Bactiscan™: Revolutionising the contamination control strategy in Pharmaceutical QC and Manufacturing

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Introduction

In the fast-paced and highly regulated pharmaceutical sector, detecting and preventing contamination is crucial for ensuring product safety and integrity. There have been numerous recent incidents of product recalls due to bacterial contamination, highlighting the limitations of current strategies and methods for their accurate identifying and mitigating such issues. Some of these cases reported by FDA, are shown in Table 1. [1-4]

TABLE 1

Date	Brand Names	Product Description	Recall Reason/Description	Company Name
03/19/2020	Neuroveen, Respitrol, Thyroveev, Compulsin	Homeopathic Medicines	Due to Possible Microbial Contamination	Mavidon
10/28/2020	Paroex	Chlorhexidine Gluconate Oral Rinse, 4 oz and 16 oz	Potential contamination with *Burkholderia lata*	Sunstar Americas, Inc.
12/02/2020	MPM Medical	Regenecare HA Topical Anesthetic Hydrogel	*Burkholderia cepacia* contamination	MPM Medical, LLC
03/24/2021	Durisan	Antimicrobial Hand Sanitizer	Due to microbial contamination	Sanit Technologies LLC d/b/a Durisan
9/15/21	Ruzurgi, 10mg tablets	tablets	Yeast, mold, and aerobic bacteria	Jacobus Pharmaceutical
11/10/21	liquid probiotics	liquid	*Pseudomonas aeruginosa*	Mary Ruth's
12/31/21	Clobetasol Propionate Ointment USP 0.05%	ointment	*Ralstonia pickettii*	Taro Pharmaceuticals
3/30/22	Milk of Magnesia Oral Suspension	liquid	Microbial contamination	Plastikon Healthcare
5/10/22	SyrSpend SF Cherry	liquid	*Burkholderia gladioli*	Fagron
6/10/22	SnoreStop NasoSpray	liquid	*Providencia rettgeri*	Green Pharmaceuticals
6/24/22	Magnesium Citrate Saline Laxative Oral solution	liquid	*Gluconacetobacter liquefaciens*	Vi-Jon Mfg. for CVS

Bactiscan, as a groundbreaking technology, is revolutionising contamination detection in the industry. By relying on UV calibrated wavelengths, Bactiscan offers a broad spectrum of detection, including bacteria, yeasts, and contaminants like detergents and dust. This article explores how Bactiscan provides a safe and effective solution, offering real-time detection of biofilms without the need for eye protection. Additionally, we will highlight the complementarity of Bactiscan with ATP testing, providing unparalleled contamination risk control in the pharmaceutical sector.

Calibrated Wavelengths for Broad Spectrum Detection

Bactiscan harnesses the power of UV technology with calibrated wavelengths to achieve unparalleled detection capabilities. This advanced technology allows for the detection of various types of contaminants, including bacteria, yeasts, and other substances that may compromise product quality. By utilising specific wavelengths, Bactiscan provides a broad spectrum of detection, ensuring comprehensive detection and minimising the risk of undetected contaminants.

Safe and Eye Protection-Free Operation

One of the remarkable features of Bactiscan is its safe operation without the need for eye protection. Unlike traditional UV-based detection methods that require eye protection due to harmful radiation, Bactiscan employs UV technology at safe levels that pose no risk to operators. This ensures the safety and well-being of quality control professionals while conducting contamination detection processes.

Real-Time Detection of Biofilms

Biofilms pose a significant challenge in the pharmaceutical industry, as they can harbour and protect harmful microorganisms, and provide sites for repeated contamination. Bactiscan addresses this issue by providing real-time detection of biofilms. By using its UV technology, Bactiscan can detect and monitor the presence of biofilms, allowing quality control personnel to take immediate action to prevent contamination and minimise the risk of product recalls.

Complementarity with ATP Testing for Unparalleled Contamination Risk Control

While Bactiscan excels in broad-spectrum contamination detection, its complementarity with ATP testing offers a comprehensive approach to contamination risk control. ATP testing focuses on measuring adenosine triphosphate (ATP), a molecule found in all living cells, to assess surface cleanliness and organic residue. By integrating Bactiscan's advanced UV technology with ATP testing, quality control professionals can obtain a comprehensive understanding of contamination risks.

Challenges associated using ATP

Despite the widespread and recognised use of ATP detection technology, it is vital to acknowledge its significant weaknesses with their implications and risks associated with the potential oversight of contamination. These weaknesses include:

- Statistical Probabilistic Nature: ATP detection is inherently a statistical and probabilistic method, introducing elements of randomness and subjectivity in the swabbing process. This variability can lead to inconsistencies and potential inaccuracies in contamination detection, posing risks to product safety and quality.
- Limitations in Comprehensive Swabbing: The practicality of swabbing all contact parts within the manufacturing area or machinery is challenging. This limitation may result in overlooked areas of potential contamination, leaving room for undetected contaminants to compromise product integrity and increase the risk of recalls.
- Consumable Costs: The cost of consumables associated with ATP detection can be significant, considering the need for swabs and reagents. These costs may accumulate, adding financial burdens to quality control processes, especially for companies with large-scale manufacturing operations.
- Incomprehensive Detection of Dead Cells: ATP detection may not provide a comprehensive method for identifying dead cells, which can still pose contamination risks. The sensitivity of ATP testing is reduced in the presence of dead or injured bacterial cells, and the inability to detect these inactive cells increases the likelihood of overlooking potential hazards and compromising product safety.
- False Negatives in Biofilm Detection: Swabbing the outer layer of biofilms with ATP testing can yield false negatives, leading to a false sense of sanitation. Biofilms, which often harbour harmful microorganisms, may remain undetected, allowing contamination to persist and potentially lead to product contamination.

These weaknesses underscore the importance of integrating advanced technologies like Bactiscan into contamination detection strategies. By addressing these limitations, Bactiscan offers a comprehensive solution that minimizes the risks associated with missed contaminations, providing enhanced detection accuracy, thorough inspection, and improved risk mitigation measures. Embracing Bactiscan empowers quality control professionals to proactively safeguard product integrity, mitigate recalls, and protect brand reputation in the face of potential contamination challenges.

Combining ATP and Bactiscan Benefits for the Pharmaceutical Sector

1. Enhanced Contamination Detection:
   Bactiscan's UV technology and broad spectrum detection capabilities significantly enhance contamination detection strategy. By Implementing the method with Bactiscan together with ATP, Quality control professionals can identify a wide range of contaminants, ensuring thorough analysis and reducing the risk of undetected contaminants for uncompromised quality control.

2. Regulatory Compliance:
   The pharmaceutical industry is subject to stringent regulatory requirements. By incorporating Bactiscan into quality control processes, companies demonstrate a commitment to robust contamination detection. Bactiscan's advanced technology and comprehensive detection capabilities provide assurance to regulators, ensuring compliance with industry standards.

3. Proactive Contamination Prevention:
   Bactiscan is able to detect the early stages of biofilms of pathogens, before they mature and become difficult to remove. Bactiscan's real-time detection of biofilms enables quality

control professionals to take immediate action to prevent contamination. By identifying and monitoring biofilms, companies can implement proactive measures, reducing the risk of product recalls and safeguarding patient safety.

4. Confidence in Cleaning
   Bactiscan excels at detecting the range of contamination typical to an industrial setting, Unlike ATP testing, its detection capability is unaffected by dead bacteria or bacteria injured by ineffective decontamination procedures. This versatility allows Bactiscan to pinpoint priority areas for further validation using ATP testing, and reveals the efficacy of routine cleaning practices.

5. Operational Efficiency
   Bactiscan streamlines contamination detection processes by providing rapid and accurate results. Its UV technology enables efficient inspections, ease of use technique, that allows quality control personnel to identify and address potential contaminants swiftly. This efficiency translates into streamlined workflows, saving time and resources.
6. Cost Savings
   By implementing Bactiscan as a part of quality control processes, pharmaceutical companies can potentially achieve cost savings. The accurate and efficient detection provided by Bactiscan helps identify contaminants early on without use of consumables, reducing the likelihood of costly product recalls. Additionally, by preventing contamination and ensuring product quality, companies can avoid expenses related to rework, disposal, and potential legal liabilities.

7. Reputation and Brand Protection
   The pharmaceutical industry relies heavily on reputation and brand trust. Product recalls and contamination incidents can have severe consequences, damaging a company's reputation and eroding consumer trust. By leveraging Bactiscan's advanced detection capabilities and proactive contamination prevention, companies can safeguard their reputation, maintain customer confidence, and protect their brand image.

8. Audit Preparedness
   Bactiscan's comprehensive contamination detection, complemented by ATP testing, strengthens audit preparedness. Regulatory audits and inspections often focus on contamination control and prevention measures. By integrating Bactiscan into quality control processes, companies can demonstrate their commitment to robust contamination detection and prevention, ensuring a smoother audit process and regulatory compliance.

Conclusion

Bactiscan's UV technology revolutionises contamination detection in the pharmaceutical sector. With its broad spectrum detection capabilities, safe operation, and real-time biofilm The complementarity of Bactiscan with ATP testing further enhances contamination risk control, providing a comprehensive approach to detecting and preventing contamination.

Embrace the power of Bactiscan's UV technology for accurate and comprehensive contamination detection in the pharmaceutical industry. With Bactiscan, companies can elevate their quality control processes, meet regulatory requirements, prevent contamination incidents, ensure product safety and integrity, achieve cost savings, protect their reputation and brand, and enhance audit preparedness. By combining Bactiscan with ATP testing, businesses can achieve unparalleled contamination risk control, gaining a comprehensive understanding of contamination risks and enhancing overall quality control efforts in the pharmaceutical sector.

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