



Standard Operating Procedure

Title: Filtration Using Disposable Bottle Filter Units

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Table of Contents

- 1.0 Purpose
- 2.0 Scope
- 3.0 Authority and Responsibility
- 4.0 Materials
- 5.0 Procedures
- 6.0 References and Related Documents
- 7.0 Attachments

1.0 Purpose

This procedure describes how to use a disposable bottle filter unit.

2.0 Scope

This procedure applies to BOP personnel using bottle filters.

3.0 Authority and Responsibility

- 3.1 The Director, **Technical Operations**, Biopharmaceutical Development Program (BOP) has the authority to define this procedure.
- 3.2 Production personnel are responsible for the implementation of this procedure.
- 3.3 Biopharmaceutical Quality Assurance (BOA) is responsible for quality oversight of this procedure.

4.0 Materials

- 4.1 Bottle Filter Unit (BOP PN 20199 or BOP approved equivalent).
- 4.2 Sterile Prefilters (BOP PN 20461 or BOP approved equivalent).
- 4.3 Vacuum Line Tubing (BOP PN 20634 or BOP approved equivalent).
- 4.4 Sterile Forceps (BOP PN 20855 or BOP approved equivalent).

- 4.5 70% Isopropanol Alcohol (BDP PN 30129 or BDP approved equivalent).

5.0 Procedures

Safety Information

Wear protective eyewear when working with any vacuum system.

- 5.1 Prepare the material for filtration according to the protocol used.
- 5.2 Decontaminate the Biological Safety Cabinet (see ***SOP 19102 - Routine Use and Disinfection of BSC, Incubators, Shakers, Centrifuges, and Bioreactors***). All materials used must be decontaminated with 70% Isopropanol Alcohol before being placed in the Biological Safety Cabinet.
- 5.3 After decontaminating the outside of the bag containing the filtration apparatus open the bag and place the filter unit in the Biological Safety Cabinet. The apparatus should consist of a bottle top filter screwed onto a collection bottle with a vacuum port on the side of the joining gasket, a sterile-wrapped spare cap (see Attachment I), and a hose barb fitting.
- 5.4 Filter Assembly
- 5.4.1 Hand tighten the bottle top filter onto the bottle neck. Do not overtighten.
- 5.4.2 Attach one end of a length of vacuum line tubing to the vacuum line valve inside the Biological Safety Cabinet. Attach the other end of the tubing to the vacuum port on the joining gasket of the bottle unit using the barbed fitting.
- 5.4.3 Remove the lid from the filter unit. Using a pipette, dampen the filter with a small amount (about 5-10 mL) of the material to be filtered.
- NOTE:** To increase flow through the filter, a pre-sterilized prefilter can be used on top of the filter. When using a prefilter, place it inside the filter unit on top of the filter with sterile forceps and dampen it with a small amount of the material to be filtered.
- 5.4.4 Slowly turn on the vacuum line.
- 5.5 Being careful to avoid spills, pour about 150 mL of the sample into the filter unit and observe the flow through the filter to the collection bottle. If the flow is satisfactory, continue filtering the rest of the sample.
- 5.6 If more than one filter unit is required to filter all of the material, assemble a new filtration apparatus and proceed as described above using the new filtration apparatus. Unwrap the spare cap, and unscrew the filter unit from the first collection bottle. Working aseptically, replace the filter unit on top of the receiver bottle with the cap and hand tighten. Label and store the material according to the protocol used.
- 5.7 If at any time the flow ceases or becomes slow, assemble a new filtration apparatus and proceed as described above in sections 3.4 – 3.5 using the new filtration apparatus.

6.0 References and Related Documentation

- 6.1 Document performance of this procedure in the appropriate batch production record or laboratory notebook.

7.0 Attachments

- 7.1 **Attachment 1** Filtration Using Disposable Bottle Filter Units

Attachment 1 Filtration Using Disposable Bottle Filter Units

