



BIOPHARMACEUTICAL DEVELOPMENT PROGRAM

SOP Title: Filtration Using Disposable Bottle Filter Units
SOP Number: 13211
Revision: 04

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1. PURPOSE

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

2. SCOPE

This procedure applies to BDP personnel using bottle filters.

3. RESPONSIBILITIES

3.1 The Director, Technical Operations, Biopharmaceutical Development Program (BDP).

- Defines the procedure.

3.2 Production personnel.

- Implements the procedure.

3.3 Biopharmaceutical Quality Assurance (BQA).

- Provides quality oversight.

4. SAFETY

Wear protective eyewear when working with any vacuum system.

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5. MATERIALS AND REAGENTS

Part Number	Description	BDP Approved Substitution Permitted?
20199	Bottle Filter Unit	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
20461	Sterile Prefilters	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
20634	Vacuum Line Tubing	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
20855	Sterile Forceps	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
30129	70% Isopropanol Alcohol	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

6. PROCEDURE

- 6.1 Prepare the material for filtration according to the protocol used.
- 6.2 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.
- 6.3 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.
- 6.4 Filter Assembly
 - 6.4.1 Hand tighten the bottle top filter onto the bottle neck. Do not overtighten.
 - 6.4.2 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.
 - 6.4.3 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.

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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.

6.4.4 Slowly turn on the vacuum line.

6.5 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.

6.6 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.

6.7 If at any time the flow ceases or becomes slow, assemble a new filtration apparatus and proceed as described above in sections 6.4 – 6.5 using the new filtration apparatus.

7. DOCUMENTATION AND RECORDS

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

8. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
19102	Routine Use and Disinfection of BSC, Incubators, Shakers, Centrifuges, and Bioreactors

9. ATTACHMENTS

Attachment 1 Filtration Using Disposable Bottle Filter Units

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