Customer Service Report CS0254

FLCO WASHING PROGRAM

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

Edition 2

Written by:

Anita Thijs
Senior Manager Material Development/Surface Treatment
Date: 7 May 2014

Reviewed by:

Renaud Janssen
Senior Manager Global Scientific Affairs
Date: 140573

Approved by:

Bram Jongen
Head of Material Development CC & IS
Date: May 15, 2014

Approved by:

Yvo Koekelkoren
Manager Global Quality and Regulatory Affairs
Date: 16 May, 2014

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1 Abstract

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

Typical for this method is the use of Purified Water for washing and rinsing, 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 FLCO 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 : Washing

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

3.3 Step 3 : 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.

3.4 Step 4 : Final rinse with Water-for-Injection (WFI)

The final rinse consists of 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.

3.5 Step 5 : 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.

3.6 Step 6: 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

- Coated closures from Datwyler are not subjected to a siliconization process.
- 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.
- FLCO 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 FLCO process are fully retrievable.
- At start-up of FLCO, part of the coated product assortment was washed with warm Purified water and finally rinsed with WFI by washing of the rubber parts in WFI followed by a shower rinse with WFI. Another part of the coated product assortment was washed with cold Purified Water and finally rinsed with WFI by a shower rinse with WFI.
  At present all coated products have been aligned on washing with cold Purified Water and final WFI rinsing by a shower rinse with WFI.
  This alignment reduces heat exposure of coated products and the residual risk on cosmetically defective products, while the validation demonstrates no negative impact neither on the FLCO endotoxin reduction capability nor on the FLCO finished product properties.

5 History

Edition (issue date)	Change (chapter + change)	Comment (rationale)
1 (December 13, 2012)	N/A	First edition
2 (May 07, 2014)	Par.3.2.: cold (i.o. warm) Purified Water Par.3.4.: only shower rinse with WFI	See last note under par.4. See last note under par.4.