Teknipure

Innovative Contamination Solutions

- Industry Growth
- Understanding Yield Loss
- Choosing the Right Tools

PHARMACEUTICAL MANUFACTURING

Contamination Control Solutions

Teknipure's Guide to Micro-Contamination Control Systems

Visit the Website

Extraordinary Growth Begins with Wisely Managed Risk

The Race to Innovate is On

The future is here. The global population is aging with the number of people over 65 projected to double to more than 1.5 billion people by 2050. With increasingly sedentary lifestyles, chronic diseases like diabetes and other costly health conditions are on the rise.

Medical innovations such as precision medicine, cell and gene therapy, and immuno-oncology are revolutionizing the treatment of many diseases. **The pressure to maximize current production and focus resources on fast-tracking innovation to market has never been more intense.**

Utilizing contract partners to strategically fill capacity and expertise gaps often brings many compliance and QA/QC challenges. Interruptions in the supply chain due to contamination can devastate a company's public reputation and result in extended drug shortages for patients relying on medicines.

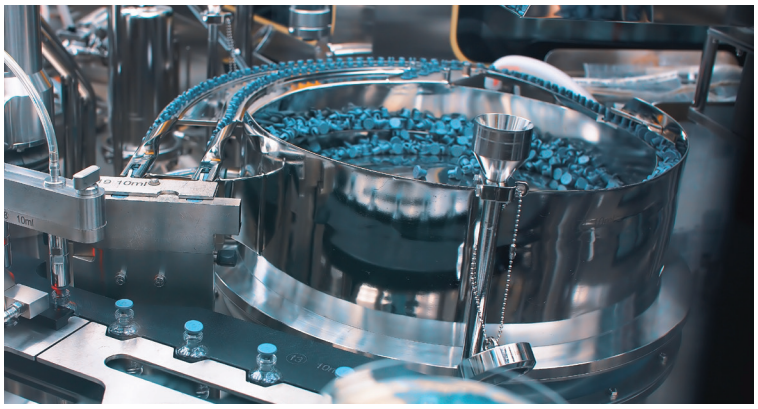
11.9% of FDA citations
in pharmaceutical manufacturing cite contamination-related issues

Red Flags

In the wake of the 2012 meningitis outbreak due to process contamination, the FDA and other regulatory agencies have heightened their scrutiny of potential contamination sources in pharmaceutical manufacturing. **Even during COVID-19 restrictions, the FDA issued 3,942 contamination-related citations between January 2018 – March 2021.**

The consequences of product contamination can be staggering, not only from a patient risk perspective, but also in terms of business. **From plant closures to millions in fines and litigation costs, the net financial impact can measure in the billions.**The impact to reputation in the medical community and among patients...immeasurable.

Reliable cGMP compliance is essential to risk management



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Toll Free: 844.309.2376 Info@Teknipure.com www.Teknipure.com

Attacking Bioburden & Cross-Contamination In Your Process

Cross-contamination, recently in the headlines as the source of "drug-doping" accusations at the 2021 Summer Olympics, is a rising concern in pharmaceutical manufacturing. As continuous manufacturing practices and quick production changeovers become the norm, even the slightest residual API left on processing sur-faces can result in cross-contamination between drug types. Bloomberg "Drug Cross-Contamination", July 2021

Winning the ongoing battle against product contamination has never been more crucial and the role of surface cleaning choices in removing contamination from your process has never been more central to an effective QA/QC and Risk Management Program.

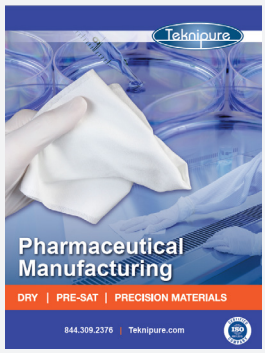
Whether removing bioburden or residual API, choosing the right wiper to achieve the highest level of single pass surface cleanliness is more critical than ever.

Choosing Wipers to Remove Micro-Contamination Wisely

Two simple choices that maximize contamination removal from your critical and controlled environments:

1. Choose engineered materials, such as microfiber, that most effectively remove surface contamination from your process.
2. Choose the ideal delivery system that aligns process effectiveness with human productivity, such as pre-saturated solutions or high-capacity delivery systems.

Pharmaceutical Manufacturing Wiping Applications Guide



FOR MORE INFORMATION

>3X ENTRAPMENT POWER

See Microfiber in Action:

Cleaner Surface = Lower Contamination Risk

Microfiber Engineered Material

Work smarter, not harder by choosing wiping materials that reduce surface contamination more effectively. Engineered microfibers have **3X more fiber surface area** to capture contaminants. **Up to 93% of residues are encapsulated** in the split microfiber structure on the first wiping pass compared to standard wiping materials that remove **≤30%**.

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Innovative Micro-Contamination Solutions

Precision Pre-Saturated Solutions

Cleanroom Studies show optimal saturation levels achieve maximum micro-contamination pick-up. Wiper studies show that limited area wetting of a wiper results in inefficiency micro-contamination capture, while an over-saturated wiper redeposits solvent contamination and leaves chemical residues on the surface.

Precision saturation delivers the right amount of fluid necessary to dislodge, pull, and capture contaminates, while leaving near zero residuals behind on first pass.

Precision saturation also minimizes chemical use & lowers worker environmental exposure to VOC's.

"Teknipure is a proud supplier to the pharmaceutical industry as a leading innovator and manufacturer of contamination control solutions. Our products meet the most critical criteria for use in aseptic and non-aseptic environments. Proper product selection is paramount to efficiently removing bioburden, and disinfectant and API residuals from your process. We have created tools to ensure the best products are selected for the appropriate applications specific to your requirements. We are committed to delivering cleaning solutions that deliver results against your risk management goals."

Chris Heiland, President

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