



Neutralisers in Media

Why Consider Neutralisers?

Cleanroom facilities, manufacturing either sterile or non-sterile products, use a multitude of biocidal and sporicidal disinfectants to maintain a clean environment depending on the graded area, ensuring that they irradiate bacteria, fungi, and spores. Neutralisers in microbiological media are used to prevent the masking of potential viable organisms that might be present in the facility. The consequence of not capturing an accurate representation of the facility can lead to prolonged shut down periods, expensive losses, and potential endangerment of the end user.

USP <797> does provide information on surface sampling that contains additives / compounds to neutralise the effects of disinfectants.

What to use?

Below is a table taken from European Pharmacopoeia section 2.6.12 that presents compounds that are used in disinfectants and the corresponding neutralising agent.

Most common and popular are Lecithin and Polysorbate 80 (Tween®) which are regularly used in combination to neutralise biocides. These are Quaternary Ammonium Compounds (QAC) and biguands. Originally discovered in 1946 by Quisno, Gibby and Foter, they found this was a beneficial recommendation as a neutraliser compared to the mercury-based compounds they were using at the time. The benefits being they are nontoxic and do not cause undesirable turbidity in growth media. Tween 80 has an additional benefit when used with Lecithin as it helps to solubilise and disperse the Lecithin in the growth medium. Their work has stood the test of time, and the concentrations of Lecithin and Tween 80 used today in prepared media are still the same.

Sodium thiosulphate, another common and popular compound, was first found mentioned as a neutraliser from a paper in 1951. It was used for the neutralisation of Iodine. Iodine is a halogen - which made it ideal to neutralise the more commonly used chlorine compounds, found in sporicidal disinfectants. On its own Sodium Thiosulphate can be inhibitory to microbial growth in low concentrations, however with Tween 80 it reduced the inhibitory properties of sodium thiosulphate without disturbing the neutralising effect. Cherwell's Neutraliser number 4 formulation contains Lecithin, Tween, Sodium thiosulphate and L-Histidine; which cover a majority of disinfectants.

70% alcohol is used often during aseptic operations as a disinfectant but does not require specific neutralisers. The reason being the only way to remove the effect of IMS is through dilution. It also leaves no dry residue and if vapour or microdroplets contact the agar surface, the dilution from the agar would eliminate the biocidal activity.

Vaporised hydrogen peroxide (VHP) is becoming increasingly popular as a sporicidal agent for decontaminating isolators, RABS and material

transfers. GMP requires that it be removed completely by aeration prior to aseptic operations. It also has no dry form, no residue, and dissociates rapidly to water and oxygen on contact with organic material, including agar. There is no neutralising agent. It is important that agar is not exposed during the gassing phase of a H₂O₂ decontamination cycle, because if the agar were to absorb sufficient H₂O₂ it would produce toxic radicals or oxidising nutrients, reducing the efficacy of the media. Therefore, the best method is protection over neutralisation and having a product that has been irradiated in a validated impermeable wrap to protect the plates in that process, such as the Redipor® Barrier Pack range.

Your Own Assessment

Facilities are required to rotate disinfectants throughout the year. The media choice will need to neutralise multiple agents and should factor in a risk assessment. The term neutralisers in the Pharma industry can be misleading, with individuals referring to the prospect of counteracting antibiotics with enzymes rather than neutralising disinfectant effects. When discussing this with your supplier ensure clarity in the neutralising factor you require. Make sure that the neutralisers do not have a detrimental effect on the growth potential of the medium, therefore perform method suitability testing and validation.

Technical Data

EP 2.6.12 Microbial examination of non-sterile products: Microbial enumeration tests

Table 2.6.12-2 - Common neutralising agents for interfering substances

Interfering substance	Potential neutralising method
Gluteraldehyde, mercurials	Sodium hydrogensulphite (Sodum bisulphite)
Phenolics, alcohol, aldehydes, sorbate	Dilution
Aldehydes	Glycine
Quaternary ammonium compounds (QAC's), parahydroxybenzoates (parabens),	Lecithin*
QAC's, iodine, parabens	Polysorbate (Tween)*
Mercurials	Thioglycollate*
Mercurials, halogens, aldehydes	Thiosulphate*
EDTA	Mg ²⁺ or Ca ²⁺ ions

Terms & Conditions

Where precise data is required please enquire about samples.

*Available in a range of Redipor® prepared media products, please ask for more information.

We reserve the right to amend specifications without any prior notice. E&OE

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