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WHITEPAPER

Disinfectant Efficacy Testing and Claim Substantiation in Healthcare Disinfectant Wipes

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Abstract

Effective infection prevention and control (IPC) depends on the consistent use of disinfectants that have been rigorously tested and whose efficacy claims are accurately represented. This paper explores the evolution of disinfectant efficacy testing, the importance of harmonised European standards, and the principles required to construct robust and compliant claim sets. It also examines common sources of misleading claims and provides interpretive guidance on applying current methodologies such as EN 14885 within healthcare contexts.

Introduction

Disinfectants are fundamental to reducing the burden of healthcare-associated infections across clinical, institutional, and community environments. Their effectiveness must be both scientifically demonstrated and transparently communicated to ensure that healthcare professionals can make informed decisions. Historically, however, the absence of harmonised testing approaches created inconsistencies in how disinfectants were evaluated and marketed, leading to variability in both product performance and the credibility of claims.

The development of standardised European methodologies has addressed many of these challenges by providing a unified framework for assessing antimicrobial efficacy. This has facilitated greater confidence in disinfectant performance and improved comparability across products.

History of Standardised Testing

The move towards harmonisation began with early efforts to define minimum efficacy requirements within healthcare environments. A significant milestone in this progression was the establishment of the European Committee for Standardisation (CEN) in 1961, which enabled the coordination of national standards into a cohesive system.

Over subsequent decades, this framework has evolved in response to scientific advances and emerging public health risks. Modern standards are regularly updated to incorporate new organisms of concern, improved testing methodologies, and more realistic representations of practical use conditions. This evolution reflects a continuous effort to ensure that disinfectant efficacy data remains relevant and reliable.

The Role of Standardisation in Healthcare

Standardisation is central to ensuring that disinfectants used in healthcare are both effective and safe.

By defining clear performance criteria, EN standards help ensure that products are capable of controlling pathogens associated with healthcare-associated infections.

Another crucial function of standardisation is the promotion of safety and regulatory compliance. Testing requirements incorporate conditions designed to reflect real-world use, including the presence of organic matter, thereby ensuring that efficacy claims are meaningful in practice. Additionally, standardisation enables benchmarking between products, allowing users to make informed choices based on verified performance data. This structured approach also encourages innovation, as manufacturers must continually refine their formulations to meet evolving standards.

Limitations of Pre-Harmonised Approaches

Prior to harmonisation, disinfectant testing was often fragmented and inconsistent. Many manufacturers relied on in-house methods that lacked

independent validation and, in some cases, were designed to favour specific chemistries. At a broader level, national standards differed significantly, making it difficult to compare products across markets.

Basic laboratory methods such as minimum inhibitory concentration or agar diffusion tests were commonly used, but these approaches did not adequately simulate the conditions under which disinfectants are actually applied.

Current Framework for Efficacy Testing

The modern regulatory framework for disinfectant efficacy in Europe is anchored in EN 14885, which defines how products should be tested and how claims should be substantiated.

This standard outlines a structured, tiered approach that progresses from basic laboratory screening through increasingly realistic simulations of practical conditions, culminating in field testing where appropriate. Through this phased methodology, products are evaluated not only for their intrinsic antimicrobial activity but also for their performance under conditions that closely resemble real-life use.

EN 14885 applies broadly across healthcare, veterinary, industrial, and domestic settings, ensuring consistency in testing expectations across different application areas. Within healthcare, it supports a wide range of use cases, including hand hygiene, surface and instrument disinfection, textile processing, and water treatment.

A particularly important requirement within this framework is that healthcare disinfectants must demonstrate, at a minimum, bactericidal and yeasticidal efficacy using both suspension and surface test methods under simulated practical conditions.

Advances in Sporicidal Testing

Recent developments in sporicidal efficacy testing illustrate the ongoing refinement of standards to better reflect healthcare needs. While earlier standards such as EN 13704 were widely used, they were primarily suited to industrial applications and have now been superseded in healthcare contexts.

Current best practice relies on a combination of EN 17126 for suspension testing and EN 17846 for surface testing of Clostridioides difficile. These standards introduce more stringent requirements, including higher levels of microbial reduction, additional test organisms, and more challenging soiling conditions. The adoption of these methodologies represents a shift towards more rigorous and clinically relevant validation of sporicidal claims.

Interpretation and Risks of Misleading Claims

Despite the availability of harmonised standards, misleading claims remain a significant issue within the disinfectant market.

Such claims often arise from incomplete testing, incorrect application of standards, or selective presentation of data. For example, products may omit required methods such as EN 16615 for wipes or EN 14476 for virucidal activity, yet still imply broad antimicrobial efficacy.

In other cases, claims may be based on inappropriate test organisms or unsupported contact times, which can significantly distort the perceived effectiveness of a product. Without full transparency regarding test conditions, including soiling and application method, users may be misled into assuming a level of efficacy that is not supported by evidence.
These issues underscore the importance of critically evaluating claim sets to ensure that they are both accurate and aligned with current standards.

Principles for Constructing Robust Claim Sets

A scientifically robust and regulatory-compliant claim set must be fully aligned with the relevant EN standards and reflect the intended use of the product. This involves not only selecting the correct test methods but also providing complete information on contact times, environmental conditions, and representative organisms.

Equally important is the requirement that testing should simulate real-world conditions as closely as possible. For example, when evaluating disinfectant wipes, efficacy should be demonstrated using eluates and surfaces that reflect actual application scenarios. Only through this level of alignment can claims be considered both credible and meaningful.

When constructed correctly, a claim set provides a clear and transparent representation of product performance. It enables users to understand exactly what a disinfectant can achieve and under what conditions, thereby supporting safe and effective use in healthcare environments.

Conclusion

The harmonisation of disinfectant efficacy testing has significantly improved the reliability and comparability of product claims within healthcare. Standards such as EN 14885 provide a comprehensive framework that ensures disinfectants are evaluated under conditions that reflect practical use.

However, the value of these standards depends on their correct application and interpretation. Misleading or incomplete claims can undermine infection control efforts and pose risks to patient safety. It is therefore essential for all stakeholders - including manufacturers, regulators, and healthcare providers - to maintain a clear understanding of current requirements and ensure that product claims are fully substantiated.

By adhering to harmonised standards and prioritising transparency, the industry can support more effective infection prevention practices and contribute to improved public health outcomes.

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