

Annex 1 2022 Comparison Factsheet: Vapourised Hydrogen Peroxide (VHP)

The 2022 revision of Annex 1 now mentions vapourised hydrogen peroxide (VHP) as part of fumigation.

Line	Wording in 2022 Annex 1
2315-2317	10.8 Any process (e.g. Vaporized Hydrogen Peroxide or VH202, Ultra Violet) used to decontaminate the external surfaces of sterility samples prior to testing should not negatively impact the sensitivity of the test method.
369-373	i. For isolators, the decontamination process should be automated and should include a sporicidal agent in a suitable form (e.g. gaseous, aerosolized or vaporized form) to ensure thorough microbial decontamination of its interior. Decontamination methods (cleaning and sporicidal disinfection) should render the interior surfaces and critical zone of the isolator free of viable microorganisms.
543-543	4.39 Fumigation or vapour disinfection (e.g. Vapour-phased Hydrogen Peroxide) of cleanrooms and associated surfaces may be useful for reducing microbial contamination in inaccessible places.



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