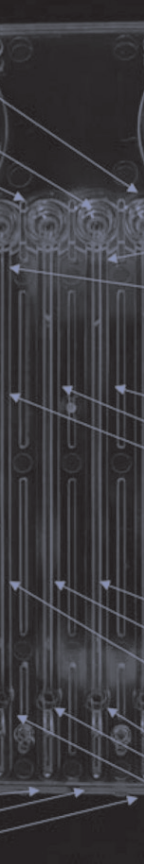
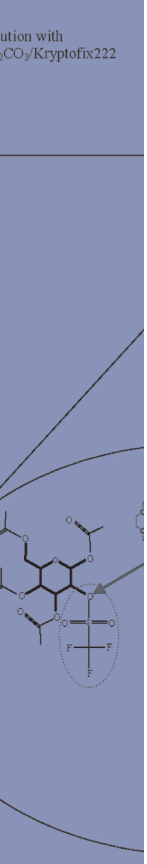
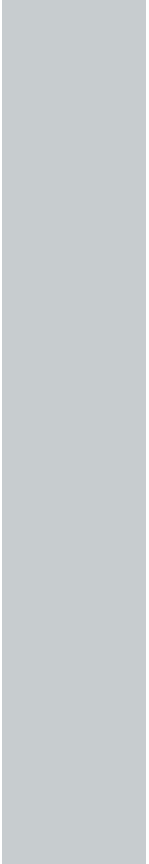
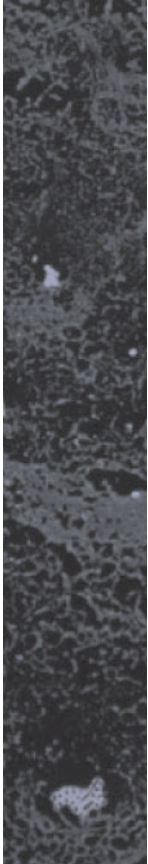
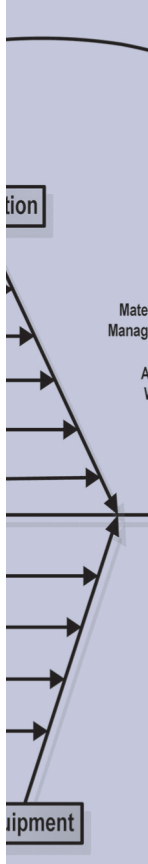


PDA Technical Series: Endotoxin Analysis and Risk Management



**Includes articles on
Low Endotoxin Recovery**

Parenteral Drug Association, Inc.

4350 East West Highway, Suite 600

Bethesda, MD 20814

tel: 1+ (301) 656-5900 fax: 1+ (301) 986-0296

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PDA Technical Series — Endotoxin Analysis and Risk Management



Foreword

PDA Technical Series: Endotoxin Analysis and Risk Management is a collection of published research on the topic from the *PDA Journal of Pharmaceutical Science and Technology*. The importance of endotoxin testing to the PDA community of pharmaceutical and biopharmaceutical manufacturers was summarized nicely by Richard Johnson, PDA President & CEO in the Foreword to *Technical Report No. 82: Low Endotoxin Recovery* (March 2019):

The reliable and sensitive detection of bacterial endotoxin is a key test underpinning patient safety in the manufacturing of parenteral drugs. The globally harmonized compendial tests linked to well-characterized reference standards have provided this assurance to industry and regulators for decades despite the complex nature of both the assays and the reference materials. This complexity has been demonstrated each time new assay approaches or reference materials have been proposed. Over the past decade, biologics manufacturing has exploded, and new products, formulations, and delivery systems continue to push the boundaries of modern manufacturing.

Based on this, the number and quality of scientific manuscripts contributed to the *PDA Journal* on this topic should be of no surprise. This volume is intended for those in the industry who perform and/or are responsible for the quality testing and manufacture of biopharmaceutical products. For those concerned with the phenomenon of “Low Endotoxin Recovery,” two articles have been published in the *PDA Journal* that cover the issue, both of which were referenced in the aforementioned *Technical Report No. 82*. This volume, plus the technical report, represent the entirety of authoritative knowledge and guidance on the subjects of endotoxin testing, risk management, and LER available from PDA.

The articles contained in this book are unedited and unaltered from their original format.

Walter Morris
Director of Publishing
PDA, Inc.

Table of Contents

Dosage Form Consideratons.....	1
The Role of Heat-Tolerant Endotoxin-Retentive Ultrafilters (Ufs) for the Remediation of Reverse Osmosis (RO) Plants Employed for Surgical Hand Antisepsis Using Periodic Thermal Disinfection–A Ten-Year Longitudinal Experience Study in the Operating Theater	2
Bacterial Endotoxin Requirements for Dry Powder Inhalants and Their Excipients: Are They Critical Quality Attributes?	20
Quality Control Testing for Tracking Endotoxin-Producing Gram-Negative Bacteria during the Preparation of Polyvalent Snake Antivenom Immunoglobulin	28
Elevated Endotoxin Levels in Human Intravenous Immunoglobulin Concentrates Caused by (1→3)-β-D-Glucans	40
Methods and Testing	49
Development of Methods for Recovering Endotoxins from Surfaces and from Air in Production Environment of Injectable Drugs	50
Application of Recombinant Factor C Reagent for the Detection of Bacterial Endotoxins in Pharmaceutical Products.....	59
Evaluation of a Rapid Microbiological Method with a Mixed Culture Biofilm Model.....	67
How pH, Temperature, and Time of Incubation Affect False-Positive Responses and Uncertainty of the LAL Gel-Clot Test.....	88
Alumina Depyrogenates F 18 Fludeoxyglucose Injection during Purification Processes	93
Evaluation of the Endosafe® Portable Testing System™ for the Rapid Analysis of Biopharmaceutical Samples	100
Low Endotoxing Recovery	111
Factors Affecting Reduction of Reference Endotoxin Standard Activity Caused by Chelating Agent/Detergent Matrices: Kinetic Analysis of Low Endotoxin Recovery	112
Evidence Against a Bacterial Endotoxin Masking Effect in Biologic Drug Products by <i>Limulus</i> Amebocyte Lysate Detection.....	122
Risk Analysis/Management	128
The Application of Quality Risk Management to the Bacterial Endotoxins Test: Use of Hazard Analysis and Critical Control Points.....	129
A Practical Discussion of Risk Management for Manufacturing of Pharmaceutical Products.....	144
Risk Analysis of Sterile Production Plants: A New and Simple, Workable Approach.....	154



Bethesda Towers
4350 East West Highway
Suite 600
Bethesda, MD 20814 USA
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-0296
E-mail: info@pda.org
Web site: www.pda.org