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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
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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

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amoebocytes (white blood cells) from the

<85> BACTERIAL ENDOTOXINS TEST

United States Pharmacopeia (USP), 2011, Chapter <85>, Bacterial Endotoxins Test. USP, 2011, Chapter

<161>, Transfusion and Infusion Assemblies and Similar Medical Devices.

Guidance for Industry

[2] United States Pharmacopeia (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 ...

The USP Endotoxin RS has a defined potency of 10,000 USP Endotoxin

Units (EU) per vial. Constitute the entire contents of 1 vial of the RSE with 5 mL of LAL Reagent Water 3, mix intermittently for 30 minutes, using a vortex mixer, and use this concentrate for making appropriate serial dilutions.Preserve the concentrate in a refrigerator for making

subsequent dilutions for not more than 14 days.

General Chapters: <85> BACTERIAL ENDOTOXINS TEST

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OTE — In this chapter, the term “tube ” includes any other receptacle such as a micro-titer well.] Change to read:

PREPARATION OF THE STANDARD ENDOTOXIN STOCK SOLUTION AND STANDARD SOLUTIONS The USP Endotoxin RS has a defined potency of 10,000 USP Endotoxin Units (EU) per vial.

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solution, 37 ... 85 dehydrated ...

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USP 41–NF 36. November 13, 2017 . In accordance with USP's Rules and Procedures of the Council of Experts ("Rules") and except as provided in Section 7.02 Accelerated Revision Processes, USP publishes proposed revisions to the United States

Pharmacopeia and the National

Commentary USP 41–NF 36 - USP–NF | USP-NF

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 ...

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book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH

guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug

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