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The <85> Bacterial Endotoxins Test General Chapter was incorporated into and became official with the Second Supplement to USP 35-NF 30. Should you have any questions about this General Chapter, please contact Rahdakrishna Tirumalai (301-816-8339 or rst@usp.org).

<85> **Bacterial Endotoxins - USP**
Chapter <85> Bacterial Endotoxins, United States Pharmacopoeia The Second Supplement to United States Pharmacopoeia (USP) 35 included a few changes to chapter <85>, Bacterial Endotoxins Test (BET) The changes became effective on December 1, 2012, and were incorporated into the BET chapter in USP 36 [1], which became effective on May 1, 2013 These Combined Index to USP 41 and NF 36 ...

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This chapter provides a test to detect or quantify bacterial endotoxins that may be present in or on the sample of the article(s) to which the test is applied.

General Chapters: <85> BACTERIAL ENDOTOXINS TEST

United States Pharmacopoeia (USP), 2011, Chapter <85>, Bacterial Endotoxins Test. USP, 2011, Chapter <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.

Guidance for Industry

Second Supplement to USP 35-NF 30 Biological Tests / [85] Bacterial Endotoxins Test 5625 General Chapters General Tests and Assays Biological Tests and REAGENTS AND TEST SOLUTIONS Assays Amoebocyte Lysate—A lyophilized product obtained from the lysate of amoebocytes (white blood cells) from the

<85> BACTERIAL ENDOTOXINS TEST

Stage 6 Harmonization Official December 1, 2012 [85] Bacterial Endotoxins Test1 [85] BACTERIAL ENDOTOXINS Change to read: TEST PREPARATION OF SOLUTIONS Standard Endotoxin Stock Solution—A Standard Endo- toxin Stock Solution is prepared from a USP Endotoxin Refer- Change to read: ence Standard that has been calibrated to the current WHO International Standard for Endotoxin.

85 BACTERIAL ENDOTOXINS Change to read: TEST ... - USP

The General Chapter <788> Particulate Matter in Injections Revision Bulletin supersedes the currently official version published in the USP 35-NF 30 and will be incorporated in USP 36-NF 31. Should you have any questions, please contact Desmond Hunt, Ph.D. (301-816-8341 or dgh@usp.org).

Particulate Matter in Injections | USP-NF

[2] United States Pharmacopoeia (USP), 2011, Chapter , Bacterial Endotoxins Test. 85> 85> [3] USP, 2011, Chapter , Transfusion and Infusion Assemblies and Similar Medical Devices. 161>

Guidance for Industry: Pyrogen and Endotoxins Testing ...

Combined Index to USP 41 and NF 36 Abaca-Aceto 1:1 Combined Index to USP 41 and NF 36, Volumes 1-5, including First ... Numbers in angle brackets such as [421] refer to chapter numbers in the General Chapters section. A capsules, 36 oral solution, 37 and (salts of) chlorpheniramine, for effervescent oral solution, 37 ... 85 dehydrated ...

Combined Index to USP 41 and NF 36 ... - USP-NF | USP-NF

Title: ¼½¾¾¾ [MOBI] Usp 36 Chapter 85 Author: ¼½¾¾¾www.istituto comprensivopetronecb.gov.it Subject: ¼½¾¾¾v'v'v Download Usp 36 Chapter 85 -

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70 [71] Sterility Tests | Microbiological Tests USP 35 Fluid Thioglycollate Medium is to be incubated at 30°-35°. Table 1. Strains of the Test Microorganisms Suitable for Use in For products containing a mercurial preservative that cannot the Growth Promotion Test and the Method Suitability be tested by the membrane filtration method, Fluid Thiog-Test (Continued)

<71> STERILITY TESTS

Chapter <85> Bacterial Endotoxins, United States Pharmacopoeia The Second Supplement to United States Pharmacopoeia (USP) 35 included a few changes to chapter <85>, Bacterial Endotoxins Test (BET). The changes became effective on December 1, 2012, and were incorporated into the BET chapter in USP 36, which became effective on May 1, 2013.

Recent Regulatory Issues Concerning Bacterial Endotoxin ...

Use an accurate temperature-sensing device such as a clinical thermometer, or thermistor probes or similar probes that have been calibrated to assure an accuracy of ±0.1 and have been tested to determine that a maximum reading is reached in less than 5 minutes. Insert the temperature-sensing probe into the rectum of the test rabbit to a depth of not less than 7.5 cm, and, after a period of ...

usp31nf26s1_c151, General Chapters: <151> PYROGEN TEST

Bacterial Endotoxins— Proceed as directed under Bacterial Endotoxins Test 85. For medical devices, the endotoxin limit is not more than 20.0 USP Endotoxin Units per device except that for those medical devices in contact with the cerebrospinal fluid the limit is not more than 2.15 USP Endotoxin Units per device.