CONFIDENTIAL RFPORT

SPONSOR

Blair Colby

Flint Hills Resources, LP

118 Huntsman Way

Longview, TX 75602

PEOPLE > SCIENCE > SOLUTIONS

Test Facility 9 Morgan

STUDY TITLE

USP Limulus Amebocyte Lysate (LAL) Testing - Kinetic-Chromogenic Method

TEST ARTICLE NAME

Polypropylene Pellets

TEST ARTICLE IDENTIFICATION

13T25A - 1905062

TEST ARTICLE PHYSICAL DESCRIPTION

See test specification.

TEST ARTICLE RECEIVED

June 26, 2019

RESULTS

Irvine, CA 92618 949.951.3110

Test Article Extract Dilution:	1
Positive Product Control Percent Recovery:	98% (between 50% and 200% is acceptable)
Test Article Extract:	< 0.00500 EU/mL (Total Concentration) < 0.0500 EU/g

TEST ACCEPTANCE CRITERIA

Type of Product	Current FDA Requirements*	Current USP Requirement
Medical Device	Less than or equal to 0.5 EU/mL	Less than or equal to 20.0 EU/device
Medical Device Contacting Cerebrospinal Fluid	Less than or equal to 0.06 EU/mL	Less than or equal to 2.15 EU/device
Water for Injection	Not Applicable	Less than or equal to 0.25 EU/mL

^{*}Based on an extraction volume of 40 mL/device

TEST INFORMATION

Date Prepared: June 28, 2019 Date Tested: June 28, 2019

METHOD

The test article was prepared per the attached LAL test specification T0008952-01 except for the test article extraction duration. The test article was extracted for at least 1 hour per USP <161>.

Individual aliquots of the test and control solutions were placed in sterile microplate wells and incubated at 37°C for at least 10 minutes in a microplate Reader. Individual aliquots of lysate, reconstituted per manufacturer's current directions, were then added to each well and testing was initiated. The concentration of the endotoxin was determined spectrophotometrically. A Positive Product Control solution (inhibition/enhancement control) was simultaneously prepared and tested to evaluate any possible interference by the test article on the lysate/endotoxin reaction.

All times and temperatures reported herein are approximate and are within ranges established by the external standards described in the References section of this report and/or NAMSA standard operating procedures.



REPORT

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Test Facility 9 Morgan Irvine, CA 92618 949.951.3110

REFERENCES

American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) ST72: Bacterial Endotoxins - Test methods, routine monitoring, and alternatives to batch testing (2011/Reapproved 2016).

United States Pharmacopeia 42, National Formulary 37 (USP), General Chapter <85>, Bacterial Endotoxins Test (2019).

United States Pharmacopeia 42, National Formulary 37 (USP), General Chapter <161>, Medical Devices-Bacterial Endotoxin and Pyrogen Tests (2019).

APPROVAL

Sherry Zachariah, BS

Laboratory Operations Manager, Quality Control

Results apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. This test was performed under all applicable GMP regulations and in compliance with the ISO 13485 standard, with the test method accredited to the ISO 17025 standard.



19C 49126

T0008952 Revision: 01

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Test Process Specification/Document

Test:	LAL			
Company:	Flint Hills Resour	ces		.0
Customer ID:	26687			X.V.
Test Article Name:	Pellets		No photograph per exception GOP_00706.	n clause in NAMSA
Description:	PP pellets			79
torage Conditions: I	Room Temperature			
est Article: Other:	Pellets			
amount of sample to	be tested: > 1 g			
Method of Sample Pr	reparation			
extraction Vessel: De	epyrogenated Vessel			
extraction Fluid: 37	7°C Water for Injecti	on		
Test as received.			10	
Fill each unit wit	IIIL OI CXU	action fluid. Receptific ca	uaction fluid in contact with	
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