TECHNICAL
INSIGHTS

ISSUE #1

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Endotoxin Testing for Cleanroom Wipers in Pharmaceutical Manufacturing

INTRODUCTION

In pharmaceutical manufacturing, maintaining a sterile and contamination-free environment is not just a matter of operational efficiency but a regulatory and safety imperative. One of the critical contamination threats in cleanroom environments is endotoxins—a type of pyrogen derived from Gram-negative bacteria. Endotoxins can persist even after sterilization and pose a serious risk when introduced into pharmaceutical products, especially injectables, biologics, and medical devices. Among the various sources of contamination, cleanroom wipers—integral to surface cleaning and aseptic practices—must be stringently controlled for endotoxin levels. This article delves into the significance of endotoxin testing for cleanroom wipers and outlines best practices and regulatory considerations.

IMPORTANCE OF ENDOTOXIN CONTROL IN PHARMACEUTICAL PRODUCTS

Endotoxins are lipopolysaccharide (LPS) components of the outer membrane of Gram-negative bacteria. When introduced into the human body, particularly through injectable routes, endotoxins can cause severe biological reactions including:

- **Fever and chills (pyrogenic response)**
- **Sepsis and shock**
- **Multi-organ failure in extreme cases**
- **Immunogenic and inflammatory responses**

These risks make endotoxin contamination a critical quality and safety concern. Regulatory bodies like the FDA and EMA mandate stringent endotoxin limits for parenteral drug products and medical devices. A single contaminated component or material used in the cleanroom—including a wiper—can compromise an entire production batch, leading to product recalls, regulatory actions, and loss of patient trust.

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THE ROLE OF CLEANROOM WIPERS AND IMPORTANCE OF LOW ENDOTOXIN LEVELS

Cleanroom wipers are widely used in controlled environments for:

- **Cleaning surfaces and equipment**
- **Wiping down gloves and materials**
- **Absorbing spills and residual solvents**

As these wipers frequently come in **direct or indirect contact** with production surfaces and critical materials, any endotoxin residue can be transferred to the product stream. Hence, using low-endotoxin or endotoxin-controlled wipers is essential, especially in:

- **Aseptic processing areas (Grade A/B cleanrooms)**
- **Sterile drug manufacturing**
- **Biopharmaceutical production**

WHY ENDOTOXIN TESTING OF CLEANROOM WIPERS IS NECESSARY

Endotoxins are **not destroyed by standard sterilization methods like gamma irradiation or autoclaving**. Therefore, testing the actual endotoxin content of cleanroom wipers is the only way to confirm their suitability for sterile manufacturing environments.

Endotoxin testing ensures:

- **Compliance with pharmacopeial and FDA standards**
- **Assurance of product safety**
- **Reduction of batch rejection risks**
- **Confidence in contamination control protocols**

GUIDELINES AND TEST LIMITS

The U.S. FDA, through 21 CFR 211 and USP <85> Bacterial Endotoxins Test, outlines specific requirements for endotoxin testing. The allowable endotoxin limits are expressed in Endotoxin Units (EU):

- **Injectable drugs: Typically ≤ 5 EU/kg/hr body weight**
- **Medical devices: Varies based on contact type (e.g., ≤ 0.5 EU/mL for intrathecal devices)**
- **Raw materials and equipment: Must have documented low endotoxin levels if used in sterile product manufacturing**

For cleanroom consumables like wipers, there are **no explicit limits in regulations**, but they must not contribute to endotoxin load. Industry standards generally accept wipers with <20 EU/device or <0.5 EU/mL, especially for aseptic and parenteral operations.

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SOURCES OF ENDOTOXIN IN THE CLEANROOM

Endotoxin contamination can originate from:

- **Water sources (non-sterile water used in manufacturing or cleaning)**
- **Human operators (skin, sweat, poor gowning hygiene)**
- **Poorly cleaned equipment or surfaces**
- **Contaminated raw materials or packaging**
- **Non-validated cleanroom supplies, including wipers and garments**

Cleanroom wipers themselves can become endotoxin carriers if manufactured or handled under non-controlled conditions.

TEST METHOD FOR ENDOTOXIN DETECTION

The most widely accepted method for endotoxin detection is the Limulus Amebocyte Lysate (LAL) assay.

TEKNIPURE'S LOW-ENDOTOXIN CLEANROOM WIPERS

Key features of Teknipure's low-endotoxin wipers include:

- **Each manufactured lot is tested for Endotoxins**
- **Guaranteed <20 EU/device or <0.5 EU/mL endotoxin levels**
- **Manufactured in ISO Class 5 cleanrooms**
- **Gamma-irradiated and validated sterile at SAL 10^{-6} per ISO 11137-2**
- **Produced using ultra-pure water**
- **Full batch traceability, CoA/CoC and LAL test report provided for each lot**
- **Available in polyester knit, nonwoven, and pre-saturated options**

These wipers are ideal for USP <797>/<800> compliance and aseptic fill-finish applications.

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CONCLUSION

Endotoxin testing for cleanroom wipers is a critical quality assurance measure in pharmaceutical manufacturing. With stringent regulatory expectations and the high risk associated with pyrogenic contamination, **only tested low-endotoxin consumables** should be used in aseptic environments. Cleanroom wipers, often overlooked, can be a hidden source of endotoxins. As such, choosing products from trusted manufacturers like Teknipure ensures both **regulatory compliance** and **product safety**.

Teknipure Low Endotoxin Products:

TekniClean®		
Part Number	*Description*	*Packaging*
TC2P12S-LE	Sterile Polyester Knit Wiper with Sealed Edge, Low Endotoxin, 12" x 12" (23 cm x 23 cm)	25 wipes/bag, 20 bags/case, Total 500 wipes/cs
TC2P99S-LE	Sterile Polyester Knit Wiper with Sealed Edge, Low Endotoxin, 9"x 9" (23 cm x 23 cm)	20 wipes/bag, 25 bags/case, Total 500 wipes/cs

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