



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

Confidential

Batch Record Number:

M4097-01B

Issued By/ Date:

dc OCT 23 2020

M4097-01B



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

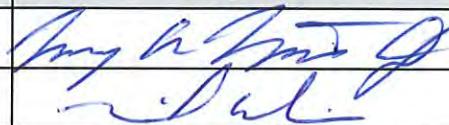
M4097-01B

DC OCT 23 2020

I. Preliminary Batch Record Approval:

This batch record was reviewed prior to its execution and was found to be acceptable. The signatures below indicate approval of this batch record as adequate, complete, and correct.

Emerson Resources, Inc. Approval

Approver	Signature	Date
Author		10/21/2020
Technical Reviewer		21 OCT 2020
Quality Assurance Representative		10/21/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative		attacted		
Representative		DC 10/23/20		



MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

I. Preliminary Batch Record Approval:

This batch record was reviewed prior to its execution and was found to be acceptable. The signatures below indicate approval of this batch record as adequate, complete, and correct.

Emerson Resources, Inc. Approval

Approver	Signature	Date
Author		10/21/2020
Technical Reviewer		21 OCT 2020
Quality Assurance Representative		10/21/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative	Alex Schwarz 25DE1565A70442B...	Alex Schwarz	VP, CMC	10/22/2020
Representative	Ashanthi Mathai E70096F912E9448...	Ashanthi Mathai	CEO	10/22/2020



**EMERSON
RESOURCES INC**

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

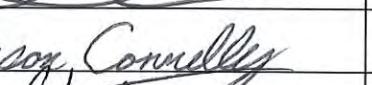
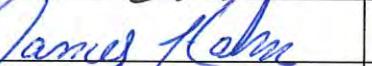
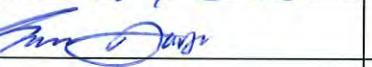
Issued By/ Date:

M4097-01B

DC OCT 23 2020

II. Operator / Reviewer Signature Log:

By signing the log, all operators are verifying that they are trained on all relevant procedures and current versions of SOPs.

Operator / Reviewer	Title	Signature	Initials	Date
Troy A. Bartvan Jr.	Formulation Scientist II		TB	10/21/2020
David M. Slifer	Sr. Manager, Form Dev		DMS	21 OCT 2020
Devin Carson	QA Specialist		DC	10/21/20
Jason Connelly	Formulation Technician		JC	10/23/20
Peter Filoon	Formulation Specialist		POF	10/23/20
Patrick Callow	Formulation Technician		PC	10/26/20
James Kohn	Formulation Technician		JK	10/26/20
Bari Darg	QA Specialist		BD	10/27/2020



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

III. Materials / Formulation:

Step	Description				Done By	Checked By														
1	The following represents approximate batch size requirements to manufacture and package 4 mg Naloxone HCl Nasal Swabs.																			
	<table border="1"><thead><tr><th>Formulation Component</th><th>mg/unit ^{1,4}</th><th>%w/w</th><th>g/batch ^{1,2}</th></tr></thead><tbody><tr><td>Filtered Naloxone Solution</td><td>74.0</td><td>100.0</td><td>65.1</td></tr><tr><td>Total</td><td>74.0</td><td>100.0</td><td>65.1</td></tr></tbody></table>	Formulation Component	mg/unit ^{1,4}	%w/w	g/batch ^{1,2}	Filtered Naloxone Solution	74.0	100.0	65.1	Total	74.0	100.0	65.1							
Formulation Component	mg/unit ^{1,4}	%w/w	g/batch ^{1,2}																	
Filtered Naloxone Solution	74.0	100.0	65.1																	
Total	74.0	100.0	65.1																	
	<table border="1"><thead><tr><th>Device Assembly Components</th><th>Quantity / unit</th><th>Quantity / batch ²</th></tr></thead><tbody><tr><td>6 Sock 1/8ZF/WHT / EXT HDL Swab</td><td>1</td><td>880</td></tr><tr><td>Pro-fax PF511 Natural Caps</td><td>1</td><td>880</td></tr><tr><td>A3333 2 3/4" X 10" Peelable Foil Pouches</td><td>1</td><td>910 ³</td></tr><tr><td>Clinical Pouch Label</td><td>1</td><td>880</td></tr></tbody></table>	Device Assembly Components	Quantity / unit	Quantity / batch ²	6 Sock 1/8ZF/WHT / EXT HDL Swab	1	880	Pro-fax PF511 Natural Caps	1	880	A3333 2 3/4" X 10" Peelable Foil Pouches	1	910 ³	Clinical Pouch Label	1	880				
Device Assembly Components	Quantity / unit	Quantity / batch ²																		
6 Sock 1/8ZF/WHT / EXT HDL Swab	1	880																		
Pro-fax PF511 Natural Caps	1	880																		
A3333 2 3/4" X 10" Peelable Foil Pouches	1	910 ³																		
Clinical Pouch Label	1	880																		

¹ Values have been rounded to nearest whole number.

² To be dispensed in excess to account for potential processing losses.

³ Includes overage to account for equipment setup.

⁴ Equivalent to 72.8 µl based on a solution density of 1.017 g/mL.



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Step	Description						Done By	Checked By
2	Raw Material List:							
	Component	Manufacturer	Receiving Number	Lot Number/Batch Record Number	Expiration/Retest Date	Net Quantity (from label)		
	A Filtered Naloxone Solution	Emerson	n/a	M4097-01A	n/a	<i>677.24</i>	g	
	B 6 Sock 1/8ZF/WHT EXT HDL	SuperBrush LLC	R200724-01A	IAQ8Z-2020-05-07	7/24/2025			
	C Pro-fax PF511 Natural Caps	Seaway Plastic Engineering	R200902-01A R200902-01B R200902-01C	235665	9/2/2021	To be dispensed	<i>TK</i>	<i>PSF</i>
	D A3333 2 3/4" X 10" Peelable Foil Pouches	Beacon Converters, Inc	R200825-01A R200825-01B	1092933	8/25/2025			
	E Clinical Pouch Labels	ClinSys	R200924-01A	03997-0004	<i>9/24/2025</i>	2000	ct	
	F Clinical Box Labels	Emerson	n/a	n/a	n/a	5	ct	
3	Affix a copy of all approved label sheets to this batch record and update the attachments list in Step 50.							
	Component	Copy Attached (✓)		Attachment List Updated (✓)			<i>TB</i>	<i>PSF</i>
	Clinical Box Labels							

(1) B.R. Envir. 9/24/2025. TB 10/23/2020 PSF 10/23/2020 DC 10/23/20



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Step	Description	Done By	Checked By
4	<p>Clinical Pouch Labels:</p> <p>With QA present affix a sample label in the space provided. Ensure the sample label text is identical to the printed text below:</p> <div style="border: 1px solid black; padding: 10px;"> <p>Protocol: PNC-20-001 Lot number: 4097-01 4 mg Naloxone Hydrochloride Nasal Swab 1 Nasal Swab</p> <p>Administer as Directed by the Protocol Specified Instructions for Use Store at controlled room temperature 20°C - 25°C (68°F - 77°F) With allowable excursions in the range of 15°C - 30°C (59°F - 86°F)</p> <p>KEEP OUT OF REACH OF CHILDREN For Nasal Use Only For Clinical Trial Use Only</p> <p>CAUTION-NEW DRUG: Limited by Federal (or United States) and Canadian Law to Investigational Use</p> <p>Sponsor: Pocket Naloxone Corp., 9101 Quintana Drive Bethesda, MD 20817</p> </div> <p>Sample label:</p> <div style="border: 1px solid black; padding: 10px; margin-top: 20px;"> <p>Protocol: PNC-20-001 Lot number: 4097-01 4 mg Naloxone Hydrochloride Nasal Swab 1 Nasal Swab</p> <p>Administer as Directed by the Protocol Specified Instructions for Use Store at controlled room temperature 20°C - 25°C (68°F - 77°F) With allowable excursions in the range of 15°C - 30°C (59°F - 86°F)</p> <p>KEEP OUT OF REACH OF CHILDREN For Nasal Use Only For Clinical Trial Use Only</p> <p>CAUTION-NEW DRUG: Limited by Federal (or United States) and Canadian Law to Investigational Use</p> <p>Sponsor: Pocket Naloxone Corp., 9101 Quintana Drive Bethesda, MD 20817</p> </div> <p>QA Label Inspection: Label text above and sample label affixed are identical (✓) (<u>✓</u>). QA Release (Initials / Date): <u>DC 10/23/20</u></p>	<i>TB</i>	<i>PJF</i>



MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/20 Initials: DC

Step	Description	Done By	Checked By
5	<p>QA Packaging Component Release:</p> <p>Components listed in Step 2 are acceptable for use per SOP R-07 (✓) (✓).</p> <p>Quantities issued in Step 2 fulfill the required quantities outlined in Step 1 (✓) (✓).</p> <p>All raw material containers are visually clean and free of foreign material (✓) (✓).</p> <p>QA Release (Initials / Date): <u>DC 10/23/20</u></p>		



MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

Date Executed: 10/23/2020 Initials: TR

IV. Room Release and Setup:

Step	Description	Done By	Checked By
6	<p>Room and Equipment Cleaning:</p> <p>Room Number: <u>218</u> Cleaning Batch Record(s): <u>C4097-12, C4097-34</u></p> <p>Room and equipment were previously cleaned, swabbed, and released.</p>	<u>TR</u>	<u>fjt</u>
7	<p>Proper gowning for dispensing and handling of this material is as follows:</p> <p>NOTE: Please confirm all hair is contained inside hair cover and beard cover (if applicable).</p> <ul style="list-style-type: none">A. Safety glasses/safety gogglesB. Hair coverC. Beard cover (if applicable)D. Disposable gowningE. Disposable sleeves (as needed)F. Shoe coversG. Non-latex gloves		



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Step	Description					Done By	Checked By
8	Equipment List:						
	Name	ID	PM Due Date	Cal. Due Date	SOP		
	Chart Recorder	L581		2/2021	E-23		
	Top Loading Balance (≥3,000g, 2g minimum weight)	A145	11/30/2020	11/30/2020	Q-15		
	Analytical Balance 1 (20mg minimum weight)	A301	11/30/2020	11/30/2020	Q-15		
	Analytical Balance 2 (20mg minimum weight)	A394	11/30/2020	11/30/2020	Q-15		
	FisherBrand Elite Pipette, 100 – 1000 µL (2)	For Project 4097		4/2021 ② 7/2021	n/a		
	Pipette Tips (1000 µL)	For Project 4097			n/a		
	FisherBrand Elite Pipette, 20 – 200 µL (2)	For Project 4097		2/2021	n/a		
	Pipette Tips (200 µL)	For Project 4097			n/a		
	Nalgene Beaker (400 mL) (5)	For Project 4097			n/a		
	Nalgene Beaker (30 mL) (2)	For Project 4097			n/a		
	PW3416 Heat Sealer	L615	7/2021	7/2021	E-100		
	Pneumatic Air Gun with Regulator	n/a			n/a		
	2 Gal HDPE Container with Lid	For Project 4097			n/a		

① BR Linner 100 OC 10/28/20 TB 11/6/2020 PSF 11/6/2020

② For clarity, 04/2021. TB 11/6/2020 PSF 11/6/2020



**EMERSON
RESOURCES INC**

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

PL OCT 23 2020

Date Executed: 10/23/2020 Initials: TB



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Step	Description				Done By	Checked By
10	In-Process Cleaning: The following may be used for cleaning throughout the process.	Material	Manufacturer/Supplier	Lot Number	Expiration Date	
	99% Isopropyl Alcohol (IPA)	ExxonMobil / Univar Solutions		MV20878218	4/20/2021	
	70% Saturated IPA Wipes	Berkshire		2004000132	6/26/2021	
	Lint-Free Cloths	Berkshire		0830181	5/7/2025	
		A	DC 10/23/2020			
11	QA Room and Equipment Release: The release of the room and equipment has been executed and documented in appropriate logbook(s) (✓) (<u> </u>). Expiry dates for cleaning materials and equipment have been verified for continued use (✓) (<u> </u>). QA's visual inspection of the room and equipment has been performed and documented in appropriate logbook(s) (✓) (<u> </u>). QA Release (Initials / Date): <u>DC 10/23/2020</u>					



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/23/20 Initials: PJJ

Step	Description	Done By	Checked By										
12	<p>Set up the temperature/% relative humidity chart recorder. Record the current date, time, room number, batch record number, ID number, and initials on the chart recorder paper. Ensure both markers are recording and that the chart recorder is set to record temperature in °C.</p> <table border="1"><tr><td>Chart Recorder ID</td><td>L581</td></tr><tr><td>Chart Paper Type (circle one)</td><td>Daily / <input checked="" type="checkbox"/> Weekly / Monthly</td></tr><tr><td>Chart Recorder Setting (circle one)</td><td>Daily / <input checked="" type="checkbox"/> Weekly / Monthly</td></tr><tr><td>Temperature Setting (circle one)</td><td>°C °F</td></tr><tr><td>Both pens are recording (✓)</td><td>✓</td></tr></table>	Chart Recorder ID	L581	Chart Paper Type (circle one)	Daily / <input checked="" type="checkbox"/> Weekly / Monthly	Chart Recorder Setting (circle one)	Daily / <input checked="" type="checkbox"/> Weekly / Monthly	Temperature Setting (circle one)	°C °F	Both pens are recording (✓)	✓	PJJ	TB
Chart Recorder ID	L581												
Chart Paper Type (circle one)	Daily / <input checked="" type="checkbox"/> Weekly / Monthly												
Chart Recorder Setting (circle one)	Daily / <input checked="" type="checkbox"/> Weekly / Monthly												
Temperature Setting (circle one)	°C °F												
Both pens are recording (✓)	✓												



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/20 Initials: PSF

Step	Description						Done By	Checked By
13	Record current room temperature, relative humidity, and Magnehelic pressure readings for the process room, which must be at least 0.020" of water to continue. Record room data in the table below when directed in the batch record and at the beginning and end of each manufacturing day. Mark N/A in the appropriate columns for gauge locations not present.							
	Notify QA at the time of recording if any pressure reading is less than 0.020" of water.							
	Room ID	<u>218</u>						Done by / Date
	Gauge Location	Room	Ante Room	Gowning Room			<i>PSF</i>	<i>TB</i>
	Gauge ID	<u>F0072</u>	<u>F00720</u>	<u>F0070</u>			<u>10/23/20</u>	<u>10/23/2020</u>
	Cal Due Date	<u>4/30/21</u>	<u>4/30/21</u>	<u>4/30/21</u>				
Step #	Time	Temperature (°C)	Relative Humidity (%)	Chart recording matches digital display (✓)	Pressure Reading (inches of water) Room	Ante Room	Gowning Room	Done by / Date
13	10:50AM	20.4	59	✓	0.055	0.040	0.055	<i>PSF 10/23/20</i>
15	11:53 AM	20.5	63	✓	0.050	0.040	0.055	<i>TB 10/23/20</i>
17	2:25 PM	20.2	65	✓	0.050	0.040	0.065	<i>JC 10/23/20</i>
24	3:05 PM	20.5	61	✓	0.050	0.040	0.050	<i>TB 10/23/2020</i>
25	5:27 PM	20.5	65	✓	0.050	0.045	0.060	<i>JC 10/23/20</i>
25	9:58 AM	20.3	44	✓	0.055	0.040	0.055	<i>PSF 10/26/20</i>
25	11:33 AM	20.4	47	✓	0.055	0.045	0.055	<i>JH 10/26/20</i>
25	12:59 PM	20.2	51	✓	0.055	0.045	0.055	<i>JH 10/26/20</i>
25	1:38 PM	20.3	52	✓	0.050	0.045	0.050	<i>TB 10/26/2020</i>
25	2:56 PM	20.3	54	✓	0.050	0.045	0.050	<i>JH 10/26/20</i>

① F0071 PSF 10/23/20 TB 10/23/2020



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DK OCT 23 2020

Date Executed: 10/23/23 Initials: RJR



MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/23/20 Initials: PJF

V. Dispensing Procedure:

Step	Description	Reviewed and Understood
14	<p>Dispensing Instructions:</p> <ol style="list-style-type: none">Only one raw material may be brought into the room at a time. Additional raw material handling requirements must be followed, as defined in SOP R-07. <u>Note:</u> Cardboard and/or fiber containers should not be placed on the working surface.Attach a label to the poly bag or container, and record the tare weight. Tare the poly bag or container on the balance. <u>Note:</u> An intermediate container may be used when appropriate, which does not require a label.Dispense the required quantity of the raw material into the poly bag or container. Record the net quantity.Ensure that the label contains the following: Batch Record#: M4097-01B Material: Receiving #: Lot #: Tare Weight: Net Quantity: Expiration Date: Initials/Date: <u>Note:</u> Additional information can be placed on label where necessary.Affix a duplicate label to the in-process section of the batch record.Update the dispensing label on the raw material container. (Note: If multiple samples from the same raw material are being dispensed, the raw material dispensing label may be updated with a lump sum at the completion of sampling.)	All operators have reviewed and understood dispensing instructions. PSF TB



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Dispensing Worksheet (for Step 14):

	Raw Material	Receiving Number	Target Quantity		Dispensed Quantity		Recorded By	Checked By	Label Prepared & Checked (✓)	Duplicate Label Prepared & Checked (✓)	Dispensing Label Updated (✓)	Done By	Checked By
A	6 Sock 1/8ZFWHT EXT HDL (For M4097-01B)	R200724-01A	930	ct	930	ct	TB	POT	✓	✓		TB	PJF
B	6 Sock 1/8ZFWHT EXT HDL (For M4097-12)		980	ct	980	ct	TB	POT	✓	✓		TB	PJF
C	6 Sock 1/8ZFWHT EXT HDL (For M4097-23)		930	ct	930	ct	TB	POT	✓	✓		TB	PJF
D	Total Dispensed				2840	ct	TB	POT			✓	TB	PJF



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Dispensing Worksheet continued (for Step 14):

	Raw Material	Receiving Number	Target Quantity		Dispensed Quantity		Recorded By	Checked By	Label Prepared & Checked (✓)	Duplicate Label Prepared & Checked (✓)	Dispensing Label Updated (✓)	Done By	Checked By
E	A3333 2 3/4" x 10" Peelable Pouches (For M4097-01B)	R200825-01A	980	ct	980	ct	TB	PJF	✓	✓		TB	PJF
F	A3333 2 3/4" x 10" Peelable Pouches (For M4097-12, Bag 1 of 2)		remaining quantity	ct	872	ct	TB	PJF	✓	✓		TB	PJF
G	Total Dispensed				1852	ct	TB	PJF			✓	TB	PJF
H	A3333 2 3/4" x 10" Peelable Pouches (For M4097-12, Bag 2 of 2)	R200825-01B	163	ct	163	ct	TB	PJF	✓	✓		TB	PJF
I	A3333 2 3/4" x 10" Peelable Pouches (For M4097-23)		980	ct	980	ct	TB	PJF	✓	✓		TB	PJF
J	Total Dispensed				1143	ct	TB	PJF			✓	TB	PJF



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DR OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Dispensing Worksheet continued (for Step 14):

	Raw Material	Receiving Number	Target Quantity		Dispensed Quantity		Recorded By	Checked By	Label Prepared & Checked (✓)	Duplicate Label Prepared & Checked (✓)	Dispensing Label Updated (✓)	Done By	Checked By
K	Pro-fax PF511 Natural Caps (For M4097-01B, Bag 1 of 2)	R200902-01A	remaining quantity	ct	847	ct	TB	POF	✓	✓	✓	TB	POF
L	Pro-fax PF511 Natural Caps (For M4097-01B, Bag 2 of 2)	R200902-01B	83	ct	83	ct	TB	POF	✓	✓		TB	POF
M	Pro-fax PF511 Natural Caps (For M4097-12, Bag 1 of 2)		remaining quantity	ct	914	ct	TB	POF	✓	✓		TB	POF
N	Total Dispensed				997	ct	TB	POF			✓	TB	POF
O	Pro-fax PF511 Natural Caps (For M4097-12, Bag 2 of 2)	R200902-01C	66	ct	66	ct	TB	POF	✓	✓		<i>EE TB 10/23/20 PSF 10/23/20</i> <i>✓ TB</i>	POF
P	Pro-fax PF511 Natural Caps (For M4097-23)		remaining quantity	ct	931	ct	TB	POF	✓	✓		TB	POF
Q	Total Dispensed				997	ct	TB	POF			✓	TB	POF



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC

OCT 23 2020

Date Executed: 10/23/20 Initials: BPF

Step	Description	Done by	Checked by
15	Record the end time, room Magnehelic pressure reading, and the current temperature and relative humidity in Step 13.	TB	Pof
16	QA In-Process Check: All steps are completed and in-process specifications met (✓) (<u>✓</u>). Content on all labels has been verified (✓) (<u>✓</u>). All quantities dispensed are within specifications (✓) (<u>✓</u>). QA Initials / Date: <u>OC 10/23/20</u>		



MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/23/20

Initials: JC

VI. Manufacturing/Packaging Procedure:

Step	Description	Done by	Checked by									
17	<p>Prepare a labeled poly bag to collect Device Assembly Waste. Device assembly waste is any swab or cap that touches a non-product contact surface. Waste also includes any pouches used for equipment setup or rejected during inspection. Waste could also be any damaged or rejected labels. Ensure that the label contains the following:</p> <p>Batch Record#: M4097-01B Material: Device Assembly Waste Lot Number: N/A Receiving Number: N/A Tare Weight: N/A Net Quantity: N/A Initials/Date:</p> <p>Update the poly bag label (✓) (✓). Update the affixed duplicate label in the in-process section of the batch record (✓) (✓).</p>	JC	PSF									
18	<p>Prepare a labeled 2 gal HDPE Container with Lid to collect Naloxone Solution Waste. Waste includes end of day solution waste or any other solution waste made during processing. Obtain the tare weight of the empty container with lid. Ensure that the label contains the following:</p> <p>Batch Record#: M4097-01B Material: Naloxone Solution Waste Receiving Number: N/A Lot Number: N/A Tare Weight: Net Quantity: Initials/Date:</p> <table border="1"><tr><td>Tare weight (with lid)</td><td>550.15</td><td>grams</td></tr><tr><td>Balance Minimum Weight</td><td>2g</td><td></td></tr><tr><td>Balance ID</td><td>A145</td><td></td></tr></table> <p>Update the container label with tare weight (✓) (✓). Update the affixed duplicate label in the in-process section of the batch record (✓) (✓).</p>	Tare weight (with lid)	550.15	grams	Balance Minimum Weight	2g		Balance ID	A145		JC	PSF
Tare weight (with lid)	550.15	grams										
Balance Minimum Weight	2g											
Balance ID	A145											



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

Date Executed: 10/23/20 Initials: BOP

Step	Description	Done by	Checked by										
19	<p>Prepare at least one labeled 12 x 12 x 12" box to collect In-process Swabs. Ensure the label contain the following information. Additional in-process boxes may be prepared as needed. Use two 12" cardboard dividers to create 3 lanes in the in-process box. Swab pouches are to be stored upright with the cap side of the packaging down in the in-process boxes, with no more than 50 pouches per lane.</p> <p>Batch Record#: M4097-01B Material: In-process Swabs, Box _____ of _____ Lot Number: N/A Receiving Number: N/A Tare Weight: N/A Net Quantity: N/A Initials/Date:</p> <p>Update the label on the box (✓) <u> </u>. Update one affixed duplicate label in the in-process section of the batch record (✓) <u> </u>.</p>	<i>PJF</i>	<i>JC</i>										
20	<p>Ensure the PW3416 Heat Sealer is set up properly in accordance with SOP E-100. The unit should be connected to compressed air supplying a minimum of 100 psi.</p> <p>Use the touch screen HMI to adjust the impulse sealer settings to the following recommendations.</p> <p>Use empty peelable foil bags to test a variety of recommended settings.</p> <table border="1"> <thead> <tr> <th>Setting</th><th>Recommendation</th></tr> </thead> <tbody> <tr> <td>Sealing Temperature</td><td>190 °C</td></tr> <tr> <td>Sealing Time</td><td>2.0 sec</td></tr> <tr> <td>Cooldown Temperature</td><td>150 °C</td></tr> <tr> <td>Sealing Pressure</td><td>80 PSI</td></tr> </tbody> </table> <p><u>Confirm sealing temperature, sealing time, cooldown temperature and sealing pressure are sufficient for adequate sealing.</u></p> <p>Note: Settings are recommendations and may be adjusted to maintain adequate sealing.</p>	Setting	Recommendation	Sealing Temperature	190 °C	Sealing Time	2.0 sec	Cooldown Temperature	150 °C	Sealing Pressure	80 PSI	<i>TB</i>	<i>PJF</i>
Setting	Recommendation												
Sealing Temperature	190 °C												
Sealing Time	2.0 sec												
Cooldown Temperature	150 °C												
Sealing Pressure	80 PSI												



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/2020 Initials: TJS

Step	Description					Done by	Checked by																					
21	<p>Using a pneumatic air gun with regulator set at 30 PSI, open 15 empty peelable foil pouches by inflating them briefly. Seal 5 of the peelable foil pouches at the target sealing temperature, 5 peelable foil pouches at a lower sealing temperature, and 5 peelable foil pouches at a higher sealing temperature. Leave a small length of pouch material (less than a centimeter) from the sealed edge by carefully aligning the back edge to be sealed with the back of the seal bar.</p> <p>Note: Allow pouch seals to rest at least 2 minutes before testing.</p> <table border="1"> <thead> <tr> <th>Setting</th><th>Range</th><th>Target</th><th>Lower Range</th><th>Higher Range</th></tr> </thead> <tbody> <tr> <td>Sealing Temperature</td><td>180 – 200 °C</td><td>190 °C</td><td>180 °C</td><td>200 °C</td></tr> <tr> <td>Sealing Time</td><td>Report</td><td></td><td>2.0</td><td>sec</td></tr> <tr> <td>Cooling Temperature</td><td>Report</td><td></td><td>130</td><td>°C</td></tr> <tr> <td>Sealing Pressure</td><td>Report</td><td></td><td>80</td><td>PSI</td></tr> </tbody> </table> <p>Visually inspect the seal integrity of each pouch. Gently pull on the edges of each pouch to ensure adequate sealing. The seal should require some force to peel apart, similar to the rest of the peelable pouch.</p> <p>If any pouches fail the seal test, notify QA and repeat all tests using a new settings configuration.</p> <p>Add all pouches used for testing and confirming sealing parameters to the poly bag labeled Device Assembly Waste.</p>	Setting	Range	Target	Lower Range	Higher Range	Sealing Temperature	180 – 200 °C	190 °C	180 °C	200 °C	Sealing Time	Report		2.0	sec	Cooling Temperature	Report		130	°C	Sealing Pressure	Report		80	PSI		
Setting	Range	Target	Lower Range	Higher Range																								
Sealing Temperature	180 – 200 °C	190 °C	180 °C	200 °C																								
Sealing Time	Report		2.0	sec																								
Cooling Temperature	Report		130	°C																								
Sealing Pressure	Report		80	PSI																								
22	<p>Following set-up, ensure parameters are returned to target settings. Record actual parameters below:</p> <table border="1"> <thead> <tr> <th>Setting</th><th>Actual</th></tr> </thead> <tbody> <tr> <td>Sealing Temperature</td><td>190 °C</td></tr> <tr> <td>Sealing Time</td><td>2.0 sec</td></tr> <tr> <td>Cooldown Temperature</td><td>130 °C</td></tr> <tr> <td>Sealing Pressure</td><td>80 PSI</td></tr> </tbody> </table> <p>Note: Parameters may be adjusted within the evaluated range during sealing to ensure adequate sealing.</p>	Setting	Actual	Sealing Temperature	190 °C	Sealing Time	2.0 sec	Cooldown Temperature	130 °C	Sealing Pressure	80 PSI																	
Setting	Actual																											
Sealing Temperature	190 °C																											
Sealing Time	2.0 sec																											
Cooldown Temperature	130 °C																											
Sealing Pressure	80 PSI																											



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Step	Description	Done by	Checked by
23	<p>QA In-Process Check:</p> <p>All steps have been completed and any in-process specifications have been met (✓) (<input checked="" type="checkbox"/>).</p> <p>Settings on the impulse sealer have been verified (✓) (<input checked="" type="checkbox"/>).</p> <p>QA Initials / Date: <u>DC 10/23/20</u></p>		



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

PC OCT 23 2020

Date Executed: 10/23/2020 Initials: TBS

Step	Description	Done by	Checked by
24	<p>Swab Preparation Instructions</p> <p>Perform swab preparation in sets of 10 swabs (the final set may contain a number of swabs outside the specified range in order to fill the required quantity). Complete the appropriate sections of the packaging worksheet for each set.</p> <p>Temperature, relative humidity, and room Magnehelic pressure should be recorded in Step 13 at the beginning and end of each packaging session, <u>and</u> prior to starting a new packaging worksheet.</p> <ul style="list-style-type: none"> A. Dispense a small amount of solution from the Filtered Naloxone Solution into a 30 mL Nalgene Beaker using a sterile transfer pipette or carefully pouring. Cover the beaker with foil when not actively in use. Additional solution may be added as needed during processing. B. Place a Pro-fax PF511 Natural Cap on an analytical balance. Zero the balance. C. Setup a FisherBrand Elite 20 – 200 μL pipette with 200μL tip. Dial in 72.8 μL on the handle. Wipe the tip down with a lint free wipe wetted with IPA prior to extraction. D. Using the pipette, extract solution from the 30 mL Nalgene beaker, ensuring no air bubbles are present in the tip. For the first extraction of the day, and any time the tip is replaced, dispense the first extraction to Naloxone Solution Waste. E. Dispense the extracted solution into the cap on the analytical balance. F. Verify that the weight of solution dispensed is between 74.0 mg \pm 3.0 mg (Acceptable Range: 71.0 – 77.0 mg). A second pipette may be used to adjust the quantity if needed. Dial set-point on the pipette may be adjusted as needed for more accurate delivery. <ul style="list-style-type: none"> a. Two operators may conduct Steps B – F simultaneously. b. Operators must confirm each other's dispensed weight for each swab. G. Place a foam swab into the cap. Gently move the swab up and down within the cap while twisting to ensure that all of the solution is absorbed. Visually confirm no significant amount of solution remains in the cap. H. Place the completed swab cap-side down into a 400 mL beaker for packaging. <ul style="list-style-type: none"> a. Beakers should be arranged in order in sets of 10 in a first in, first out fashion for continuous production. If no empty beakers remain, pause swab preparation and assist packaging as outlined in Step 25. I. Repeat steps B – H in sets of 10 until not less than 880 swabs have been prepared. J. Pausing for end of day: <ul style="list-style-type: none"> a. Any Filtered Naloxone Solution remaining in the 30 mL Nalgene beaker(s) must be discarded in the Naloxone Solution Waste container. Clean the 30 mL beaker(s) with IPA and lint frees to remove any residual material. b. All prepared swabs must complete the pouching and labeling operation. c. All in-process materials will be returned to their designated GMP storage location. Do not leave materials in the manufacturing room overnight. 	<p>Instructions read and understood by: (sign/date daily)</p> <p><i>TBS 10/23/2020 JC 10/23/20 PSF 10/23/20 SFC 10/26/20 POT 10/26/20 TBS 10/26/2020 PC 10/26/20 POT 10/27/20 SFC 10/27/20 JC 10/27/20</i></p>	

Analytical Balance 1:

Balance ID: A394

Minimum Weight: 20 mg

Analytical Balance 2:

Balance ID: A301

Minimum Weight: 20 mg

TBS

POT



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Step	Description	Done by	Checked by
25	<p><u>Swab Packaging Instructions</u></p> <p>Note: After the initial set of 10 swabs has been prepared, swab preparation and packaging may occur in parallel. Packaging will occur in a first in, first out method so that prepared swabs do not sit for extended periods prior to packaging. All prepared swabs must be packaged on the same day. Complete the appropriate sections of the packaging worksheet for each set.</p> <p>A. Neatly place one label as shown in Step 4 on a foil pouch. The label should be centered as much as possible, sufficiently distanced from the location where the seal will be made, with text reading left to right with the closed chevron of the bag on the left side and the open end on the right.</p> <p>B. Use the compressed air gun to gently open the pouch at a setting of 30 PSI.</p> <p>C. Insert one swab into the pouch with the handle end going in first towards the chevron seal, taking care to minimize squeezing or manipulating the bag. Ensure that the swab has been placed far enough into the pouch as to not interfere with the sealing location.</p> <p>a. If the swab inadvertently punctures the pouch at any location, the pouch and label must be placed into the Device Assembly Waste bag. The swab should be packaged into a new pouch/label set.</p> <p>D. Carefully place the pouch between the seal bars so that the edge of the bag is parallel with the back end of the bottom seal bar. Seal the pouch using the settings identified in Step 22. Parameters for the heat sealer may be adjusted, as necessary, to ensure adequate seal. Document parameter adjustments if/when necessary in the Comments section of the batch record.</p> <p>E. Repeat Steps A – D for all 10 swabs from the same 400 mL Nalgene beaker.</p> <p>F. Visually confirm the seal integrity of all 10 swab pouches. Gently run a finger along the sealed end of each pouch to confirm the bag is sealed. Inspect the pouch for holes or tears.</p> <p>a. Pouches that pass inspection should be placed into an In-process Swabs box, sealed side down. Maximum of 50 pouches per divider lane. See Step 19 for specific box set-up directions if more boxes are necessary.</p> <p>b. Swabs should be removed from any pouches that fail inspection. The failed pouch with label will be placed into the poly bag labeled Device Assembly Waste. The swab must be re-packaged according to Steps A-F.</p> <p>G. Repeat steps A – F for each subsequent set of 10 prepared swabs until the target quantity of not less than 880 packaged & labeled swabs is reached.</p> <p>H. Pausing for end of day:</p> <p>a. All prepared swabs must complete the pouching and labeling operation.</p> <p>b. All in-process materials will be returned to their designated GMP storage location. Do not leave materials in the manufacturing room overnight.</p> <p>c. Record the temperature, relative humidity and room Magnehelic pressure in the table in Step 13.</p>	<p>Instructions read and understood by: (sign/date daily)</p> <p>TB 10/23/2020 JC 10/23/20 POF 10/23/20 JL 10/26/20 PJF 10/26/20 TJB 10/26/2020 PL 10/26/20 POF 10/27/20 JL 10/27/20 JC 10/28/20①</p>	

① Late Entry for 10/27/20 JC 10/28/20



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/23/2020 Initials: TB

Packaging Worksheet (for Steps 24 & 25):

Temperature, relative humidity, and Magnehelic pressure must be recorded in Step 13 at the start and end of each day, or each pause in activity. If previously recorded, indicate 'N/A' for the line entry, or else record all room data in Step 13 and indicate 'Yes.'

Target Dispensing Weight (mg)	74.0	Acceptable Range (mg):	71.0 – 77.0	Done By:	TB	Check By:	JC
-------------------------------	------	------------------------	-------------	----------	-----------	-----------	-----------

All operators have reviewed and understood instructions found in Steps 24 & 25 (initial/date, daily) <i>JL 10/23/20</i> <i>TB 10/23/20</i> <i>PJF 10/23/20</i>	Set #	Date	Room Data Recorded (Yes or N/A)	Swab/Cap Prepared By	Swab/Cap Verified By	Pouch Label Applied By	Pouch Label Verified By	Pouch Sealed By	Seal Verified By	Acceptable # Units	Room Data Recorded (Yes or N/A)	Recorded By	Checked By
	1	10/23/2020	Yes	POT	JC	JC	TB	TB	JL	10	N/A	TB	JC
	2	10/23/2020	N/A	POT	JC	JC	TB	TB	JL	10	N/A	TB	JC
	3	10/23/2020	N/A	PJF	JC	JL	TB	TB	JC	10	N/A	TB	JC
	4	10/23/2020	N/A	POT	JC	JC	TB	TB	JC	10	N/A	TB	JC
	5	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	6	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	7	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	8	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	9	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	10	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	11	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	12	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	13	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	14	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	N/A	TB	JC
	15	10/23/2020	N/A	TB	JC	JC	TB	JC	TB	10	Yes	TB	JC

A	Total # of units packaged (sum of 1-15):	# of units	Done by	Checked by
		150	TB	JC



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/26/20 Initials: PSF

Packaging Worksheet (for Steps 24 & 25, continued):

Temperature, relative humidity, and Magnehelic pressure must be recorded in Step 13 at the start and end of each day, or each pause in activity. If previously recorded, indicate 'N/A' for the line entry, or else record all room data in Step 13 and indicate 'Yes.'

Target Dispensing Weight (mg)	74.0	Acceptable Range (mg):		71.0 – 77.0		Done By:	TB	Check By:	PSF
-------------------------------	------	------------------------	--	-------------	--	----------	----	-----------	-----

All operators have reviewed and understood instructions found in Steps 24 & 25 (initial/date, daily) <i>PJF 10/26/20 JK 10/26/20 TB 10/26/2020 PC 10/26/20</i>	Set #	Date	Room Data Recorded (Yes or N/A)	Swab/Cap Prepared By	Swab/Cap Verified By	Pouch Label Applied By	Pouch Label Verified By	Pouch Sealed By	Seal Verified By	Acceptable # Units	Room Data Recorded (Yes or N/A)	Recorded By	Checked By
	16	10/26/20	Yes	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	17	10/26/20	^① Yes N/A	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	18	10/26/20	N/A	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	19	10/26/20	N/A	PSF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	20	10/26/20	N/A	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	21	10/26/20	N/A	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	22	10/26/20	N/A	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	23	10/26/20	N/A	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	24	10/26/20	N/A	PJF	JK	JK	TB	TB	JK	10	N/A	TB	JK
	25	10/26/20	N/A	PJF	JK	JK	TB	TB	PJF	10	N/A	TB	JK
	26	10/26/20	N/A	PJF	JK	JK	TB	TB	PJF	10	Yes	TB	JK
	27	10/26/2020	Yes	TB	PJF	PJF	JK	JK	PC	10	N/A	JK	PC
	28	10/26/2020	N/A	TB	POF	POF	JK	JK	PC	10	N/A	JK	PC
	29	10/26/2020	N/A	TB	PJF	PJF	JK	JK	PC	10	N/A	JK	PC
	30	10/26/2020	N/A	TB	PJF	PJF	JK	JK	PC	10	N/A	JK	PC

	# of units	Done by	Checked by
B Total # of units packaged (sum of 16-30):	150	TB	PSF

^①PSF 10/26/20 JK(10/26/20)



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/26/2020 Initials: TB

Packaging Worksheet (for Steps 24 & 25, continued):

Temperature, relative humidity, and Magnehelic pressure must be recorded in Step 13 at the start and end of each day, or each pause in activity. If previously recorded, indicate 'N/A' for the line entry, or else record all room data in Step 13 and indicate 'Yes.'

Target Dispensing Weight (mg)	74.0	Acceptable Range (mg):		71.0 – 77.0		Done By:	TB	Check By:	JH
-------------------------------	------	------------------------	--	-------------	--	----------	----	-----------	----

All operators have reviewed and understood instructions found in Steps 24 & 25 (initial/date, daily)	Set #	Date	Room Data Recorded (Yes or N/A)	Swab/Cap Prepared By	Swab/Cap Verified By	Pouch Label Applied By	Pouch Label Verified By	Pouch Sealed By	Seal Verified By	Acceptable # Units	Room Data Recorded (Yes or N/A)	Recorded By	Checked By
	31	10/26/2020	Yes	TB	PJF	PJF	POF	JJC	PC	10	N/A	JJC	TB
TB 10/26/2020	32	10/26/2020	N/A	TB	PC	PJF	PJF	JJC	PC	10	N/A	JJC	TB
PC 10/26/2020	33	10/26/2020	N/A	TB	PC	POF	PJF	JJC	PC	10	N/A	JJC	TB
JJC 10/26/2020	34	10/26/2020	N/A	TB	PC	PJF	PJF	JJC	PC	10	N/A	JJC	TB
POF 10/26/2020	35	10/26/2020	N/A	TB	PC	POF	PJF	JJC	PC	10	N/A	JJC	TB
	36	10/26/2020	N/A	TB	PC	POF	POF	JJC	PC	10	N/A	JJC	TB
	37	10/26/2020	N/A	TB	PC	POF	POF	JJC	PC	10	N/A	JJC	TB
	38	10/26/2020	N/A	TB	PC	POF	POF	JJC	PC	10	N/A	JJC	TB
	39	10/26/2020	N/A	TB	PC	POF	POF	JJC	PC	10	N/A	JJC	TB
	40	10/26/2020	N/A	TB	PC	POF	POF	JJC	PC	10	N/A	JJC	TB
	41	10/26/2020	N/A	TB	PC	POF	POF	JJC	PC	10	N/A	JJC	TB
	42	10/26/2020	N/A	TB	PC	POF	PJF	JJC	PC	10	N/A	JJC	TB
	43	10/26/2020	N/A	TB	PC	PJF	PJF	JJC	PC	10	N/A	JJC	TB
	44	10/26/2020	N/A	TB	PC	POT	POT	JJC	PC	10	N/A	JJC	TB
	45	10/26/2020	N/A	TB	PC	POF	POF	JJC	PC	10	N/A	JJC	TB

	# of units	Done by	Checked by
C Total # of units packaged (sum of 31-45):	150	TB	JJC



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/26/2020 Initials: TB

Packaging Worksheet (for Steps 24 & 25, continued):

Temperature, relative humidity, and Magnehelic pressure must be recorded in Step 13 at the start and end of each day, or each pause in activity. If previously recorded, indicate 'N/A' for the line entry, or else record all room data in Step 13 and indicate 'Yes.'

Target Dispensing Weight (mg)	74.0	Acceptable Range (mg):		71.0 – 77.0	Done By:	TB	Check By:	JH
-------------------------------	------	------------------------	--	-------------	----------	----	-----------	----

All operators have reviewed and understood instructions found in Steps 24 & 25 (initial/date, daily)	Set #	Date	Room Data Recorded (Yes or N/A)	Swab/Cap Prepared By	Swab/Cap Verified By	Pouch Label Applied By	Pouch Label Verified By	Pouch Sealed By	Seal Verified By	Acceptable # Units	Room Data Recorded (Yes or N/A)	Recorded By	Checked By
	46	10/26/2020	Yes	JH	PC	TB	POF	POF	TB	10	N/A	TB	JH
TB 10/26/2020 JH 10/26/2020 PC 10/26/2020 POF 10/26/20	47	10/26/2020	N/A	JH	PC	TB	POF	POF	TB	10	N/A	TB	JH
	48	10/26/2020	N/A	JH	PC	TB	POF	POF	JH	10	N/A	TB	JH
	49	10/26/2020	N/A	JH	PC	TB	POF	POF	JH	10	N/A	TB	JH
	50	10/26/2020	N/A	JH	PC	TB	POF	POF	JH	10	N/A	TB	JH
	51	10/26/2020	N/A	JH	PC	TB	POF	POF	JH	10	N/A	TB	JH
	52	10/26/2020	N/A	JH	PC	TB	POF	POF	JH	10	N/A	TB	JH
	53	10/26/2020	N/A	JH	PC	JH	TB	JH	TB	10	N/A	TB	JH
	54	10/26/2020	N/A	TB	JH	JH	TB	JH	TB	10	N/A	TB	JH
	55	10/26/2020	N/A	TB	JH	JH	TB	JH	TB	10	N/A	TB	JH
	56	10/26/2020	N/A	TB	JH	JH	TB	JH	TB	10	N/A	TB	JH
	57	10/26/2020	N/A	TB	JH	JH	TB	JH	TB	10	N/A	TB	JH
	58	10/26/2020	N/A	TB	JH	JH	TB	JH	TB	10	N/A	TB	JH
	59	10/26/2020	N/A	TB	JH	JH	TB	JH	TB	10	N/A	TB	JH
	60	10/26/2020	N/A	TB	JH	JH	TB	JH	TB	10	N/A	TB	JH

	# of units	Done by	Checked by
D Total # of units packaged (sum of 46-60):	150	TB	JH



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

Date Executed: 10/26/2020 Initials: TB

Packaging Worksheet (for Steps 24 & 25, continued):

Temperature, relative humidity, and Magnehelic pressure must be recorded in Step 13 at the start and end of each day, or each pause in activity. If previously recorded, indicate 'N/A' for the line entry, or else record all room data in Step 13 and indicate 'Yes.'

Target Dispensing Weight (mg)	74.0	Acceptable Range (mg):		71.0 – 77.0		Done By:	TB	Check By:	SJL
-------------------------------	------	------------------------	--	-------------	--	----------	----	-----------	-----

All operators have reviewed and understood instructions found in Steps 24 & 25 (initial/date, daily)	Set #	Date	Room Data Recorded (Yes or N/A)	Swab/Cap Prepared By	Swab/Cap Verified By	Pouch Label Applied By	Pouch Label Verified By	Pouch Sealed By	Seal Verified By	Acceptable # Units	Room Data Recorded (Yes or N/A)	Recorded By	Checked By
	61	10/26/2020	Yes	TB	SJL	SJL	TB	SJL	TB	10	N/A	TB	SJL
TB 10/26/2020 SJL 10/26/20	62	10/26/2020	N/A	TB	SJL	SJL	TB	SJL	TB	10	N/A	TB	SJL
PJF 10/27/20 SJL 10/27/20	63	10/26/2020	N/A	TB	SJL	SJL	TB	SJL	TB	10	N/A	TB	SJL
	64	10/26/2020	N/A	TB	SJL	SJL	TB	SJL	TB	10	N/A	TB	SJL
	65	10/26/2020	N/A	TB	SJL	SJL	TB	SJL	TB	10	N/A	TB	SJL
	66	10/26/2020	N/A	TB	SJL	SJL	TB	SJL	TB	10	Yes	TB	SJL
	67	10/27/2020	Yes	PJF	SJL	SJL	POF	SJL	POF	10	N/A	SJL	POF
	68	10/27/2020	N/A	PJF	SJL	SJL	POF	SJL	POF	10	N/A	SJL	POF
	69	10/27/2020	N/A	POF	SJL	SJL	POF	SJL	POF	10	N/A	SJL	POF
	70	10/27/2020	N/A	PJF	SJL	SJL	POF	SJL	POF	10	N/A	SJL	POF
	71	10/27/2020	N/A	POF	SJL	SJL	POF	SJL	PJF	10	N/A	SJL	POF
	72	10/27/2020	N/A	POF	SJL	SJL	PJF	SJL	PJF	10	N/A	SJL	POF
	73	10/27/2020	N/A	PJF	SJL	SJL	POF	SJL	POF	10	N/A	SJL	POF
	74	10/27/2020	N/A	POF	SJL	SJL	POF	SJL	PJF	10	N/A	SJL	POF
	75	10/27/2020	N/A	POF	SJL	SJL	POF	SJL	POF	10	N/A	SJL	POF

	# of units	Done by	Checked by
E Total # of units packaged (sum of 61-75):	150	POF	SJL



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

Date Executed: 10/27/20 Initials: POT

Packaging Worksheet (for Steps 24 & 25, continued):

Temperature, relative humidity, and Magnehelic pressure must be recorded in Step 13 at the start and end of each day, or each pause in activity. If previously recorded, indicate 'N/A' for the line entry, or else record all room data in Step 13 and indicate 'Yes.'

Target Dispensing Weight (mg)	74.0	Acceptable Range (mg):		71.0 – 77.0	Done By:		<u>POT</u>	Check By:		<u>JL</u>
-------------------------------	------	------------------------	--	-------------	----------	--	------------	-----------	--	-----------

All operators have reviewed and understood instructions found in Steps 24 & 25 (initial/date, daily) <i>POT 10/27/20 JL 10/27/20 JC 10/27/20</i>	Set #	Date	Room Data Recorded (Yes or N/A)	Swab/Cap Prepared By	Swab/Cap Verified By	Pouch Label Applied By	Pouch Label Verified By	Pouch Sealed By	Seal Verified By	Acceptable # Units	Room Data Recorded (Yes or N/A)	Recorded By	Checked By
	76	<i>10/26/2020</i>	<i>Yes</i>	<u>POT</u>	<u>JL</u>	<u>JL</u>	<u>POT</u>	<u>JL</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	77	<i>10/26/2020</i>	<i>N/A</i>	<u>POT</u>	<u>JL</u>	<u>JL</u>	<u>POT</u>	<u>JL</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	78	<i>10/26/2020</i>	<i>N/A</i>	<u>POT</u>	<u>JL</u>	<u>JL</u>	<u>POT</u>	<u>JL</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	79	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	80	<i>10/27/20</i>	<i>N/A</i>	<i>① PTF JL</i>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	81	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	82	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	83	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	84	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	85	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	86	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	87	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>N/A</i>	<u>JL</u>	<u>POT</u>
	88	<i>10/27/20</i>	<i>N/A</i>	<u>JL</u>	<u>POT</u>	<u>POT</u>	<u>JC</u>	<u>JC</u>	<u>POT</u>	10	<i>Yes</i>	<u>JL</u>	<u>POT</u>

	# of units	Done by	Checked by
F Total # of units packaged (sum of 76-88):	130	<u>JL</u>	<u>POT</u>

① N/A POT 10/27/20 JL 10/27/20

② 10/27/20 POT 10/27/20 JL 10/27/20



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/27/20 Initials: JL

Step	Description	Done by	Checked by																														
26	Number of units packaged: <u>880</u> units (Sum of Totals on Packaging Worksheet(s), Steps 24 & 25, A + B + C + D + E + F)	<u>JL</u>	<u>POT</u>																														
27	<p>QA Inspection of Packaging:</p> <p>QA will perform a 100% visual seal inspection, label, and swab orientation check. Pouches will be inspected for damage, punctures and tears. The sealed edge will be visually inspected to confirm a complete seal has been made. All swabs should be oriented with the cap end closest to the straight impulse sealed edge. QA will instruct operators to re-package and re-label the swab if there is damage or the swab was inserted in the incorrect direction. If required, perform re-packaging & re-labeling below.</p> <p>QA will verify all pouches have been labeled and the labels are neat and legible. If a pouch label is rejected due to illegible text or label positioning, QA may instruct operators to remove failed label and affix a new label. If required, perform relabeling below.</p> <table border="1"> <thead> <tr> <th></th> <th>Number of Units</th> <th>Done By</th> <th>Checked By</th> <th>QA Initials</th> </tr> </thead> <tbody> <tr> <td>A Number of pouch seals & labels checked</td> <td><u>880</u></td> <td></td> <td></td> <td><u>DC RD</u></td></tr> <tr> <td>B Initial number of units accepted</td> <td><u>879</u></td> <td></td> <td></td> <td><u>DC RD</u></td></tr> <tr> <td>C Initial number of units rejected</td> <td><u>1</u></td> <td></td> <td></td> <td><u>DC RD</u></td></tr> <tr> <td>D Number of repackaged and/or relabeled</td> <td><u>1</u></td> <td><u>JL</u></td> <td><u>POT</u></td> <td><u>DC RD</u></td></tr> <tr> <td>E Total number of units accepted (B + D)</td> <td><u>880</u></td> <td></td> <td></td> <td><u>DC RD</u></td></tr> </tbody> </table> <p>Place empty pouches and removed/damaged labels into Device Assembly Waste (✓ or N/A) (<u>✓</u>).</p> <p>Place units from rejected pouches not successfully repackaged or relabeled into the poly bag labeled Device Assembly Waste (✓ or N/A) (<u>✓</u>).</p>		Number of Units	Done By	Checked By	QA Initials	A Number of pouch seals & labels checked	<u>880</u>			<u>DC RD</u>	B Initial number of units accepted	<u>879</u>			<u>DC RD</u>	C Initial number of units rejected	<u>1</u>			<u>DC RD</u>	D Number of repackaged and/or relabeled	<u>1</u>	<u>JL</u>	<u>POT</u>	<u>DC RD</u>	E Total number of units accepted (B + D)	<u>880</u>			<u>DC RD</u>	<u>JL</u>	<u>JC</u>
	Number of Units	Done By	Checked By	QA Initials																													
A Number of pouch seals & labels checked	<u>880</u>			<u>DC RD</u>																													
B Initial number of units accepted	<u>879</u>			<u>DC RD</u>																													
C Initial number of units rejected	<u>1</u>			<u>DC RD</u>																													
D Number of repackaged and/or relabeled	<u>1</u>	<u>JL</u>	<u>POT</u>	<u>DC RD</u>																													
E Total number of units accepted (B + D)	<u>880</u>			<u>DC RD</u>																													
28	Determine the quantity of pouch labels remaining and return to QA for GMP storage. Quantity remaining: <u>1115</u> pouch labels	<u>JL</u>	<u>JC</u>																														
29	Determine and record the number of pouch labels in Device Assembly Waste . Quantity: <u>4</u> waste pouch labels	<u>JL</u>	<u>JC</u>																														



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

PC OCT 23 2020

Date Executed: 10/27/20

Initials: JL

Step	Description	Done by	Checked by																																				
30	QA verification of remaining pouch label quantity: Quantity received: <u>115</u> pouch labels QA Initials / Date: <u>DC 10/27/20</u>																																						
31	Determine and record the number of waste swabs in Device Assembly Waste . Quantity: <u>1</u> waste swabs	<i>JL</i>	<i>JL</i>																																				
32	Prepare 2 boxes (12 x 12 x 12") lined with poly bags with attached label for 4 mg Naloxone HCl Nasal Swabs (Finished Product Retain) . Ensure the box labels includes the following: Batch Record#: M4097-01B Material: 4 mg Naloxone HCl Nasal Swabs (Finished Product Retain) Receiving #: N/A Lot #: 4097-01 Net Quantity: units Initials/Date : Retain Expiration date: (10 years from current date) Retain Box ___ of ___ Update the affixed duplicate labels in the in-process section of the batch record (✓) (<u> </u>).	<i>JL</i>	<i>JL</i>																																				
33	With QA present, neatly place the required quantity of units into the boxes prepared in Step 32 lined with poly bags. Use two 12" cardboard dividers to create 3 lanes in the boxes. Swab pouches are to be stored upright with the cap side down in the boxes, with no more than 40 pouches per lane. After the quantities in each box are verified by QA, seal the boxes with packing tape. Record the total number of units in the boxes in the below table:																																						
	<table border="1"> <thead> <tr> <th>Retain Box Number</th> <th>Required Number of Units</th> <th>Number of Units Added</th> <th>Box Label Updated (✓)</th> <th>Duplicate Label Updated (✓)</th> <th>Box Sealed (✓)</th> <th>Done By</th> <th>Checked By</th> <th>QA Verified By</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>100</td> <td><u>100</u></td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>JL</i></td> <td><i>JL</i></td> <td><i>DC</i></td> </tr> <tr> <td>2</td> <td>100</td> <td><u>100</u></td> <td>✓</td> <td>✓</td> <td>-</td> <td><i>JL</i></td> <td><i>JL</i></td> <td><i>DC</i></td> </tr> <tr> <td>Total</td> <td>200</td> <td><u>200</u></td> <td></td> <td></td> <td></td> <td><i>JL</i></td> <td><i>JL</i></td> <td><i>DC</i></td> </tr> </tbody> </table>	Retain Box Number	Required Number of Units	Number of Units Added	Box Label Updated (✓)	Duplicate Label Updated (✓)	Box Sealed (✓)	Done By	Checked By	QA Verified By	1	100	<u>100</u>	✓	✓	✓	<i>JL</i>	<i>JL</i>	<i>DC</i>	2	100	<u>100</u>	✓	✓	-	<i>JL</i>	<i>JL</i>	<i>DC</i>	Total	200	<u>200</u>				<i>JL</i>	<i>JL</i>	<i>DC</i>		
Retain Box Number	Required Number of Units	Number of Units Added	Box Label Updated (✓)	Duplicate Label Updated (✓)	Box Sealed (✓)	Done By	Checked By	QA Verified By																															
1	100	<u>100</u>	✓	✓	✓	<i>JL</i>	<i>JL</i>	<i>DC</i>																															
2	100	<u>100</u>	✓	✓	-	<i>JL</i>	<i>JL</i>	<i>DC</i>																															
Total	200	<u>200</u>				<i>JL</i>	<i>JL</i>	<i>DC</i>																															



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/27/20 Initials: JL

Step	Description						Done by	Checked by																																																																								
34	<p>Prepare 6 boxes (12 x 12 x 12") lined with poly bags with attached label for 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability). Ensure the box label(s) includes the following:</p> <p>Batch Record#: M4097-01B Material: 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability) Receiving #: N/A Lot #: 4097-01 Net Quantity: units Initials/Date : Release/Micro/Stability Box ___ of ___</p> <p>Update the affixed duplicate labels in the in-process section of the batch record (✓) (<input checked="" type="checkbox"/>).</p>						<i>JL</i>	<i>JC</i>																																																																								
35	<p>With QA present, neatly place the required quantity of units into the boxes prepared in Step 34 lined with poly bags. Use two 12" cardboard dividers to create 3 lanes in the boxes. Swab pouches are to be stored upright with the cap side down in the boxes, with no more than 40 pouches per lane. After the quantities in each box are verified by QA, seal the boxes with packing tape.</p> <p>Record the total number of units in the boxes in the below table:</p> <table border="1"> <thead> <tr> <th>Release/Micro/ Stability Box Number</th> <th>Required Number of Units</th> <th>Number of Units Added</th> <th>Box Label Updated (✓)</th> <th>Duplicate Label Updated (✓)</th> <th>Box Sealed (✓)</th> <th>Done By</th> <th>Checked By</th> <th>QA Verified By</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>107</td> <td>107</td> <td>/</td> <td>✓</td> <td>/</td> <td><i>JL</i></td> <td><i>JC</i></td> <td><i>DC</i></td> </tr> <tr> <td>2</td> <td>107</td> <td>107</td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>JL</i></td> <td><i>JC</i></td> <td><i>DC</i></td> </tr> <tr> <td>3</td> <td>107</td> <td>107</td> <td>✓</td> <td>/</td> <td>/</td> <td><i>JL</i></td> <td><i>JC</i></td> <td><i>DC</i></td> </tr> <tr> <td>4</td> <td>107</td> <td>107</td> <td>✓</td> <td>✓</td> <td>/</td> <td><i>JL</i></td> <td><i>JC</i></td> <td><i>DC</i></td> </tr> <tr> <td>5</td> <td>107</td> <td>107</td> <td>✓</td> <td>/</td> <td>/</td> <td><i>JL</i></td> <td><i>JC</i></td> <td><i>DC</i></td> </tr> <tr> <td>6</td> <td>105</td> <td>105</td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>JL</i></td> <td><i>JC</i></td> <td><i>DC</i></td> </tr> <tr> <td>Total</td> <td>640</td> <td>640</td> <td></td> <td></td> <td></td> <td><i>JL</i></td> <td><i>JC</i></td> <td><i>DC</i></td> </tr> </tbody> </table>	Release/Micro/ Stability Box Number	Required Number of Units	Number of Units Added	Box Label Updated (✓)	Duplicate Label Updated (✓)	Box Sealed (✓)	Done By	Checked By	QA Verified By	1	107	107	/	✓	/	<i>JL</i>	<i>JC</i>	<i>DC</i>	2	107	107	✓	✓	✓	<i>JL</i>	<i>JC</i>	<i>DC</i>	3	107	107	✓	/	/	<i>JL</i>	<i>JC</i>	<i>DC</i>	4	107	107	✓	✓	/	<i>JL</i>	<i>JC</i>	<i>DC</i>	5	107	107	✓	/	/	<i>JL</i>	<i>JC</i>	<i>DC</i>	6	105	105	✓	✓	✓	<i>JL</i>	<i>JC</i>	<i>DC</i>	Total	640	640				<i>JL</i>	<i>JC</i>	<i>DC</i>							
Release/Micro/ Stability Box Number	Required Number of Units	Number of Units Added	Box Label Updated (✓)	Duplicate Label Updated (✓)	Box Sealed (✓)	Done By	Checked By	QA Verified By																																																																								
1	107	107	/	✓	/	<i>JL</i>	<i>JC</i>	<i>DC</i>																																																																								
2	107	107	✓	✓	✓	<i>JL</i>	<i>JC</i>	<i>DC</i>																																																																								
3	107	107	✓	/	/	<i>JL</i>	<i>JC</i>	<i>DC</i>																																																																								
4	107	107	✓	✓	/	<i>JL</i>	<i>JC</i>	<i>DC</i>																																																																								
5	107	107	✓	/	/	<i>JL</i>	<i>JC</i>	<i>DC</i>																																																																								
6	105	105	✓	✓	✓	<i>JL</i>	<i>JC</i>	<i>DC</i>																																																																								
Total	640	640				<i>JL</i>	<i>JC</i>	<i>DC</i>																																																																								



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

Date Executed: 10/27/20

Initials: JL

Step	Description	Done by	Checked by																								
36	<p>Clinical Box Labels must contain the following information.</p> <p>Box _____ of _____ Batch Record: M4097-01B Material: 4 mg Naloxone HCl Nasal Swabs Lot: 4097-01 Storage Condition: Controlled Room Temperature Net Quantity: _____ units (1 swab/pouch) Initials/date: _____ Caution - Limited by federal (US) law to investigational use</p> <p style="text-align: right; transform: rotate(-90deg);">JL/10/27/20</p>	<p>Box _____ of _____ Batch Record: M4097-01B Material: 4 mg Naloxone HCl Nasal Swabs Lot: 4097-01 Storage Condition: Controlled Room Temperature Net Quantity: _____ units (1 swab/pouch) Initials/date: _____ Caution - Limited by federal (US) law to investigational use</p>	<p>JL</p> <p>JL</p>																								
37	<p>With QA present, neatly place the required quantity of units into a 10 x 10 x 10" box lined with a poly bag. Affix a box label as shown in Step 36 onto the box. Use two 10" cardboard dividers to create 3 lanes in the boxes. Swab pouches are to be stored upright with the cap side down in the boxes, with no more than 20 pouches per lane. After the quantities in each box are verified by QA, seal the boxes with packing tape.</p> <p>Record the total number of units in boxes in the below table:</p> <table border="1"> <thead> <tr> <th>Clinical Box Number</th> <th>Minimum Required Number of Units</th> <th>Number of Units Added</th> <th>Box Label Updated (✓)</th> <th>Box Sealed (✓)</th> <th>Done By</th> <th>Checked By</th> <th>QA Verified By</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>40</td> <td>40</td> <td>✓</td> <td>✓</td> <td>JL</td> <td>JL</td> <td>JL</td> </tr> <tr> <td>Total</td> <td>40</td> <td>40</td> <td></td> <td></td> <td>JL</td> <td>JL</td> <td>JL</td> </tr> </tbody> </table>	Clinical Box Number	Minimum Required Number of Units	Number of Units Added	Box Label Updated (✓)	Box Sealed (✓)	Done By	Checked By	QA Verified By	1	40	40	✓	✓	JL	JL	JL	Total	40	40			JL	JL	JL		
Clinical Box Number	Minimum Required Number of Units	Number of Units Added	Box Label Updated (✓)	Box Sealed (✓)	Done By	Checked By	QA Verified By																				
1	40	40	✓	✓	JL	JL	JL																				
Total	40	40			JL	JL	JL																				



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

Date Executed: 10/27/20

Initials: JK

Step	Description				Done by	Checked by
38	With QA present, seal the cardboard box from Step 37 with security tape across both top and bottom of tape seals on the box.					
	Box number	Security Tape Serial Number (Top Seal)	Security Tape Serial Number (Bottom Seal)	Done By	Checked By	QA Verified By
	1	A7436506	A7436567	JK	JC	OC
39	Determine and record the number of clinical box labels remaining: <u>3</u> box labels				JK	JC
40	Determine and record the number of box labels in Device Assembly Waste .				JK	JC
	Quantity: <u>0</u>	waste box labels			JK	JC
41	Determine the net quantity of Filtered Naloxone Solution remaining.				JK	JC
	Gross Weight (includes bottle and cap)	<u>1125.30</u>	grams			
	Tare weight of container (from label)	<u>587.09</u>	grams			
	Net Quantity (gross – tare)	<u>538.21</u>	grams			
	Balance Minimum Weight	<u>24</u>				
	Balance ID	<u>A45</u>				
	Update the bottle label with the new net quantity (✓) (<u>✓</u>).					



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OK

OCT 23 2020

Date Executed: 10/27/20 Initials: SL

Step	Description	Done by	Checked by																				
42	<p>Collect any remaining solution waste into the container labeled Naloxone Solution Waste. Determine the net quantity collected.</p> <table border="1"> <tr> <td>Gross Weight</td><td><u>595.56</u></td><td>grams</td></tr> <tr> <td>Tare Weight (with lid)</td><td><u>550.15</u></td><td>grams</td></tr> <tr> <td>Net Quantity (gross – tare)</td><td><u>45.41</u></td><td>grams</td></tr> <tr> <td>Balance Minimum Weight</td><td><u>2g</u></td><td></td></tr> <tr> <td>Balance ID</td><td><u>A145</u></td><td></td></tr> </table> <p>Update the container label (✓) (<u>✓</u>). Update the affixed duplicate label in the in-process section of the batch record (✓) (<u>✓</u>).</p>	Gross Weight	<u>595.56</u>	grams	Tare Weight (with lid)	<u>550.15</u>	grams	Net Quantity (gross – tare)	<u>45.41</u>	grams	Balance Minimum Weight	<u>2g</u>		Balance ID	<u>A145</u>		<i>SL</i>	<i>JC</i>					
Gross Weight	<u>595.56</u>	grams																					
Tare Weight (with lid)	<u>550.15</u>	grams																					
Net Quantity (gross – tare)	<u>45.41</u>	grams																					
Balance Minimum Weight	<u>2g</u>																						
Balance ID	<u>A145</u>																						
43	<p>Packaged Swab Reconciliation:</p> <table border="1"> <tr> <td>A</td><td>Number of swabs packaged (Step 27E)</td><td><u>880</u></td><td>swabs</td></tr> <tr> <td>B</td><td>Number of Finished Product Retain swabs packaged (Step 33, Total)</td><td><u>200</u></td><td>swabs</td></tr> <tr> <td>C</td><td>Number of Release/Micro/Stability swabs packaged (Step 35, Total)</td><td><u>640</u></td><td>swabs</td></tr> <tr> <td>D</td><td>Number of Clinical swabs packaged (Step 37, Total)</td><td><u>40</u></td><td>swabs</td></tr> <tr> <td>E</td><td>% Accountability (B + C + D) / A × 100 Note: Accountability should be 100%. If not 100%, notify QA.</td><td><u>100</u></td><td>%</td></tr> </table>	A	Number of swabs packaged (Step 27E)	<u>880</u>	swabs	B	Number of Finished Product Retain swabs packaged (Step 33, Total)	<u>200</u>	swabs	C	Number of Release/Micro/Stability swabs packaged (Step 35, Total)	<u>640</u>	swabs	D	Number of Clinical swabs packaged (Step 37, Total)	<u>40</u>	swabs	E	% Accountability (B + C + D) / A × 100 Note: Accountability should be 100%. If not 100%, notify QA.	<u>100</u>	%	<i>SL</i> <i>JC</i> <i>10/28/20</i>	
A	Number of swabs packaged (Step 27E)	<u>880</u>	swabs																				
B	Number of Finished Product Retain swabs packaged (Step 33, Total)	<u>200</u>	swabs																				
C	Number of Release/Micro/Stability swabs packaged (Step 35, Total)	<u>640</u>	swabs																				
D	Number of Clinical swabs packaged (Step 37, Total)	<u>40</u>	swabs																				
E	% Accountability (B + C + D) / A × 100 Note: Accountability should be 100%. If not 100%, notify QA.	<u>100</u>	%																				



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

M4097-01B

Issued By/ Date:

OCT 28 2020

Date Executed: 10/28/20

Initials: JL

Step	Description			Done by	Checked by
44	Swab Label Reconciliation:				
A	Number of pouch labels issued (Step 2E)	<u>2000</u>	labels		
B	Number of pouch labels affixed to the batch record (Step 4)	<u>1</u>	labels		
C	Number of pouch labels on acceptable pouches (Step 27E)	<u>880</u>	labels		
D	Number of pouch labels remaining (Step 28)	<u>1115</u>	labels		
E	Number of waste pouch labels (Step 29)	<u>4</u>	labels		
F	% Accountability $(B + C + D + E) / A \times 100$	<u>100</u>	%		
	Note: Accountability should be 100%. If not 100%, notify QA.				
45	Clinical Box Labels Reconciliation:				
A	Number of clinical box labels issued (Step 2F)	<u>5</u>	labels		
B	Number of box labels affixed to the batch record (Step 36)	<u>1</u>	labels		
C	Number of box labels on box(es) (Step 37)	<u>1</u>	labels		
D	Number of box labels remaining (Step 39)	<u>3</u>	labels		
E	Number of waste box labels (Step 40)	<u>0</u>	labels		
F	% Accountability $(B + C + D + E) / A \times 100$	<u>100</u>	%		
	Note: Accountability should be 100%. If not 100%, notify QA.				



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

Date Executed: 10/28/20 Initials: JL

Step	Description	Done by	Checked by																												
46	Naloxone Solution Reconciliation: <table border="1"> <tr> <td>A</td><td>Net quantity of solution issued (Step 2A)</td><td><u>677.24</u></td><td>grams</td></tr> <tr> <td>B</td><td>Net quantity of solution packaged (Step 27E x 0.074g)</td><td><u>65.12</u></td><td>grams</td></tr> <tr> <td>C</td><td>Net quantity of solution on waste swabs (Step 31 x 0.074g)</td><td><u>0.874</u></td><td>grams</td></tr> <tr> <td>D</td><td>Net quantity of remaining solution (Step 41)</td><td><u>538.21</u></td><td>grams</td></tr> <tr> <td>E</td><td>Net quantity of waste solution (Step 42)</td><td><u>45.41</u></td><td>grams</td></tr> <tr> <td>F</td><td>% Accountability $(B + C + D + E) / A \times 100$</td><td><u>96</u></td><td>%</td></tr> <tr> <td>G</td><td>Note: Accountability should be $\geq 90\%$ and $\leq 101\%$. Notify QA if < 90% or > 101%. % Yield (For Informational Purposes Only) $(B) / (A - D) \times 100$</td><td><u>47</u></td><td>%</td></tr> </table>	A	Net quantity of solution issued (Step 2A)	<u>677.24</u>	grams	B	Net quantity of solution packaged (Step 27E x 0.074g)	<u>65.12</u>	grams	C	Net quantity of solution on waste swabs (Step 31 x 0.074g)	<u>0.874</u>	grams	D	Net quantity of remaining solution (Step 41)	<u>538.21</u>	grams	E	Net quantity of waste solution (Step 42)	<u>45.41</u>	grams	F	% Accountability $(B + C + D + E) / A \times 100$	<u>96</u>	%	G	Note: Accountability should be $\geq 90\%$ and $\leq 101\%$. Notify QA if < 90% or > 101%. % Yield (For Informational Purposes Only) $(B) / (A - D) \times 100$	<u>47</u>	%	<i>JL</i>	<i>PJF</i>
A	Net quantity of solution issued (Step 2A)	<u>677.24</u>	grams																												
B	Net quantity of solution packaged (Step 27E x 0.074g)	<u>65.12</u>	grams																												
C	Net quantity of solution on waste swabs (Step 31 x 0.074g)	<u>0.874</u>	grams																												
D	Net quantity of remaining solution (Step 41)	<u>538.21</u>	grams																												
E	Net quantity of waste solution (Step 42)	<u>45.41</u>	grams																												
F	% Accountability $(B + C + D + E) / A \times 100$	<u>96</u>	%																												
G	Note: Accountability should be $\geq 90\%$ and $\leq 101\%$. Notify QA if < 90% or > 101%. % Yield (For Informational Purposes Only) $(B) / (A - D) \times 100$	<u>47</u>	%																												
47	Record the current room temperature, relative humidity, and Magnehelic pressure reading in the table in Step 13 (✓) (<u>✓</u>).	<i>JL</i>	<i>PJF</i>																												
48	Remove the chart recorder paper and store it with the batch record. Record the date, current time, and initials on the chart recorder paper. Update the "Attachments List" in the Technical Review section of this batch record to indicate that the chart paper has been filed with the record (✓) (<u>✓</u>).	<i>JL</i>	<i>PJF</i>																												
49	QA Final In-Process Check: All steps have been completed and all in-process specifications have been met (✓) (<u>✓</u>). Content on all labels has been verified (✓) (<u>✓</u>). QA Initials / Date: <u>DC 10/28/20</u>																														



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

VII. In-Process Section:

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: 6 Sock 1/8ZF/WHT EXT HDL (For M4097-01B)

Receiving#: R200724-01A

Lot#: IAQ8Z-2020-05-07

Tare Weight: *N/A*

Net Quantity: *930 Swabs*

Material Exp. 7/24/2025

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: 6 Sock 1/8ZF/WHT EXT HDL (For M4097-12)

Receiving#: R200724-01A

Lot#: IAQ8Z-2020-05-07

Tare Weight: *N/A*

Net Quantity: *980 Swabs*

Material Exp. 7/24/2025

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

DMS 06 Nov 2020

① L.E. for 10/23/2020. TB 10/28/2020

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: 6 Sock 1/8ZF/WHT EXT HDL (For M4097-23)

Receiving#: R200724-01A

Lot#: IAQ8Z-2020-05-07

Tare Weight: *N/A*

Net Quantity: *930 Swabs*

Material Exp. 7/24/2025

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: A3333 2 3/4" x 10" Peelable Pouches (For M4097-01B)

Receiving#: R200825-01A

Lot#: 1092933

Tare Weight: *N/A*

Net Quantity: *980 Pouches*

Material Exp. 8/25/2025

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: A3333 2 3/4" x 10" Peelable Pouches (For M4097-12, Bag 1 of 2)

Receiving#: R200825-01A

Lot#: 1092933

Tare Weight: *N/A*

Net Quantity: *872 Pouches*

Material Exp. 8/25/2025

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OK OCT 23 2020

VII. In-Process Section (Continued):

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: A3333 2 3/4" x 10" Peelable Pouches (For M4097-23)

Receiving#: R200825-01B

Lot#: 1092933

Tare Weight: *N/A*

Net Quantity: *980 Pouches*

Material Exp: 8/15/2025

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: Pro-fax PF511 Natural Caps (For M4097-01B, Bag 1 of 2)

Receiving#: R200902-01A

Lot#: 235665

Tare Weight: *N/A*

Net Quantity: *847 caps*

Material Exp: 9/2/2021

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

TB 10/23/2020

DMS 06 Nov 2020

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: Pro-fax PF511 Natural Caps (For M4097-01B, Bag 2 of 2)

Receiving#: R200902-01B

Lot#: 235665

Tare Weight: *N/A*

Net Quantity: *83 caps*

Material Exp: 9/2/2021

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: Pro-fax PF511 Natural Caps (For M4097-12, Bag 1 of 2)

Receiving#: R200902-01B

Lot#: 235665

Tare Weight: *N/A*

Net Quantity: *914 caps*

Material Exp.: 9/2/2021

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

Clinical Batch In Process Label

TB 10/23/2020

Batch Record#: M4097-01B

Material: Pro-fax PF511 Natural Caps (For M4097-12, Bag 2 of 2)

Receiving#: R200902-01C

Lot#: 235665

Tare Weight: *N/A*

Net Quantity: *66 caps*

Material Exp.: 9/2/2021

Initials/Date: *TB 10/23/2020*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: Pro-fax PF511 Natural Caps (For M4097-23)

Receiving#: R200902-01C

Lot#: 235665

Tare Weight: *N/A*

Net Quantity: *931 caps*

Initials/Date: *TB 10/23/2020*

Material Exp.: 9/2/2021

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020
OC

VII. In-Process Section (Continued):

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: Device Assembly Waste

Receiving#: N/A

Lot#: N/A

Tare Weight: *N/A*

Net Quantity: *N/A*

Initials/Date: *JL 10/23/20*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

JL 10/23/20

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: Naloxone Solution Waste

Receiving#: N/A

Lot#: N/A

Tare Weight: *550.15g*

Net Quantity: *45.41g*

Initials/Date: *JL 10/23/20*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

JL 10/23/20

DMS 06 Nov 2020

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: In-process Swabs, Box of

Receiving#: N/A

Lot#: N/A

Tare Weight: *N/A*

Net Quantity: *N/A*

Initials/Date: *PJT 10/23/20*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

PJT 10/23/20

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Finished Product Retain)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: *N/A*

Retain Box 1 of 2

Net Quantity: *100 units*

Retain Exp: *10/27/2030*

Initials/Date: *JL 10/27/20*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

JL 10/27/20

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Finished Product Retain)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: *N/A*

Retain Box 2 of 2

Net Quantity: *100 units*

Retain Exp: *10/27/2030*

Initials/Date: *JL 10/27/20*

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

JL 10/27/20

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: *N/A*

Net Quantity: *107 units*

Initials/Date: *JL 10/27/20*

Release/Micro/Stability Box 1 of 6

Emerson Resources – 600 Markley Street – Norristown, PA 19401 – (Phone) 610-279-7450

JL 10/27/20

M4097-01B
Page 42 of 50



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

VII. In-Process Section (Continued):

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: N/A

Release/Micro/Stability Box 2 of 6

Net Quantity: 107 units

Initials/Date: 31/10/27/20

Emerson Resources - 600 Markley Street - Norristown, PA 19401 - (Phone) 610-279-7450

31/10/27/20

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: N/A

Release/Micro/Stability Box 3 of 6

Net Quantity: 107 units

Initials/Date: 31/10/27/20

Emerson Resources - 600 Markley Street - Norristown, PA 19401 - (Phone) 610-279-7450

31/10/27/20

N PC 11/6/20
A

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: N/A

Release/Micro/Stability Box 4 of 6

Net Quantity: 107 units

Initials/Date: 31/10/27/20

Emerson Resources - 600 Markley Street - Norristown, PA 19401 - (Phone) 610-279-7450

31/10/27/20

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: N/A

Release/Micro/Stability Box 5 of 6

Net Quantity: 107 units

Initials/Date: 31/10/27/20

Emerson Resources - 600 Markley Street - Norristown, PA 19401 - (Phone) 610-279-7450

31/10/27/20

Clinical Batch In Process Label

Batch Record#: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-01

Tare Weight: N/A

Release/Micro/Stability Box 6 of 6

Net Quantity: 106 units

Initials/Date: 31/10/27/20

Emerson Resources - 600 Markley Street - Norristown, PA 19401 - (Phone) 610-279-7450

31/10/27/20



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

M4097-01B

Issued By/ Date:

JL

OCT 23 2020

VII. In-Process Section (Continued):



MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

VII. In-Process Section (Continued):

DMS 06 Nov 2020



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

VII. In-Process Section (Continued):

DMS 06 Nov 2020



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

DC OCT 23 2020

VIII. Comments:

A large, blank rectangular area for comments, with handwritten markings on the left side. The markings include a diagonal line from the bottom-left corner to the top-right corner, with the date "11/16/20" written along it. On the left side of this line, there are three small handwritten marks: a checkmark ("✓"), the letters "DC", and the letter "A".



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

VIII. Comments (Continued):

A large rectangular area containing a grid of approximately 20 horizontal lines spaced evenly apart. Handwritten in black ink across the top right portion of the grid is the date "OC 11/6/20". Below this date, near the beginning of the grid lines, are the handwritten initials "J" and "A".



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OC OCT 23 2020

IX. Technical Review:

Step	Description	Reviewed by/Date
50	<p>Technical Review:</p> <p>A. All pages are present. B. All signatures and dates are present. C. All calculations have been checked and are correct. D. All results and/or yields are within the specified range. E. All in process criteria were satisfied. F. Any deviations were documented. G. All attachments listed below are present.</p> <p>Attachment Name # of pages Done by/Date</p> <p>Copy of Clinical Box Labels for M4097-01B 1 TB 10/23/2020</p> <p>Chart Recorder Paper 1 SJ 10/28/2020</p> <p>DMS 06 Nov 2020</p>	DMJ 06 Nov 2020



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

4 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-01B

OCT 23 2020

X. Final Batch Record Approval:

This batch record was reviewed after its execution and was found to be acceptable. The signatures below indicate approval of this batch record as adequate, complete, and correct.

Emerson Resources, Inc. Approval

Approver	Signature	Date
Quality Assurance Representative		11/6/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative				
Representative				

**Label Sheet Approval
Batch Record M4097-01B**

100% Review

Page | 1 of 1

iB 9/24/2020

Label Author (Initials/Date)

DUS 25 Sep 2020

Technical Reviewer (Initials/Date)

DC 10/15/20

QA Representative (Initials/Date)

Box _____ of _____

Batch Record: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs

Lot: 4097-01

Storage Condition: Controlled Room Temperature

Net Quantity: _____ units (1 swab/pouch)

Initials/date: _____

Caution - Limited by federal (US) law
to investigational use

Box _____ of _____

Batch Record: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs

Lot: 4097-01

Storage Condition: Controlled Room Temperature

Net Quantity: _____ units (1 swab/pouch)

Initials/date: _____

Caution - Limited by federal (US) law
to investigational use

Box _____ of _____

Batch Record: M4097-01B

Material: 4 mg Naloxone HCl Nasal Swabs

Lot: 4097-01

Storage Condition: Controlled Room Temperature

Net Quantity: _____ units (1 swab/pouch)

Initials/date: _____

Caution - Limited by federal (US) law
to investigational use

copy

