

# Customer Service Report CS0255

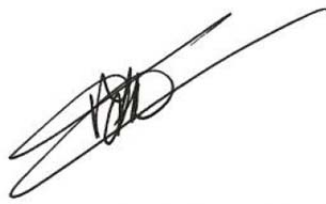
## ISDC WASHING PROGRAM

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

Edition 1


**Written by:**

Anita Thijs  
Senior Product Support Manager  
Date: 13 December 2012




**Reviewed by:**

Renaud Janssen  
Global Director Scientific Affairs  
Date: 12/12/19



**Approved by:**

Bram Jongen  
Global Product Support Manager  
Date: Dec 19, 2012



**Approved by:**

Yvo Koekelkoren  
Global Quality and Regulatory Affairs Manager  
Date: Dec 14, 2012



**Distribution List:**

VP R&D and Technology, Global Product Support Mgr, Tooling Mgr, Materials Development Mgr, Product Development Mgr, Global Dir. of Scientific Affairs, Alu/Plastic R&D Mgr, R&D and Technology Project Mgrs

Report type: General

## **1 Abstract**

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

Typical for this method is the use of a low-viscosity (350 cSt) silicone oil and the use of Purified Water in rinsing steps preceding a final rinse of the products with Water-for-Injection.

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.

## 2 Table of Contents

1	Abstract .....	2
2	Table of Contents .....	3
3	Description of ISDC washing program .....	4
3.1	Step 1 : Loading .....	4
3.2	Step 2 : Washing .....	4
3.3	Step 3 : First rinse .....	4
3.4	Step 4 : Second rinse .....	4
3.5	Step 5 : Rinse with Water-for-Injection .....	4
3.6	Step 6 : Siliconization .....	4
3.7	Step 7 : Drying .....	4
3.8	Step 8 : Unloading .....	4
4	Notes .....	5
5	History .....	6

### **3 Description of ISDC 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 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.

#### **3.3 Step 3 : First 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 : Second rinse**

The second rinse is a rinse with closed drain: the products are tumbling in cold Purified Water.

#### **3.5 Step 5 : Rinse with Water-for-Injection**

The rinse with Water-for-Injection 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.

#### **3.6 Step 6 : Siliconization**

In the washing machine, the rubber parts are covered with Water-for-Injection. Low viscosity (350cSt) silicone oil (DC360 Medical Fluid from Dow Corning) is injected into the water. This silicone oil meets the requirements of the USP Official Monograph for Dimethicone and also of the European Pharmacopoeia 3.1.8. for "Silicone oil used as a lubricant".

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 : Drying**

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

#### **3.8 Step 8 : 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

- 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.
- ISDC 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 ISDC process are fully retrievable.

## 5 History

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