NAMSA

CONFIDENTIAL
REPORT

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Test Facility
9 Morgan
Irvine, CA 92618
949.951.3110

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

SPONSOR
Blair Colby
Flint Hills Resources, LP
118 Huntsman Way
Longview, TX 75602

RESULTS

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.

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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 7/1/19

Sherry Zachariah, BS
Laboratory Operations Manager, Quality Control

Date

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.

Test Process Specification/Document

Test:	LAL	
Company:	Flint Hills Resources	
Customer ID:	26687	
Test Article Name:	Pellets	No photograph per exception clause in NAMSA SOP_00706.
Description:	PP pellets	

Storage Conditions: Room Temperature

Test Article: Other: Pellets

Amount of sample to be tested: > 1 g

Method of Sample Preparation

Extraction Vessel: Depyrogenated Vessel

Extraction Fluid: 37°C Water for Injection

☐ Test as received.

☐ Fill each unit with mL of extraction fluid. Keep the extraction fluid in contact with the relevant pathway for at least 1 hour ☐ at controlled room temperature (20-25°C). ☐ in a 37°C shaker incubator. ☐ Flush each unit with an additional mL of extraction fluid. Pool the eluates.

☐ Fill each unit with mL of extraction fluid. Keep the extraction fluid in contact with the relevant pathway for at least 1 hour at controlled room temperature (20-25°C). Flush each unit with an additional mL of extraction fluid. Pool the fill and flush eluates. Cover each unit with the fill and flush eluates plus an additional mL of extraction fluid. Extract the products in a 37°C shaker incubator for 40-60 minutes.

☒ Cover each 1 gram with 10 mL of extraction fluid. Extract the products ☐ for at least 1 hour at controlled room temperature (20-25°C). ☒ in a 37°C shaker incubator for 40-60 minutes.

☐ Prepare a dilution with ☐ Water for Injection ☐ Water for Irrigation ☐ 0.05M TRIS – GB Buffer ☐ 100 MMOL TRIS Buffer ☐ 10mM $MgCl_2$

☒ **Comments/Special Instructions**: If interference occurs, dilute the extract with Water for Injection. There is no established ERL by the sponsor; however, if dilution is needed, start at a low dilution, such as 1:2 or 1:5.

Check All That Apply	LAL Test Method	Endotoxin Release Limit (ERL)	Preferred Dilution	Maximum Valid Dilution (MVD)
☒	Kinetic Chromogenic	Not provided by the sponsor	Undiluted	(see comments)
☐	Kinetic Turbidimetric			
☐	Gel Clot			

☐ Inhibition/Enhancement has been performed. Reference Lab Number:

Reference(s): NAMSA LAL test SOP series