

Disinfectant Efficacy Testing for Fungi on Non-Porous Surfaces: A Case Study



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Introduction

An important aspect of the selection and evaluation of disinfectants is the disinfectant qualification programme. After a disinfectant has been chosen based on its chemical properties and expected performance/effectiveness, each disinfectant should be assessed to ensure its efficacy (and for European Medicines Inspectorate and U. S. FDA regulated premises this is mandatory). Efficacy is demonstrated through performance testing to show that the disinfectant is capable of reducing the microbial bioburden in either suspension (planktonic state) or from cleanroom surfaces to an acceptable level. The disinfectant efficacy validation should provide documented evidence that the disinfectant demonstrates bactericidal, fungicidal, and/or sporicidal activity necessary to control microbial contamination in the facility. This chapter summarises the test requirements and the different standards that are currently available.

Regulatory agencies expected the users of disinfectants within cleanrooms to evaluate the efficacy of disinfectants. Various standards are available to guide the microbiologist through this process. What is more difficult is the content of some of the standards themselves because they have not been written specifically for the healthcare sector or the pharmaceutical industry (more typically they have evolved from the food, cosmetics or environmental control sectors). It may be necessary for the microbiologist to adapt the standards to suit practical situations (backing this up with a well-thought out rationale). Another point to be considered before embarking on such validation is whether all of the standards are to be replicated or whether experimental work required by some of the standards can be provided by the manufacturer of the disinfectants (1).

Given that most regulators and microbiologists regard the surface test as the most meaningful of the laboratory methods, this paper addresses this test. This paper outlines an approach taking for the assessment of a disinfectant to kill fungi on a surface. Of the different disinfectant efficacy studies, surface studies are generally regarded as the most challenging and representative of actual cleanroom conditions. For this, one organism is used as an example – the fungus *Cladosporium*, which as presented here was an environmental isolate from a pharmaceutical cleanroom. *Cladosporium* is one of the most commonly detected fungi from the as-built environment (2).

Surface tests, however, are not straightforward. The approach presented here is based on European surface test requirements; while other approaches differ slightly, the overall methodologies are similar. Hence the approach here can be used as a case study for others to evaluate against.