

Master Production Record (MPR)

Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	1 of 12



Biopharmaceutical Development Program (BDP)
 National Cancer Institute at Frederick
 SAIC-Frederick, Inc., P.O. Box B
 Frederick, MD 21702-1201

MPR Approval

Author Approval: _____ Date: _____

Purification Manager Approval: _____ Date: _____

Project Scientist Approval: _____ Date: _____

Biopharmaceutical Quality Assurance (BQA) Approval: _____ Date: _____

Comparison of Copy to Master Document

This document is an accurate reproduction of MPR-P- Section , as found in the Master Document File.

Checked by: _____ Date: _____

Post-Manufacturing Document Review

This completed MPR has been reviewed and has been found to be complete, correct, and in conformance with relevant standard operating procedures (SOPs) and other documents.

Reviewed by: _____ Date: _____


BQA Approval: _____ Date: _____



Master Production Record (MPR)

Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>	2 of 12

Document the personnel involved in the production process in the table below.

Operator Name (Print)	Signature	Initials

Master Production Record (MPR)

Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	[REDACTED]	<input type="text"/>	<input type="text"/>	4 of 12

1.1 Final Filtration

1.1.1 In a class 100 area, filter the product solution from section through a 0.22µm filter(s) using an autoclaved Filtration Tubing Assembly (APA-0016) into a tared L labeled "" with the Lot #, date and initials. Weigh the of "" and calculate the net weight. Include the balance printouts as Attachment .

Final Filtration Step Start Date/Time: _____	
Room # for Filtration: _____	
(If Necessary) BSC BDP #: _____	Balance BDP #: _____
Pump BDP #: _____	Pump Setting: _____ %
Filtration Tubing APA #: _____	Autoclave Cycle/Date: _____
Bag/Bottle Part #: _____	Lot #: _____ Exp. Date: _____
Type of filter used: _____	Part #: _____ Lot#/Serial #: _____ Exp date: _____ # Used: _____
Filtration Start Time: _____	Filtration End Time: _____ Duration: _____
Net Wt. Filtered <input type="text"/> = Gross Wt: _____ g – Tare Wt. <input type="text"/> : _____ g = _____ g	

Performed By: _____	Date: _____	Verified By: _____	Date: _____
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Master Production Record (MPR)

Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	[REDACTED]	<input type="text"/>	<input type="text"/>	5 of 12

1.1.1.1 Integrity test the 0.22 µm filter used for final filtration as per SOP . Verify that the filter being tested is the filter that was used for filtration in Section . The bubble point of the filter must exceed 50 psig to meet specifications. If the results of the integrity test do not meet specifications, repeat Section with a new filter. Record details of additional filtering and integrity tests in the comments section.

Serial # of Filter: _____
Date/Time of Testing: _____
Bubble Point of Filter: _____ psig
Results of Integrity Test Meet Specifications (Y/N): _____

Performed By: _____	Date: _____	Verified By: _____	Date: _____
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1.2 Distribution of Product

1.2.1 If the "" will be stored in one container as a bulk, complete the remaining pages of this section. If the "" will be distributed for storage, proceed to the "Bulk, Aliquoting, Sampling and Storage" section of this BPR and N/A the remaining pages of this BPR.

Product will be distributed (Y/N): _____
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Performed By: _____	Date: _____	Verified By: _____	Date: _____
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Master Production Record (MPR)

Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	██████████	<input type="text"/>	<input type="text"/>	6 of 12

1.3 Sampling of Product

1.3.1 Using a pipette, aseptically remove samples of the "██████" as described in the table below as per section ██████. Label the samples as per Section ██████ of this BPR.

Pipette BDP Part #: _____		BDP Lot #: _____		Expiration Date: _____	
Number of Samples	Sample Vol., mL	Sample Volume Removed, mL	Purpose		
≥ ██████	██████		Process Retains		
██████	██████		Assays in Section ██████		
██████	██████		Assays in Section ██████		

Performed By: _____	Date: _____	Verified By: _____	Date: _____
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1.3.2 If the QC samples and/or retain samples, from section ██████, are temporarily stored until submitted to QC/MMIC, record the requested information in the table below.

Refrigerator/Freezer BDP #: _____	Temperature: _____ °C
Retain Samples Stored (Y/N): _____	Date of Storage, if applicable: _____
QC Samples Stored (Y/N): _____	Date of Storage, if applicable: _____

Performed By: _____	Date: _____	Verified By: _____	Date: _____
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Master Production Record (MPR)

Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	<div style="background-color: black; width: 100px; height: 15px;"></div>	<input type="text"/>	<input type="text"/>	7 of 12

1.3.3 Submit the samples to QC for testing and enter the QC test request numbers in the table below. Store the product samples at °C. Include the QC Request Verification as described in the table below.

Test	SOP Number/Vendor	Sample Volume, mL	QC Request Number	Test Specification (If Required)	Attachment Number
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>
<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>		<div style="background-color: red; width: 30px; height: 15px;"></div>	<div style="background-color: red; width: 30px; height: 15px;"></div>

Performed By:	Date:
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Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	[REDACTED]	<input type="text"/>	<input type="text"/>	8 of 12

1.3.4 Submit the retain samples to MMIC for storage at °C and include a copy of the sample input form as Attachment .

Refrigerator/Freezer ID number: _____	Cal. Exp. Date: _____
Number of Samples	Sample Volume, mL
	<input type="text"/>

Submitted By: _____	Date: _____
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1.4 Weighing/Labeling of

1.4.1 Weigh the of the "" and calculate the net weight. Include balance printouts as Attachment .

Balance BDP #: _____
Net Wt. <input type="text"/> = Gross Wt: _____ g – Tare Wt., sec. <input type="text"/> : _____ g = _____ g

Performed By: _____	Date: _____	Verified By: _____	Date: _____
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Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
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1.4.1 Request for a label to be printed for the "[REDACTED]". The label must contain, at a minimum, the information below. Include a copy of the actual label as Attachment [REDACTED].

NOTE: If the product is being shipped to an outside vendor, the label must be requested from QA and a copy of the label galley must be included as Attachment [REDACTED].

Product Name: [REDACTED]
BDP Lot # _____
Store At: [REDACTED] °C Container Volume: _____ mL
Buffer: _____
Concentration: _____ mg/ml Fill Date: _____
Container # _____ of _____
** FOR FURTHER MANUFACTURING USE ONLY **
BDP NCI-Frederick

Performed By:	Date:	Verified By:	Date:
Purification Manager Approval:			Date:

1.4.2 Apply the approved label to the container of [REDACTED].

Performed By:	Date:	Verified By:	Date:
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Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	██████████	<input type="text"/>	<input type="text"/>	10 of 12

1.5 Storage of ██████

1.5.1 Store the container(s) at ██████ °C until transferred to MMIC for long-term storage. Record the end date and time of the final filtration step in the table below and calculate the duration of the entire step.

Refrigerator BDP #: _____	Temperature: _____ °C
Date/Time of Storage: _____	
Start Date/Time of Final Filtration Step, Sec ██████ : _____	
End Date/Time of Final Filtration Step: _____ Duration: _____	

Performed By: _____	Date: _____	Verified By: _____	Date: _____
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1.5.2 Transfer the "██████" container(s) to Materials Management and Inventory Control (MMIC). Include a copy of Form 20303-01, "MMIC CGMP Manufacturing Product Inventory", as Attachment ██████.

NOTE: If the bulk is stored in bottles, individually seal each bottle(s) prior to transferring to MMIC.

Seal Part #: _____	Lot #: _____	Exp. Date: _____
Freezer ID #: _____		Calibration Exp. Date: _____
Date/Time of Transfer: _____		

Submitted By: _____	Date: _____	Received By: _____	Date: _____
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Master Production Record (MPR)

Production of

Section : Final Filtration Using a 0.22µm Filter

Document No.	Project No.	Lot No.	Location	Revision	Effective	Page
MPR-P- <input type="text"/>	<input type="text"/>	<input type="text"/>	██████████	<input type="text"/>	<input type="text"/>	11 of 12

1.6 Calculate the yield from this step. Transcribe the information from the appropriate sections of this BPR.

Amount of Protein Before Final Filtration
Amt. Protein Before Final Filtration = Volume ██████ Solution, Sec. ██████ : _____ mL X Protein Conc., Sec. ██████ : _____ mg/mL = _____ mg
Amount Protein After Final Filtration
Amt. Protein After Final Filtration = Volume ██████ Solution, Sec. ██████ : _____ mL X Protein Conc., Sec. ██████ : _____ mg/mL = _____ mg
% Yield After Final Filtration
% Yield = (Amt. Protein After Final Filtration: _____ mg ÷ Amt. Protein Before Final Filtration: _____ mg) X 100 = _____ %

Performed By:	Date:	Verified By:	Date:
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