Cleaning and Sanitization of the Flexicon FMB200 Monoblock

SOP 15124 **Rev. 06**

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1.0 Purpose

This procedure describes the methods used for cleaning and sanitization of the Flexicon FMB200 Monoblock.

2.0 Scope

The scope of this procedure is to define the requirements for cleaning and sanitization of the Flexicon FMB200 (BDP 73660) located in Room A2518 of the ATRF. The FMB200 is intended for liquid filling of a variety of biological products and therefore must be cleaned and sanitized prior to and post use. All components of the FMB200 that have direct product contact (product container, tubing, connectors, and fill nozzle) are single use, disposable items that are discarded after each fill process. Non-product contact surfaces of the FMB200 are cleaned to minimize the possibility of cross-contamination from one product to the next. Cleaning and sanitization will be performed on the FMB200 following filling operation and again just prior to being set-up for reuse. The FMB200 is **not** intended for use in the filling of non-sterile products. The cleaning and sanitization procedures described in this SOP are intended to remove any residues of product that may exist following a filling operation and to sanitize surfaces that may have been contaminated by exposure to the surrounding environment. Surface samples will be taken as specified in this SOP in order to verify the effectiveness of the cleaning and sanitization procedures.

3.0 Authority and Responsibility

3.1 The Director, Technical Operations, Biopharmaceutical Development Program (BDP) has the authority to define this procedure.

3.2 The Supervisor is responsible for training personnel in this procedure and for documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.3 Manufacturing personnel are responsible for performing the work as specified in this procedure.

3.4 BQA is responsible for quality oversight of this procedure.

4.0 Materials

4.1 Sterile 70% IPA, BDP Part #30129 or equivalent.

4.2 Steri-Perox 6%, BDP Part #10665

4.3 Cleanroom wipes, BDP Part #20315 or equivalent.

4.4 RODAC plates, BDP Part #10005 or equivalent.

5.0 Procedure

5.1 Pre-Use Cleaning

5.1.1 Cleaning procedure must be performed within 48 hours of intended use. Record cleaning performed in the equipment log.

5.1.2 Spray all surfaces of the FMB200 with sterile 70% IPA or Steri-Perox 6% and wipe off with a lint free wipe.

5.2 Post-Use Cleaning

5.2.1 Cleaning and disassembly of the filling line must be performed by the next working day**.** Following procedure described in this SOP. Record **the** cleaning in the equipment logbook. Refer to ***SOP 15127 - Operation of the Flexicon FMB200*** for detailed instructions and drawings of how to disassemble the Flexicon FMB200.

5.2.1.1 On completion of the filling operation, remove the product reservoir and the tubing set with filling needle from the Flexicon. Clean any spills that may have occurred using sterile cleanroom wipes and Sterile 70% IPA or Steri-Perox 6%.

5.2.1.2 Follow the guidelines for surface sampling as specified in ***SOP 22315 - Environmental Monitoring in BDP GMP Areas at the ATRF,*** take a RODAC touch plate of the surface of the FMB200 below the filling stand, spray the sampling area with sterile 70% IPA or Steri-Perox 6% and wipe clean. Submit plate to PA/QC along with a negative control for incubation.

5.2.1.2.1 The following limits for Colony Forming Units apply.

5.2.1.2.1.1 Alert limit = 1 CFU

5.2.1.2.1.2 Action limit = 2 CFU

5.2.2 The following parts are wiped off with a sterile lint free cloth wetted with sterile 70% IPA or Steri-Perox 6%. The parts may be left on the filler or removed from the filler and stored in the designated cart in the Class 5 area of Room A2518.

5.2.2.1 Vial guide

5.2.2.2 Star wheel and Ejector

5.2.2.3 Height setting rods for vibratory bowls

5.2.2.4 Height setting rods

5.2.2.5 Scroll and scroll support

5.2.3 The following parts are wiped off with a sterile lint free cloth wetted with sterile 70% IPA or Steri-Perox 6%. They may be left on the filler or removed and stored in the Class 5 area of Room A2518.

5.2.3.1 Vibratory bowls for crimps and stoppers

5.2.3.2 Crimp chute

5.2.3.3 Stopper chute

5.2.3.4 Crimp placer

5.2.3.5 **Stopper placer base plate**

NOTE: Before next production use, transport parts to A2506 and ensure that parts are rinsed thoroughly with hot WFI and autoclaved.

5.2.4 Spray all surfaces of the FMB200 with sterile 70% IPA or Steri-Perox 6% and wipe off with a lint free wipe.

6.0 References and Related Documents

6.1 **SOP 15127** *Operation of Flexicon FMB200*

6.2 **SOP 22315** *Environmental Monitoring in BDP GMP Areas at the ATRF*