24h and 48h, and the body weight is recorded.

7.2.1 Intradermal induction phase

Make a pair of 0.1 mL intradermal injections of each of the following, into each animal, at the injection sites (e.g. sites A, B and C), as shown in Figure 1, in the clipped intrascapular region.



1——cranial end; 2——0.1mL intradermal injections; 3——clipped intrascapular region; 4——caudal end; A, B, C——injection sites

Figure 1 — Location of intradermal injection sites

Site A: A stable emulsifier mixed by injection of Freund's complete adjuvant with 0.9%NaCl injection or Cotton oil solvent in 50:50 (volume ratio) ratio.

Site B: The test sample (undiluted extract); inject the control animals with the extraction vehicle/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/extraction vehicle; inject the control animals with an emulsion of the blank liquid with adjuvant.

7.2.2 Topical induction phase

At 7d 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 8cm^2 (absorbent gauze) soaked with extract, so as to cover the intradermal injection sites. Use the concentration selected in the intradermal induction phase for site B. The concentration in Intradermal induction phase I did not produce irritation, animals were pretreated with 10% sodium dodecyl sulfate 24±2hours before the topical induction application. Secure the patches with an occlusive dressing. Remove the dressings and patches after 48±2h.

7.2.3 Challenge phase

At 14±1d after completion of the topical induction phase, challenge all test and control animals with the test sample. The local sticker is applied to the unbound site during the induction phase, and then covered with a layer of glass paper, and then fixed with no stimulating tape. After (24±2) h, remove the bandaging band and apply the fillet.

7.3 Observation

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. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading scale for each challenge site and at each time interval.

Table 7-1 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

7.4 Evaluation standard

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. Occasionally, the test group has a greater number of animals showing a response than the controls, although the intensity of the reaction is not greater than that exhibited by the controls. In these instances, a rechallenge can be necessary to define the response clearly. A rechallenge shall be carried out 1 week to 2 weeks after the first challenge. The method used shall be as described for the first challenge, using a naïve side on the animal.

8 Test result

The skin reaction grade and positive excitation rate of guinea pigs in this experiment are shown in Table 8-1, and the positive test results are shown in Table 8-2.

Table 8-1 Skin sensitization reaction

Extraction solvent	Group	Animal No.	Weight before test (g)	Weight after test (g)	Topical induction phase grade	Challenge phase grade		positive activation rate
						24h	48h	
0.9% NaCl injecti	Control	1101	347	436	0	0	0	0
		1102	319	445	0	0	0	
		1103	320	420	0	0	0	

Extraction solvent on	Group	Animal No.	Weight before test (g)	Weight after test (g)	Topical induction phase grade	Challenge phase grade		positive activation rate
						24h	48h	
		1104	354	437	0	0	0	
		1105	362	448	0	0	0	
	Sample	2101	357	470	0	0	0	0
		2102	342	468	0	0	0	
		2103	355	470	0	0	0	
		2104	326	459	0	0	0	
		2105	341	462	0	0	0	
		2106	350	437	0	0	0	
		2107	319	455	0	0	0	
		2108	322	426	0	0	0	
		2109	330	475	0	0	0	
		2110	341	480	0	0	0	
Cotton oil	Control	3101	342	456	0	0	0	0
		3102	317	466	0	0	0	
		3103	325	430	0	0	0	
		3104	361	478	0	0	0	
		3105	354	459	0	0	0	
	Sample	4101	339	469	0	0	0	0
		4102	342	466	0	0	0	
		4103	331	439	0	0	0	
		4104	314	458	0	0	0	
		4105	359	441	0	0	0	
		4106	345	451	0	0	0	
		4107	360	462	0	0	0	
		4108	355	463	0	0	0	
		4109	317	474	0	0	0	
		4110	329	476	0	0	0	

Table 8-2 Skin sensitization reaction of positive control

Group	Animal No.	Weight before test (g)	Weight after test (g)	Challenge phase grade		positive activation rate
				24h	48h	
Positive control	2001	351.10±21.25	452.90±15.95	2	1	100
	2002			2	2	
	2003			1	1	

Group	Animal No.	Weight before test (g)	Weight after test (g)	Challenge phase grade		positive activation rate
				24h	48h	
	2004			1	1	
	2005			2	2	
	2006			2	2	
	2007			1	2	
	2008			2	2	
	2009			2	2	
	2010			2	2	
Remarks	Quote: report of project WP-23071911-BC-01 Test date: 2023.08.10~2023.09.03					

9 Test conclusion

Under the conditions of this experiment, the skin reaction grading of all animals in each period was grade 0, and the positive activation rate of the experimental group was 0%, indicating that the extract of the sample did not produce allergic reaction.

10 Deviations

The test was carried out in strict accordance with the standard operating procedures, and no deviation affecting the validity of the test data occurred.

11 Record Preservation

All raw data and records related to this test and copies of the final report are kept in the archives。

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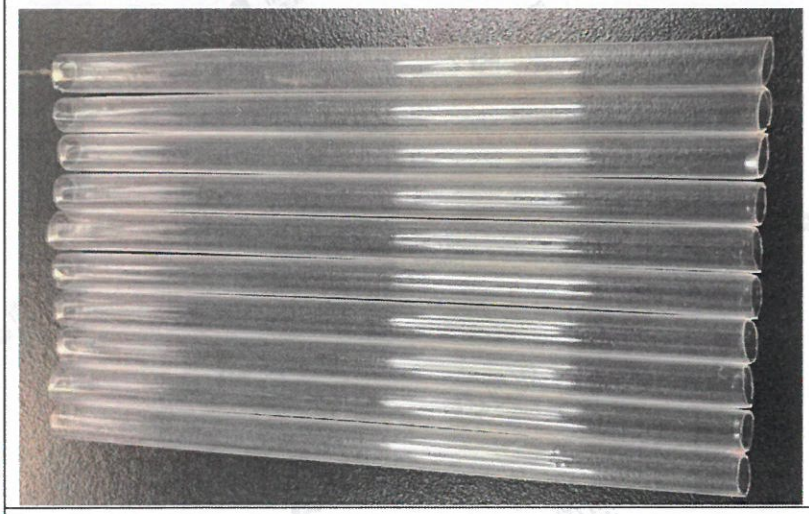
Test report photo page

Photos and descriptions
 FIG. 1 Detailed diagram
 FIG. 2 Sample enlargement
Test component description
Overall sampling
Model, specification or other description
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***** End of report *****