

## **Introduction to vial washing**

21CFR directive part 211.92 states that containers used for parenteral drugs, shall be "clean", "sterile" and "pyrogene free".

The standard glass for parenteral applications is "Type 1 borosilicate", a type of glass that is extremely resistant to chemical attack and which suffers minimal thermal expansion. While the glass itself is of high quality, after the manufacturing process vials are often subject to uncontrolled environments and may become contaminated with particulates and micro-organisms. For this reason it is necessary to decontaminate the vials before usage. Sterilisation and depyrogenation is facilitated by the use of ovens or heat tunnels, after the initial stage of washing. The aim of washing is to reliably remove particulates, chemical contaminants, and bacterial toxins.

### **Contaminant Removal**

The most effective way to remove these contaminants from vials is through "scrubbing" with pure water. Most commonly used is Water For Injection (WFI), which is not only without particulates, but also without microorganisms and pyrogens and is therefore pure enough to clean without leaving contamination behind. This "scrubbing" is accomplished by high pressure water jets alone, as any mechanical action would be particulate-generating.

A good washer design will keep all moving parts, such as gears and chains, motors and drives, as far from the washing area as possible, or eliminate them altogether. A bad washer design will risk re-contaminating the vials before they have even left the machine.

### **WFI Consumption**

WFI consumption is the primary expense of vial washing and it makes good sense to consume this commodity as sparingly as required. This cost involves not only the volume of WFI used, but the energy level of the WFI - high pressure and high temperature WFI (80-90° C) is more effective at washing than low pressure WFI at ambient temperature. However, the higher the pressure and the temperature, the higher the costs. Optimising the WFI consumption for the vial type and size and specifics is vital to avoid unnecessary expense.

## Other Considerations

Some vial washing protocols allow for slightly lower-grade water for the preliminary washes and specify pure WFI only for the final rinses. In these instances a WFI recirculation system can be beneficial, returning the final-rinse water, via filtering and re-heating, for preliminary washing and consequent significant cost savings in the overall use of WFI.

Very few organizations are in the lucky position of only having one vial type to handle. A “one size fits all” approach to vial washing is tremendously wasteful and inefficient but downtime, to change parts and amend cycle programs, is expensive. Washers should therefore be quick and simple to adapt to different vial sizes, with different washing cycles for each type.

Finally, consideration must also be given to vial handling pre- and post- washing. Automatic tray loaders / unloaders, conveyors, and infeed / outfeed systems will help keep human interaction with the vials to a minimum. Human operators are not only expensive, they are a potential source of contamination. Repetitive tasks such as loading and unloading can also risk repetitive strain injuries such as carpal tunnel. Vial washers should therefore be able to run with as few operators as possible.

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- Unique non-penetrating nozzle design means *no nozzle bending, no glass damage and no particulate generation.*
- Dedicated change parts with spray manifolds and orifice sizes optimized for each vial type to reduce WFI consumption. Simple HMI recipe selection completes the changeover between vial type and all machine parameters are automatically adjusted and set. Changeover can be completed in less than fifteen minutes
- Designed to run virtually maintenance free, and fully automated for minimal human intervention
- Single-file vial outfeed, allowing controlled infeed to down-stream equipment
- Compact design: short supply lines, optimized manifolds, smaller foot print.

Simple good design, making the best use of modern materials and methods, ensures PennTech rotary vial washers are the most compact and efficient washers. PennTech also supply a full range of production line equipment including infeed / outfeed, tray-loaders, sterilizing / depyrogenating tunnels, and more.

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