SOP Title:	**Cleaning and Sanitization of the Flexicon FMB210 Monoblock**
SOP Number:	**15124**
Revision:	**07**

TABLE OF CONTENTS

1. PURPOSE

This procedure describes the methods used for cleaning and sanitization of the Flexicon FMB210 Monoblock.

2. SCOPE

The scope of this procedure is to define the requirements for cleaning and sanitization of the Flexicon FMB210 (BDP 91670) located in Room [redacted] of the ATRF. The FMB210 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 FMB210 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 FMB210 are cleaned to minimize the possibility of cross-contamination from one product to the next. Cleaning and sanitization will be performed on the FMB210 following filling operation and again just prior to being set-up for reuse. The FMB210 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. RESPONSIBILITIES

3.1 Director / Technical Operations, Biopharmaceutical Development Program (BDP)

- Defines procedure

3.2 Supervisor / Manufacturing (BDP)

- Trains personnel

3.3 Manufacturing personnel

- Performs procedure

3.4 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight

4. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
10005	RODAC plates	☒ YES ☐ NO
10665	Steri-Perox 6%	☐ YES ☒ NO
20315	Cleanroom wipes	☒ YES ☐ NO
30129	Sterile 70% IPA	☒ YES ☐ NO

5. 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 FMB210 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 15155 Operation of the WM Flexicon FMB210** for detailed instructions and drawings of how to disassemble the Flexicon FMB210.

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 FMB210 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.

5.2.2 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 [redacted].

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 [redacted].

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 [redacted] and ensure that parts are rinsed thoroughly with hot WFI and autoclaved.

5.2.4 Spray all surfaces of the FMB210 with sterile 70% IPA or Steri-Perox 6% and wipe off with a lint free wipe.

6. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
15155	Operation of WM Flexicon FMB210
22315	Environmental Monitoring in BDP GMP Areas at the ATRF