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<b>Approval Block</b>		
<b>Prepared by:</b>	<b>Signature</b>	<b>Date</b>
<b>Evan Parnell</b>		<b>18 JUN 2014</b>
<b>Reviewed by:</b>	<b>Signature</b>	<b>Date</b>
<b>Brian Flynn</b>		<b>18 JUN 2014</b>
<b>Approved by:</b>	<b>Signature</b>	<b>Date</b>
<b>Kristal Jewell</b>		<b>18 JUN 2014</b>

**Historical Reference Section:**

<i>Section Name</i>	<i>Section Number (i.e., 5.2.1)</i>	<i>Revision Affected</i>	<i>Explanation of Change</i>
<b>References</b>	<b>3.0</b>	<b>A</b>	<b>Added references</b>
<b>Quality Control</b>	<b>10.0</b>	<b>A</b>	<b>Added section</b>
<b>Approval Block</b>	<b>N/A</b>	<b>A</b>	<b>Added Approval Block</b>

**1. Purpose**

This document provides instruction for air and contact viable sample incubation and analysis for USP <1116> compliant Water For Injection (WFI) systems.

**2. Scope**

This procedure shall be followed by personnel performing viable sample analysis. Additional testing and or deviation from this SOP shall be agreed upon prior to the start of testing.



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### 3. References

1. USP<1116> Pharmaceutical Compounding – Sterile Preparations
2. ATS SOP 720.00 Rev (A) Standard Operating Procedure for the Operation of the NuAire Model NU-425-300 Labgard Class II, Type A2 Laminar Flow Biological Safety Cabinet
3. ATS SOP 700.00 Rev (A) Standard Operating Procedure for the Operation of the Model 3110 Forma Series II Water Jacket CO<sub>2</sub> Incubator
4. ATS SOP 705.00 Rev (A) Standard Operating Procedure for the Operation of the Dickson KT621 Remote Sensing Temperature Recorder
5. ATS SOP 715.00 Rev (A) Standard Operating Procedure for Scientific Revco Laboratory Refrigerator
6. ATS SOP 725.00 Rev (A) Standard Operating Procedure for the Operation of the UVP Colony Doc-It Imaging Station
7. ATS SOP 735.00 Rev (A) Standard Operating Procedure: Milliflex Plus Pump
8. ATS SOP for the Autoclave being used (SOPs 730 and 731)
9. ATS SOP 725.00 Rev (A) Standard Operating Procedure for the Operation of the UVP Colony Doc-It Imaging Station
10. ATS SOP 735.00 Rev (A) Standard Operating Procedure for the Milliflex Plus Pump
11. ATS SOP 820.00 Rev (A) Standard Operating Procedure: Viable Sample Workflow
12. ATS SOP 880.00 Rev (A) Standard Operating Procedure: Gowning Procedures
13. ATS SOP 900.00 Rev (A) Logbook Entries
14. ATS SOP 905.00 Rev (A) Standard Operating Procedure: Organization of plates in the incubator
15. ATS SOP 920.00 Rev (A) Standard Operating Procedure: Fungi Slide Preparation
16. ATS SOP 925.00 Rev (A) Standard Operating Procedure: Identification of Microorganisms
17. Quality Manual Section 4.11
18. MSDS for all relevant chemicals

### 4. Equipment and Materials

1. UVP Colony Doc-It Imaging Station or equivalent.
2. Milliflex PLUS Pump
3. Refrigerator
4. Incubators



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## 5. Safety

1. Wear proper attire as specified by SOP 880.
2. Refer to manufacturer's safety precautions and Material Safety Data Sheet (MSDS) for appropriate protective equipment and safe handling procedures when using chemicals.

## 6. Responsibility

1. It is the responsibility of the President to maintain this document and oversee these activities.
2. It is the responsibility of the individual(s) performing this task to follow this procedure.

## 7. Preliminary Operations

1. Collect all materials and equipment necessary to conduct the project.
2. Ensure all equipment is within calibration prior to the start of use.

## 8. Incubation and Analysis Procedures

1. If samples are noted during the daily refrigerator check, the Microbiologist or qualified lab personnel, gowned as per SOP 880, will remove the samples from the laboratory media refrigerator while still in the sealed storage bag. Qualified personnel are trained in the following SOPs: 700, 705, 715, 720, 800, 820, 850, 855, 856, 860, 880, 900 and 905. The refrigerator door will remain open no longer than three minutes.
2. Samples will be processed using the Milliflex Plus Pump as per SOP 735.
3. The samples will then be organized into the 30-35°C Incubator per SOP 905. Samples will be stacked together and not placed into racks. The incubator door will remain open no longer than three minutes during any single evolution. They will remain there for 7 or more days.



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4. Upon completion of this incubation period, samples will be removed and placed in the BSC to be analyzed for growth.
5. Document all movement and procedures on laboratory chain of custody forms and in appropriate logbooks.

Sample type	USP <1116> Class 100	EU Grade A	USP <1116> Class 1,000	EU Grade B	USP <1116> Class 10,000	EU Grade C	USP <1116> Class 100,000	EU Grade D
Air sample/m <sup>3</sup> air	<3 CFU	NS* <1 CFU**	NS	NS* ≤10 CFU**	<20 CFU	NS* ≤100 CFU**	<100	NS* ≤200 CFU**
Settling plates/ 4-hr exposure	NS	NS* <1 CFU**	NS	NS* ≤5 CFU**	NS	NS* ≤50 CFU**	NS	NS* ≤100 CFU**
Surface viables (except floors)/plate	≤3 CFU	NS* <1 CFU**	NS	NS* ≤5 CFU**	≤5 CFU	≤25 CFU	NS	NS* 50 CFU**
Surface viables (floors)/plate	≤3 CFU	NS* <1 CFU**	NS	NS* ≤5 CFU**	≤10 CFU	NS	NS	NS
Gloves/plate	≤3 CFU	NS* <1 CFU**	NS	NS* ≤5 CFU**	≤10 CFU	NS	NS	NS
Personal gown/plate	≤5 CFU	NS	NS	NS	≤20 CFU	NS	NS	NS

\*At rest

\*\*Dynamic

NS: Not stated

5. Transfer in an aseptic manner to the second incubator at 20-25°C for 7 or more days.
6. Remove plates and place in the BSC for analysis and identification. All plates, regardless of growth, will be documented pictorially following SOP 725 and any growth will be analyzed following SOPs 920 and 925.
7. Complete laboratory chain of custody forms with colony counts and fill out all appropriate logbooks.
8. Samples which have completed analysis will be stored and refrigerated for two weeks after the issuance of the final report. They will then be disposed of in accordance with the SOP for the autoclave being used.



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9. Complete all appropriate paperwork. All completed paperwork will be reviewed by the Quality Manager.
10. Document all movement and procedures on laboratory chain of custody forms and in appropriate logbooks.

### **9. Equipment Power Failure**

1. In the event of a power failure that results in the equipment (i.e. the laboratory media refrigerator or any incubator) drifting outside of operational parameters, an internal investigation will be performed, as per SOP 930.