

COPY CSB - UNCONTROLLED

Production System

PRD.SOP.102.04

Overwrapping of Commodities

Form 2 – Overwrapping of Commodities using a Multivac Lot No: 1234-25 Processing Date: 16 May 25 Sheet of

Room #	Operator	Activities	Entry (hrs)	Remask (hrs)	Exit (hrs)
(circle one)					
109	C. Broadnax	Unload Oven, Overwrap	0830	N/A	1200
	B. Mulhall	Unload Autoclave, Overwrap	0845	N/A	1215
	D. Pereira	EM	1100	N/A	1145
or					
402					

Items	# of Items / Wrap	# of Overwraps / Item	# Overwrapped Components Completed	# Rejects (Note Reason Below)	Bag ASC #	Recipe # / # of Sealing Plates (Primary Overwrap)	Recipe # / # of Sealing Plates (Secondary Overwrap)	Recipe # / # of Sealing Plates (Tertiary Overwrap)
Vial Trays						/	/	/
Stopper Pouches						/	/	/
Stopper QC Pouches						/	/	/
Seal Pouches						/	/	/
Seal QC Pouches						/	/	/
Vial, Stopper, Seal Kits	1 vial tray, 1 stopper pouch, 1 seal pouch	2	54	0	4106	12 / 3 ^①	9 / 3	N/A / N/A
3-Sided Tray Ring Tool						/	/	/
						/	/	/
Multivac Equipment ID:	SLR029-000			Multivac Equipment ID:		N/A		
Completed By/Date	CSB16 May 25			Verified By/Date		BM16 May 25		

Sanitization performed per **FAC.SOP.511** (Room 109) or **FAC.SOP.515** (Rooms 402 & 403):

Initial/Date: CSB16 May 25

Comments:

① The recipe for the primary overwrap was changed from 12/3 to 10/3 due to poor vacuum. CSB16 May 25

Reviewed By: _____

Date: _____

Afton Scientific

COPY CSB - UNCONTROLLED

Production System

PRD.SOP.102.04

Overwrapping of Commodities

Form 2 – Overwrapping of Commodities using a Multivac Lot No: 1234-25 Processing Date: 15 May 25 Sheet of

Room #	Operator	Activities	Entry (hrs)	Remask (hrs)	Exit (hrs)
(circle one)	<u>C. Broadnax</u>	<u>Unload Oven, Overwrap</u>	<u>0800hrs</u>	<u>N/A</u>	<u>1100hrs</u>
109	<u>B. Mulhall</u>	<u>Unload Anticline, Overwrap</u>	<u>0810hrs</u>	<u>N/A</u>	<u>1115hrs</u>
	<u>D. Pereira</u>	<u>EM</u>	<u>1000hrs</u>	<u>N/A</u>	<u>1045hrs</u>
or					
402					

Items	# of Items / Wrap	# of Overwraps / Item	# Overwrapped Components Completed	# Rejects (Note Reason Below)	Bag ASC #	Recipe # / # of Sealing Plates (Primary Overwrap)	Recipe # / # of Sealing Plates (Secondary Overwrap)	Recipe # / # of Sealing Plates (Tertiary Overwrap)
Vial Trays						/	/	/
Stopper Pouches						/	/	/
Stopper QC Pouches						/	/	/
Seal Pouches						/	/	/
Seal QC Pouches						/	/	/
Vial, Stopper, Seal Kits	1 vial tray, 1 stopper pouch, 1 seal pouch	<u>2</u>	<u>53</u>	<u>1 ①</u>	<u>4106</u>	<u>12 / 3</u>	<u>9 / 3</u>	<u>N/A / N/A</u>
3-Sided Tray Ring Tool						/	/	/
						/	/	/
Multivac Equipment ID:	<u>SLR039-000</u>			Multivac Equipment ID:		<u>N/A</u>		
Completed By/Date	<u>CSB 15 May 25</u>			Verified By/Date		<u>BM 15 May 25</u>		

Sanitization performed per **FAC.SOP.511** (Room 109) or **FAC.SOP.515** (Rooms 402 & 403): Initial/Date: CSB 15 May 25

Comments:

① 1 tray rejected in APA due to logo defect. Vials, stoppers, and seals were disposed of in the APA. CSB 15 May 25

Reviewed By: _____ Date: _____

Afton Scientific