



# BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Use of WFI System Points of Use [REDACTED]  
 SOP Number: 19401  
 Revision: 06

## TABLE OF CONTENTS

1. PURPOSE ..... 1  
 2. SCOPE ..... 1  
 3. RESPONSIBILITIES ..... 1  
 4. MATERIALS AND REAGENTS ..... 1  
 5. EQUIPMENT ..... 2  
 6. PROCEDURE ..... 2  
 7. REFERENCES AND RELATED DOCUMENTS ..... 4

### 1. PURPOSE

This SOP describes the proper procedure for use of the WFI points of use (POU) in the A2 manufacturing areas [REDACTED]. Strict adherence to these procedures will maximize WFI quality and minimize the risk of cross contamination.

### 2. SCOPE

This SOP applies to the WFI use points in the [REDACTED] manufacturing areas [REDACTED].

### 3. RESPONSIBILITIES

3.1 Director / Technical Operations, Late Processing Sciences

- Defines procedure

3.2 Personnel / Biopharmaceutical Development Program (BDP)

- Performs procedure

3.3 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight

### 4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
	1" or 1½" sanitary gaskets, end caps, and clamps	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
	Cable ties	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO

## BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

**SOP Title:** Use of WFI System Points [REDACTED]  
**SOP Number:** 19401  
**Revision:** 06

Part Number	Description	BDP Approved Substitution Permitted?
	Gloves (nitrile, neoprene, or latex).	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
	Medical-grade Silicone tubing	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
	Smooth bore flex lines dedicated with tags for WFI use	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO

### 5. EQUIPMENT

- WFI System [REDACTED].
- Diaphragm valve, 1½" sanitary connection

### 6. PROCEDURE

- 6.1 The WFI System consists of two loops that originate in the Central Utilities Plant (CUP), run to use points in [REDACTED], and returned to the CUP. The system is under pressure and constantly flowing to deliver WFI and prevent microbiological contamination. Sanitary end caps are placed on each point of use when not in use to prevent accidental discharge of WFI onto the floor.
- 6.2 The system must be released for use by BQA Engineering.
- 6.3 The temperature of WFI at the use points varies from ambient to approximately 85°C depending on location and time of day. Operators must exercise caution to avoid being burned when drawing hot WFI (HWFI).
- 6.4 Usage of any WFI Point-Of-Use (POU) should be done while wearing gloves (nitrile, latex, neoprene) to reduce the risk of contamination to the POU. Also, any sanitary gaskets used for connecting to a POU should be new or dedicated to WFI system use and free of any potential contaminants. If at any time they fall on the floor or show signs of deterioration, a new or clean gasket should be used.
- 6.5 Verify the pneumatic valve is closed (LED on the valve body is blue). Attach a non-product contact (Stored appropriately to allow free draining and covered open ends) secondary diaphragm valve to the desired POU and then attach an appropriate length of new, unused medical-grade silicone tubing or a dedicated WFI flex line to the diaphragm valve, secure with a cable tie or sanitary gasket, and clamp as appropriate. When using silicone tubing, record the date the tubing was attached on the outside of the tubing.

**SOP Title:** Use of WFI System Points of Use [REDACTED]  
**SOP Number:** 19401  
**Revision:** 06

---

**NOTE:** A secondary diaphragm valve is required to regulate the flow of water from the WFI POU. Not using a secondary valve could reduce the pressure in the loop too quickly and cause the loop to shut down on a low-pressure fault. This diaphragm valve must be clean and stored appropriately (open, vertical to allow free draining, ends covered) when not in use. Also see section 5.11 for secondary valve maintenance.

**NOTE:** Silicone tubing may be used for (5 days) maximum before replacement. The dating on the tubing is to ensure that tubing is not inadvertently used after 5 days. Dedicated WFI flex-lines are not to be marked with dates and are intended for repeated use.

- 6.6 For all POU's not connected to dedicated equipment (vial washer, parts washer, CIP skid, etc.), the controls for the POU are located on the electrical panel on the same wall as the POU. There are two lights, green indicates the POU is available for use and red indicates the POU is not available (due to high temperature in the loop).
- 6.6.1 Additional steps If the green light is illuminated, pressing the green button on the panel associated with the POU will open the pneumatic valve (LED light on the valve body will turn green) and allow the flow of water.
- 6.6.2 If the red light is illuminated, the loop is currently too hot for use. This is either due to an ongoing sanitization or the night setback. During normal working hours, if the red light is illuminated it is likely due to a sanitization and the Facilities Manager should be consulted prior to attempting to override the system. If outside of normal working hours, the system is in night setback mode. To override this, press the black button associated with the WFI POU. In a few minutes the loop will cool down for use and the green light will illuminate. At this point WFI may be used as in 6.6.1. This override lasts for one hour before the system returns to setback mode.
- 6.7 Flush the POU for 15-30 seconds.
- 6.8 Draw WFI as needed. Be careful not to allow the open end of the flex line/tubing to become contaminated by contact with other surfaces, liquids, etc. WFI drawn and not sterile-filtered into a container for future use is good for one day per **SOP 19001 – Guidelines for Use of Water in Production Processes Used in the Biopharmaceutical Development Program**, after which it must be discarded and fresh WFI drawn.

## BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

**SOP Title:** Use of WFI System Points [REDACTED]

**SOP Number:** 19401

**Revision:** 06

---

6.9 If no more WFI is to be drawn for an hour or more, press the red button associated with the POU to close the pneumatic valve (LED will change to blue). Then disconnect the secondary valve and flex line/tubing, drain any water from the flex line/tubing and hang so that open ends are protected from contamination. Replace the sanitary end cap. Follow Steps 6.4 – 6.8 if the hose is needed later in the day to draw water.

**NOTE:** Dedicated WFI flex-lines are not discarded but have open ends covered at the end of the day after draining.

6.10 If elevated levels of contaminants are detected during routine water monitoring, typical responses to address the issue may include, but are not limited to: cleaning or autoclaving the secondary valve; cleaning, autoclaving, or replacing the sanitary gaskets or endcaps; chemical disinfection of the POU, cleaning of the flex line in the parts washer, and heat sanitization of the entire loop.

6.11 Secondary Valve Maintenance

6.11.1 Secondary valves for drawing water and collecting EM samples are routinely autoclaved at a recommended weekly interval. This is particularly important for high usage points such as those used for room cleaning.

6.11.2 Each week, open the autoclave pouch containing a fresh autoclaved valve.

6.11.3 At the end of the week, or if the valve integrity is believed compromised, return the valve to the designated area [REDACTED] for autoclaving.

6.11.4 Valves are autoclaved using **SOP 19500 Operation and Maintenance of the BMT Steam Sterilizers** and the process is captured in the autoclave logbook denoting the valve unique identifier.

### 7. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
19001	Guidelines for Use of Water in Production Processes Used in the Biopharmaceutical Development Program
19500	Operation and Maintenance of the BMT Steam Sterilizers