

SPONSOR

12855

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REPORT DATE: 3/4/13

MSP NUMBER: 12L0155H

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CERTIFICATE

CLASS VI – 121°C PLASTIC TESTS (USP 35 <88>, REV. 5/2012)

Name: Fluoroplast 4 Perm

Physical Description: Solid. Decomposition Temperature - >260°C, Solubility - Insoluble, Explosive properties -

Not explosive.

Total Quantity Received for Testing: 8 samples (5 x 6 cm), 8 samples (1mm x 1mm x 10mm)

Batch Number: 3377

Expiration Date: Two years from the date of manufacture

Storage Condition: Room Temperature

Date Received: 12/6/12

Class VI - Intracutaneous Test

PBL Report No.: 12L0155H-X02G

Class VI - Systemic Injection Test

PBL Report No.: 12L0155H-X03G

Class VI - Implantation Test

PBL Report No.: 12L0155H-X04G

The test article met the requirements for Plastic Class VI - 121°C testing per USP <88>.

tiple Study Project Coordinator

QAU Review

Date