Customer Service Report CS0015

SAF WASHING PROGRAM

A washing, siliconization and drying method

for pharmaceutical rubber closures

Edition 4

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1 Abstract

The SAF washing program is a method for washing, siliconization and drying of pharmaceutical rubber parts.

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

The washing process takes place in a proprietary drum-type washing machine.

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3 Description of SAF washing program

3.1 Step 1 : Washing

The rubber parts are first washed with cold, softened water that is filtered through a 1-µm filter. A small quantity of an alkyl-glycol polyether is added as a non-ionic detergent.

3.2 Step 2 : First rinse

After drainage of the wash water, the products are rinsed by means of a high-pressure water shower. The rinsing water is of the same quality as the one used for washing. The rinsing water is immediately drained.

3.3 Step 3 : Siliconization

In the washing machine, the rubber parts are covered with water of the same quality as in steps 1 and 2. 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.

3.4 Step 4 : Final rinse

The products are shower-rinsed with Purified Water.

3.5 Step 5 : Drying

Drying occurs by means of HEPA-filtered air.

4 Notes

- After drying, stoppers are packed in bags under unidirectional flow conditions.

- Washing and packaging for components for parenteral use 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.

  (Washing and packaging for components for diagnostic or medical device applications may not take place in an area with aforementioned qualification.)

- 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 SAF process are fully retrievable.

- Standard siliconization degrees SAF1 and SAF2 correspond with the following target ranges :

  - ✓ SAF1 : 10 – 25 µg silicone/cm² rubber ; SAF1 is a standard siliconization degree for stopper applications.
  - ✓ SAF2 : 15 – 35 µg silicone/cm² rubber ; SAF2 is a standard siliconization degree for plunger applications.

Instead of Purified Water, Water-for-Injection can be used for the final rinse. In that case the name of the washing process is ISAF. The ISAF washing process contains the use of Purified Water in preceding rinsing steps, followed by a final rinse with Water-for-Injection.
(A description of the ISAF process is available upon request).

5 History

Edition (issue date)	Change (chapter + change)	Comment (rationale)
1 (March 16, 2006)	N/A	First edition
2 (July 1, 2008)	New lay out	Updated lay-out
3 (November 6, 2012)	Datwyler logo Name change from Rhodia towards Bluestar Silicones	New company logo Supplier name change
4 (November 7, 2012)	Par.3.3 (reference to USP) Par.4 (reference to EU guidelines)	Updated references