210020344474

Report No: BP-A-2335542EN

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	Intracutaneous reactivity test
Date of Issue:	2024.01.09

Shanghai WEIPU Testing Technology Group Co., LTD.

DECLARE

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Organization name: **Shanghai WEIPU Testing Technology Group Co., LTD.**

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First Page of Test Report

Task No.	BP-A-2335542	Detection category	Commission test
Sample No.	BP-S-23093131	Sample source	Sent by client
Sample name	FEP Heat Shrink Tube	Batch number	/
Model	4.9mm*0.25mm*100mm	Sample number	2
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 2023.12.03		
Test item	Intracutaneous reactivity test		
Test criterion	GB/T 16886.10-2017/ISO 10993-10:2010		
Test conclusion	Under this condition of test, final test sample score of polar and non-polar extract group were both 0.0, meet the requirements of relevant standards. 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	王菲	
Date: 2024.01.09	Date: 2024.01.09	Date: 2024.01.09

Catalogue

1 Objective

The relevant animal models are tested in the test for medical devices and materials. The injecting material is performed through the injection of the material to evaluate the potential of intracutaneous reactivity of the material under the test conditions.

2 Test method

Intracutaneous Reactivity Test.

3 Test conclusion

Under this condition of test, final test sample score of polar and non-polar extract group were both 0.0, meet the requirements of relevant standards.

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

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
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：SDS	
Manufacturer	Adamas-Beta
Specification	500g/bottle
Batch No.	P1880786
Characteristics	Powder
Color	White
Preservation condition	Room temperature

5 Reagents and Instrument

5.1 Reagents

Name	Supplier
0.9%NaCl injection	Shandong Qidu Pharmaceutical Co., Ltd.
Cotton oil	Shanghai Macklin Biochemical Co., Ltd.

5.2 Instrument

Name	Instrument ID
Electronic balance	WPE-TL0055
Clean bench	WPE-TL0127
Constant temperature incubator	WPE-TL0081
pH meter	WPE-TL0079

6 Test system

6.1 Test animal selection

The intracutaneous reactivity test of the rabbit's skin is the most sensitive method, and it has been widely used in evaluation of medical equipment/materials.

6.2 Test animal information

Species	New Zealand white rabbit
Number	3
Sex	Male

Weight	2.220~2.325kg
Age	young adult
Health condition	Healthy, nulliparous and not pregnant
Adaptation	5 days
Source	Chedundongwu, 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
Padding	Shanghai Zhouyu Biotechnology Co., LTD., License number: Shanghai Feed Certificate (2021) 04027
Water	Tap water (in line with GB5749-2006 sanitary standards for drinking water), free drinking water.
Environment	Common animal room 323, the temperature range of 16~26℃, 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 rabbits" 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

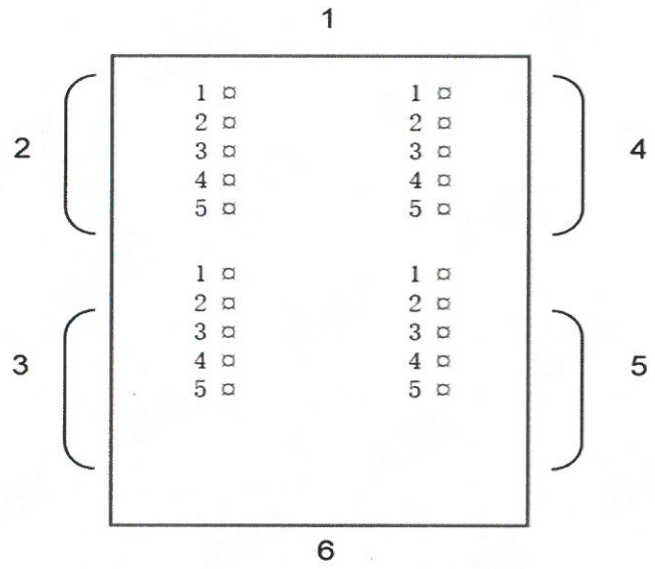
Take the sample, the extracts were prepared according to the method in the table below. After the extraction, the changes of the extracts were checked. The extracts were not centrifuged and etc. The pH was not adjusted. positive control samples were prepared by the same method.

Table 7-1 Preparation of extracts

Extraction solvent	Actually sample	Samplin g ratio	Solvent volume	Sampling condition	Whether the extract is clear	pH
0.9%NaCl injection	129.368cm^2	6cm^2:1mL	21.56mL	37±1℃ 72±2h 60rpm	Yes	7.79
Cotton oil	129.368cm^2		21.56mL		Yes	6.32

7.2 Test procedure

Fur was generally clipped and rabbits were weighed 4~18 h before testing on the backs of the rabbits, allowing a sufficient distance on both sides of the spine for injection of the extracts.



1—Cranial end; 2—0.2 ml injections of polar extract; 3—0.2 ml injections of Non-polar extract; 4—0.2 ml injections of polar solvent control; 5—0.2 ml injections of Non-polar solvent control; 6—Caudal end.

Figure 1 Arrangement of injection sites

Choose 5 points on the rabbit back at one side in interval appropriate. Inject 0.2mL polar extract. Choose 5 points on the rabbit back at one side in interval appropriate. Inject 0.2mL non-polar extract each point.

Choose 5 points on the rabbit back on the other side. Inject 0.2mL polar solvent control each point. Choose 5 points on the rabbit back on the other side. Inject 0.2mL non-polar solvent control each point.

To observe the instant, 24 h, 48 h and 72 h reaction of local and surrounding skin tissue reactions including erythema, edema and necrosis and recorded.

Table 7-2 Scoring system for intracutaneous (intradermal) reaction

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 definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the injection sites were recorded and are reported.	

7.3 Evaluation standard

After the (72±2) h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) hare totalled separately 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 × 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 three 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 of the test are met if the final test sample score is 1.0 or less. Should results be inconsistent between animals or controls not perform as anticipated making interpretation of the overall results questionable, the study can be repeated using three additional rabbits.

8 Test result

Table 8-1 Scores for intracutaneous (intradermal) reaction

Extraction solve	Animal No.	Results					
		Sample group			Control group		
		24h	48h	72h	24h	48h	72h

nt		Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
0.9% NaCl injection	111	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	112	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	113	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
Final test sample score		0											
Cotton oil	111	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	112	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	113	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
Final test sample score		0											

Table 8-2 Positive sample scores for intracutaneous (intradermal) reaction

Extraction solvent	Animal No.	Results											
		Positive group						Control group					
		24h		48h		72h		24h		48h		72h	
		Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
0.9% NaCl injection	111	4	3	4	3	4	3	0	0	0	0	0	0
		4	2	4	2	4	1	0	0	0	0	0	0
		4	3	4	2	4	2	0	0	0	0	0	0
		4	2	4	3	4	2	0	0	0	0	0	0
		4	4	4	4	4	4	0	0	0	0	0	0
	112	4	3	4	3	4	3	0	0	0	0	0	0
		4	4	4	4	4	3	0	0	0	0	0	0
		4	3	4	2	4	1	0	0	0	0	0	0
		4	3	4	3	4	3	0	0	0	0	0	0
		4	3	4	3	4	2	0	0	0	0	0	0
	113	4	4	4	3	4	3	0	0	0	0	0	0
		4	3	4	3	4	2	0	0	0	0	0	0
		4	2	4	2	4	3	0	0	0	0	0	0
		4	3	4	3	4	3	0	0	0	0	0	0
		4	4	4	3	4	3	0	0	0	0	0	0
Final test sample score		6.82											
Cotton oil	111	3	3	3	3	3	2	0	0	0	0	0	0
		4	3	4	2	4	2	0	0	0	0	0	0
		3	3	3	3	3	3	0	0	0	0	0	0
		3	3	3	3	3	2	0	0	0	0	0	0
		3	3	3	3	3	3	0	0	0	0	0	0
	112	4	3	4	3	3	3	0	0	0	0	0	0
		4	2	4	3	4	3	0	0	0	0	0	0
		4	3	3	2	3	3	0	0	0	0	0	0
		3	3	4	3	4	3	0	0	0	0	0	0
		3	3	3	3	4	2	0	0	0	0	0	0
	113	4	3	3	4	4	3	0	0	0	0	0	0
		4	2	4	3	3	3	0	0	0	0	0	0
		3	3	4	2	3	3	0	0	0	0	0	0
		3	3	3	3	4	2	0	0	0	0	0	0
		4	4	4	2	3	2	0	0	0	0	0	0
Final test sample score		6.22											
Remarks		Test date: 2023.08.24 to 2023.08.27 The positive data comes from SHA03-23082953-JC-01											

9 Test conclusion

Under this condition of test, final test sample score of polar and non-polar extract group were both 0.0, meet the requirements of relevant standards.

10 Deviations

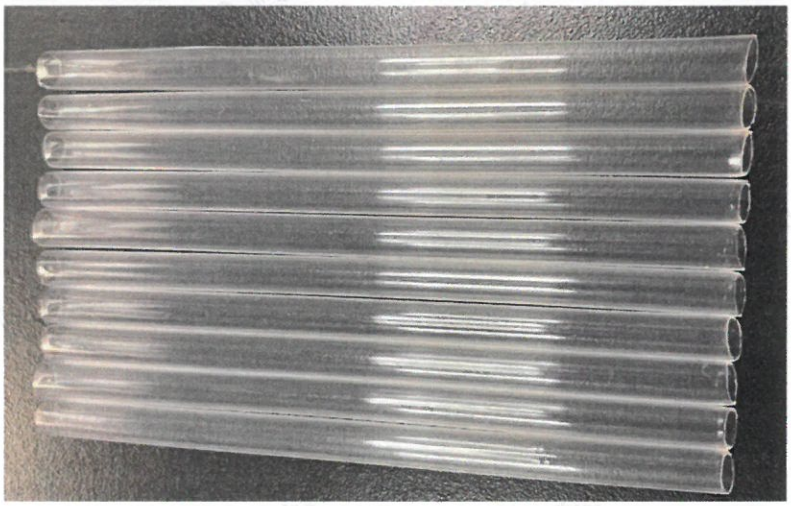
The test was carried out in strict accordance with the standard operating procedures, and no deviation affecting the validity of the test data occurred.

11 Record Preservation

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

Shanghai WEIPU Testing Technology Group Co., LTD.

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
/

***** End of report *****