Customer Service Report CS0253

FLNC WASHING PROGRAM

A washing, siliconization and drying method for pharmaceutical rubber closures using Purified Water and Water-for-Injection

Edition 1

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1 Abstract

The FLNC washing program is a method for washing, siliconization and drying of pharmaceutical rubber parts in Datwyler's First Line plant.

Typical for this method is the use of a high-viscosity (30,000 cSt) silicone oil and the use of Purified Water for washing and drying, and the use of Water-for-Injection for the final rinse of the products.

Both the washing and drying process take place in a proprietary pass-through drum-type washing machine.
The process of loading the machine and of unloading it after drying, and transport of the products to the packing station is automated and does not require operator intervention.

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3 Description of FLNC washing program

3.1 Step 1 : Loading

The washing machine is automatically loaded. A container with rubber parts is docked to the washing machine and products are loaded into the washing drum by means of a special loading installation.

3.2 Step 2 : First Washing

The rubber parts are washed with warm Purified Water. A small quantity of an alkyl-glycol polyether is added as a non-ionic detergent.

3.3 Step 3 : First rinse

After drainage of the wash water, the products are rinsed with closed drain: the products are tumbling in cold Purified Water.

3.4 Step 4 : Second Washing

After drainage of the rinsing water, the products are washed a second time with warm Purified Water and a small quantity of an alkyl-glycol polyether as a non-ionic detergent.

3.5 Step 5 : Second rinse

After drainage of the wash water, the products are rinsed by means of a high-pressure water shower. The rinsing water is cold Purified Water. The rinsing water is immediately drained.

3.6 Step 6 : Siliconization

In the washing machine, the rubber parts are covered with cold Purified Water. High viscosity silicone oil (Silbione Oil 70047 V30000 from Bluestar Silicones) is injected into the water. This silicone oil meets the requirements of the European Pharmacopoeia 3.1.8. for "Silicone oil used as a lubricant" and also the requirements of the USP Official Monograph for Dimethicone.

The quantity of oil is calculated based on the required siliconization degree and taking into account the type of product, the product compound and the quantity of rubber parts being processed.

3.7 Step 7 : Final rinse with Water-for-Injection (WFI)

The final rinse consists of a washing of the rubber parts in WFI followed by a shower rinse with WFI. This WFI is prepared by the technique of distillation and is kept circulating in a loop at 80 °C min. Compliance of Water-for-Injection with Datwyler requirements is documented. Datwyler requirements are equivalent with USP and European Pharmacopoeia requirements, whichever is the strictest.

3.8 Step 8 : Drying

Drying occurs by means of HEPA-filtered air. Since the rubber products after the final rinse with WFI are already high in surface temperature, the drying air is not continuously being heated.

3.9 Step 9 : Unloading

The unloading of the washing machine is done by means of a handsfree unloading device into a closed transport container in a cleanroom area

4 Notes

- After drying, stoppers are transferred in a closed container to the next processing step (camera inspection or automated or semi-automated packaging).

- Datwyler Pharma Packaging "Ready-for-Sterilization" (RfS®) closures are manufactured to very high standards of particulate and biological cleanliness. Washing and packaging takes place in a clean room area which complies with the requirements for supporting clean areas of the 2004 FDA "Guideline for Sterile Products produced by aseptic processing" and the Grade C requirements of the 2008 'EU Guidelines to Good Manufacturing Practice - Medicinal Products for Human and Veterinary Use - Annex 1 : Manufacture of Sterile Medicinal Products'. Of these two guidelines, the most stringent of any particular requirement is applied.

- FLNC washing is a validated process.

- As part of the Datwyler Pharma Packaging Quality System cleanroom air, process air and all water types used for washing and rinsing products are subjected to frequent particulate and microbiological controls.

- All batch data pertaining to the FLNC process are fully retrievable.

- Standard siliconization degrees FLNC1 and FLNC2 correspond with the following target ranges :

  ✓ FLNC1 : 10 – 25 µg silicone/cm² rubber ; FLNC1 is a standard siliconization degree for stopper applications.
  ✓ FLNC2 : 15 – 35 µg silicone/cm² rubber ; FLNC2 is a standard siliconization degree for plunger applications.

5 History

Edition (issue date)	Change (chapter + change)	Comment (rationale)
1 (December 13, 2012)	N/A	First edition