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Life Science Services Laboratory

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Test Report

Date: 17th Jan. 2019

Client name: WACKER CHEMICALS (CHINA) CO., LTD

Client address: 3rd Building WACKER CHEMICALS, 1535 HONGMEI ROAD, XUHUI DISTRICT, SHANGHAI

Assignment ID: 14A1806516

Sample No.: 14S18025747-01

Report on the submitted sample identified by the client as below:

Product Name	ELASTOSIL® LR 3038/40 K1 CN
Quantity Received	1 bag
Batch Number	3038/40K1:ZR13590
Expiry Date	unlimited storage life
Type of Material	Synthetic Elastomer
Sample Receiving Condition	Room temperature
Sample Receiving Date	29th Oct.2018
Testing Period	27th Nov. 2018–30th Nov. 2018

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The test was carried out by SGS subcontractor certified ISO 17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

Racy Li

Racy Li
Life Science Quality Assurance
Authorized Signature

Attachment 1: Test for Pyrogenicity

SUMMARY

The test article: ELASTOSIL® LR 3038/40 K1 CN, was extracted in 0.9% sterile nonpyrogenic sodium chloride injection (SC). The extract was evaluated in the rabbit for material medicated pyrogenicity. This study was conducted based on the requirements for ISO 10993-11:2017: Biological Evaluation of Medical Device, Part 11: Test for Systemic Toxicity; ISO 10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

A single dose of 10ml/kg was injected intravenously via the marginal ear vein to each of three rabbits. Rectal temperatures were measured and recorded prior to injection and at 30 min intervals between 1 and 3h after injection. The maximum temperature rise (as compared to baseline) for each rabbit was determined, and whether the extract of the test article induced a pyrogenic response was evaluated.

Under the conditions of this study, the total rise of rabbit temperature during the 3h observation period was within acceptable limits. The extract of the test article was judged as nonpyrogenic.

MATERIALS

The test article provided by the sponsor was identified and handled as follows:

Test Article:	ELASTOSIL® LR 3038/40 K1 CN
Sterilization Status :	Non sterile
Storage Conditions:	Room temperature
Extract Vehicle:	0.9% sterile nonpyrogenic sodium chloride injection (SC)
Test Article Preparation:	According the requirement of the sponsor, the test articles were sterilized by ethylene oxide two weeks before the treatment. Based on the ISO10993-12:2012, the ratio of 1.25 cm^2:1 ml (Surface area of the test sample to volume of extraction vehicle), 125 cm^2 of the test article was covered with 100 ml extraction vehicle under aseptic conditions for preparing the SC test extract at 37 ℃ for 72 hours respectively.

The fresh extracts was warmed in a 38 ℃ water bath for a minimum of 10 min prior to injection.

Instrument Preparation: Render the syringes, needles, and glassware free from pyrogens by heating at 180 ℃ for 2h.

Condition of Extracts: The extract of the test articles were clear.

METHODS

Test System

Species:	Rabbit
Grade:	New Zealand White
Source:	SHANGHAI JIAGAN BIOLOGICAL TECHNOLOGY CO., LTD
Sex:	Male
Body Weight Range:	2.4 kg ~ 2.6 kg
Age:	Adult
Number of animals:	Three

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from Shanghai Pu Lu Teng Biological Technology Co., Ltd.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment， and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The room temperature was 23℃. The room humidity was 59%.
Personnel	Associates involved were appropriately qualified and trained.

Selection: Only healthy animals were selected. Prior to using, the animals in this test were conditioned for 5d by a sham test that includes all of the steps as directed under procedure except injection.

Experimental Procedure:

Not more than 30 min prior to injection, the temperature of each animal was measured by ZRY-2D Pyrogen Tester. This temperature was recorded as the baseline temperature for the study.

Each rabbit was received a single intravenous injection of the extract via the marginal ear vein at 10ml/kg of the body weight. Rectal temperature were measured and recorded at 30 min intervals between 1h and 3h after injection.

The maximum temperature rise (as compared to baseline) for each rabbit was determined.

Consider any temperature decreases as zero rises. If no rabbit showed an individual temperature rise of 0.5 ℃ or more above the baseline temperature, the extract of the test article met the requirements for the absence of pyrogens. If any rabbit showed an individual temperature rise of 0.5 ℃ or more, a retest was conducted using five other rabbits. If not more than three of the eight rabbits showed individual rises in temperature of 0.5 ℃ or more, and if the sum of the eight individual maximum temperature rises did not exceed 3.3 ℃, the test article met the requirements for the absence of pyrogens.

RESULTS

No single rabbit showed a temperature increased of 0.5 ℃ or more above its baseline temperature.

Individual temperatures were presented below:

No	Weight (kg)	Sex	Dose volume (ml)	Baseline (℃)	Hours after injection						Maximum Rise
					0.5	1.0	1.5	2.0	2.5	3.0	
1	2.4	♂	24	39.0	39.0	39.0	39.0	39.0	39.0	39.0	0.0
2	2.4	♂	24	39.1	39.1	39.1	39.1	39.2	39.2	39.2	0.1
3	2.6	♂	26	39.1	39.1	39.1	39.1	39.1	39.1	39.1	0.0

CONCLUSION

Under the conditions of this study, the total rise of rabbit temperature during the 3h observation period was within acceptable limits. No evidence of material-mediated pyrogenicity was observed. The extract of the test article was judged as nonpyrogenic.

PHOTOGRAPH OF THE TEST ARTICLE

Remark: Results and conclusions apply only to the test article sample tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***