Summary - Microbiological Testing in Cleaning Validation for APIs and Drug Products

This document describes the rationale and recommended microbiological methodology for consideration during cleaning validation of product contact surfaces for Active Pharmaceutical Ingredients (APIs) and drug products.

Microbiological cleaning validation for product contact surfaces for drug products and the final stage of drug substances is advisable when the surfaces are not sterilized and water is used as a final rinse. When cleaning validation microbiological sampling is required, a final purified water (PW) or water-for-injection (WFI) rinse sample of product contact surfaces following the cleaning procedure is the preferred sample collection method. Alternatively, if a water rinse sample is not practical, then direct sampling (e.g. contact plates or swabbing) of the product contact surfaces may be used.

If surface sampling is needed, sterile swabs saturated with a sterile diluent such as Sterile Water for Injection or Sterile Saline Solution are used. The following sampling guidelines and associated limits are recommended.

For manufacturing equipment for non-sterile drug product and the final stage of drug substance where applicable: Final Purified Water rinse samples – Recommended limits should be based on preliminary or historical studies and action limits should take into consideration the microbiological limit of the rinse water, for example, not to exceed 100 cfu/ml (USP <1231> and EP “Water, Purified”). Drug substances using other than USP Purified Water must comply with site standards for water used as the final rinse.

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