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

Master Production Record 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- [redacted] section [redacted], as found in the Master Document File.

Checked by:_____ Date:_____

Post-Manufacturing Document Review

This completed production record has been reviewed and has been found to be complete, correct, and in conformance with relevant SOP's and other documents.

Reviewed by: _____ Date:_____

Quality Assurance:_____ Date:_____

[redacted]

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

Operator (Print Name)	Signature	Initials

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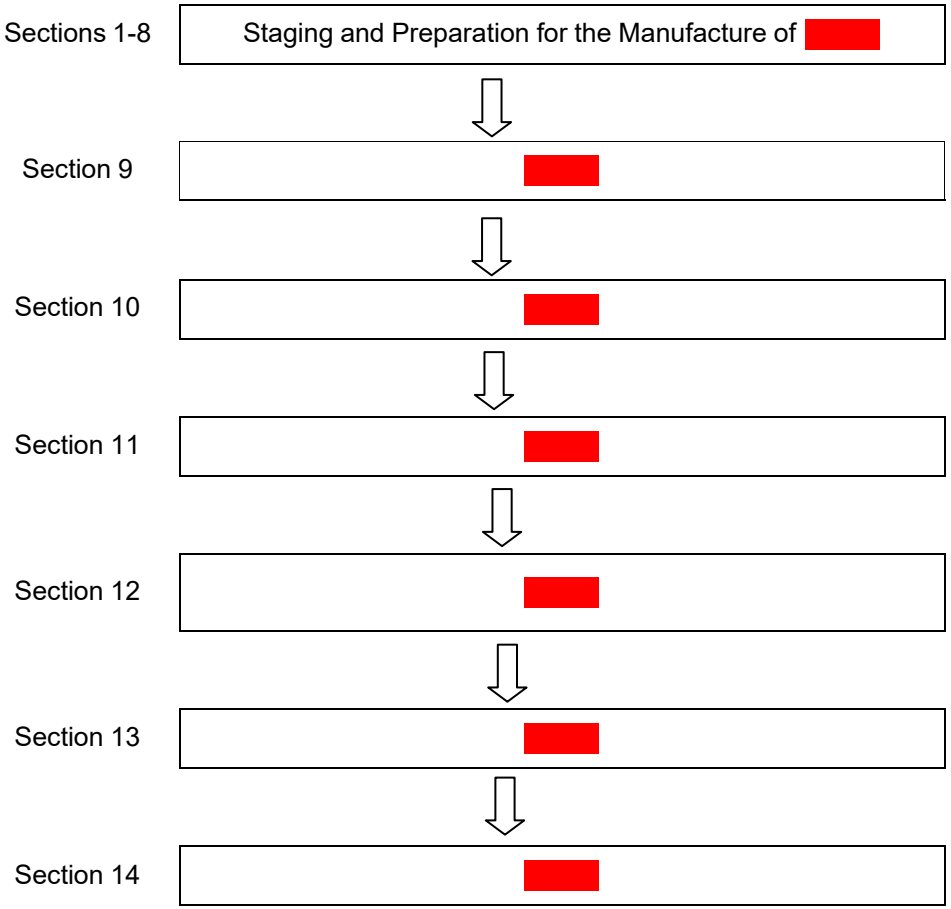
1.0 Production of

Scheduled Tests



Critical Parameters:

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1.1 Distribution of Product

1.1.1 Distribution must take place in a class 100 area. Prior to distributing the "", verify that EM was performed in the room/BSC where filling will take place. Assemble settling plates in the back two corners of the BSC for environmental monitoring during the fill process.

Room Number:_____BSC BDP #: _____

EM Performed (Y/N):_____ QC Request # for EM:_____

Settling Plates Part #:_____ Lot #:_____ Exp. Date:_____

Performed By:	Date:	Verified By:	Date:

1.1.2 The "", from section , will be distributed into tared containers with a fill volume of approximately mL per container for storage at °C until further processing. Weigh the bag of "" and calculate the number of L containers needed. Round the containers needed to the nearest whole number. Record the requested information in the table below. Include the balance printouts as Attachment .

Bulk Aliquot, Sampling and Storage Step Start Date/Time: _____

Balance BDP #: _____

Net Wt. of = Gross Weight of :_____g – Tare Weight of L Bag, sec ,:_____g =_____ g

Number of Containers Needed = Net Wt. of :_____ g / mL =_____containers

Performed By:	Date:	Verified By:	Date:

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1.1.3 Using the tubing on the bag that was not used during sterile/final filtration, aseptically distribute, in a class 100 area, the product into the calculated number of tared containers. Weigh each container after transfer and calculate the net weight. Label each container with " ", Container Number, Fill Volume, Date, For Further Processing". Include the balance printouts as Attachment .

Balance BDP #:_____ Container Part #:_____Lot #:_____Expiration Date:_____
Container # 1: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 2: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 3: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 4: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 5: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 6: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 7: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 8 Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 9: Net Wt. = Gross Wt. :_____ g –Tare Wt. of Container:_____g =_____g
Container # 10: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____g =_____ g

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Container # 11: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g =_____ g

Container # 12: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g = _____ g

Container # 13: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g = _____

Container # 14: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g =_____ g

Container # 15: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g =_____ g

Container # 16: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g =_____ g

Container # 17: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g =_____ g

Container # 18 Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g =_____ g

Container # 19: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____ g =_____ g

Container # 20: Net Wt. = Gross Wt. :_____g –Tare Wt. of Container:_____g =_____ g

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1.1.4 Upon completion of the distribution of the product, individuals that performed the operation must perform personnel monitoring by submitting touch plates to QC. Submit the settling plates assembled in Section to QC for environmental monitoring. Include the QC Request Verification for personnel and environmental monitoring as Attachment .

Persons Touch Plated (Print Names):_____

QC Request # for Personnel Monitoring:_____QC Request # for EM:_____

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1.2 Sampling and Sample Distribution

1.2.1 Aseptically remove samples from ONE of the containers filled in Section using a new pipette with each sampling. Distribute the samples as described in the table below in a class 100 area. Label the samples as per Section of this BPR.

NOTE: Sterility samples, if applicable, must be removed in equal portions from each of the containers filled in Section , i.e. if there are five containers, remove 2 X 2mL from each container, using a new pipette each time.

Pipette BDP Lot #:_____ BDP Part #:_____Expiration Date: _____

Container Used for Sampling of Non-Sterility Samples:_____Sterility Samples Taken (Y/N): _____

Volume of Sample Removed from Each Container for Sterility:_____mL

Number of Samples	Sample Vol., mL	Sample Volume Removed, mL	Purpose
			Process Retains
	1.0 ± 0.1mL Glass Vial		Corporate Retains
			Assays in Section
			Assays in Section

Performed By:	Date:	Verified By:	Date:

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1.2.1.1 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:_____ ºC

Retain Sample Stored (Y/N):_____Date of Storage, if applicable:_____

QC Sample Stored (Y/N):_____Date of Storage , if applicable:_____

Performed By:	Date:	Verified By:	Date:

1.2.2 Submit the samples (Part #) to QC for testing and enter the QC test request numbers in the table below. Store the samples at °C (**if applicable, sterility sample must be stored at 2-8°C**). Include the QC Request Verification as described in the table below.

Test	SOP Number	QC Test Request #	Sample Volume, mL	Attachment #

Submitted By:	Date:

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1.2.3 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

Submitted By:	Date:

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1.3 Weighing/Labeling of "[redacted]"

1.3.1 Weigh each of the **sampled containers** of "[redacted]" and calculate the final volume. Include the balance printouts as Attachment [redacted].

Balance BDP #:_____

Net Wt. [redacted] Container #1 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #2 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #3 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____g =_____g

Net Wt. [redacted] Container #4 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #5 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #6 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #7 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #8 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #9 = Gross Wt.:_____ g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____g

Net Wt. [redacted] Container #10 = Gross Wt.:_____g – Tare Wt. [redacted] L PETG, Sec. [redacted] :_____ g =_____ g

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Net Wt. Container #11 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #12 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #13 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____g =_____ g

Net Wt. Container #14 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #15 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #16 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #17 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #18 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #19 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____ g

Net Wt. Container #20 = Gross Wt.:_____g – Tare Wt. L PETG, Sec. :_____ g =_____g

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1.3.2 Request for a label to be printed for each container of the "". The label must contain, at a minimum, the information below. Include a copy of the actual label(s) as Attachment .

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 .

Product Name:

BDP Lot # _____

Store At: °C Container Volume:_____mL

Buffer:_____

Concentration:_____mg/ml Fill Date: _____

Container #_____of_____

** FOR FURTHER MANUFACTURING USE ONLY **

BDP NCI-Frederick

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1.3.3 Apply ONE label to each of the containers of " " and record the requested information in the table below.

Note: If the label, from section , was requested from QA, include a copy of the label reconciliation to this BPR as Attachment .

Room # for Labeling:_____

Container Cracks/Leaking Observed (Y/N):_____

Container Deterioration Observed (Y/N):_____

Container Capped and Sealed Properly (Y/N):_____

Label Correctly and Securely Applied (one per Container) (Y/N):_____

Label Information Legible and Correct (Y/N):_____

Performed By:	Date:	Verified By:	Date:

1.4 Storage of " "

1.4.1 Store the containers of " " at °C until transferred to MMIC for long term storage. Record the requested information in the table below.

Refrigerator/Freezer BDP #:_____Temperature:_____°C

Date/Time of Storage:_____

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1.4.2 Transfer the " " containers to Materials Management and Inventory Control for storage at °C. Include a copy of Form 20303-01, "MMIC CGMP Manufacturing Product Inventory", as Attachment .

NOTE: Prior to transferring the containers to MMIC, it is ideal to individually shrink wrap each of the containers.

Shrink WrapPart #:_____Lot #:_____Exp. Date:_____

Refrigerator/Freezer BDP #:_____ Calibration Exp. Date:_____ Temperature:_____°C

Date/Time of Storage:_____

Submitted By:	Date:	Received By:	Date:

1.4.3 Record the end date/time of the Bulk Aliquot, Sampling and Storage step. Calculate the duration of the entire step, using the step start date/time from section , in the table below.

Step Start Date/Time, sec. :_____Step End Date/Time:_____Duration:_____hrs/min.

Performed By:	Date:	Verified By:	Date:

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