



MANUFACTURING BATCH RECORD

Confidential

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

M4097-12



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

OCT 27 2020

DC

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		23 OCT 2020
Quality Assurance Representative		10/26/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative		attached	dc	10/26/20
Representative				



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Approver	Signature	Date
Author		10/21/2020
Technical Reviewer		23 OCT 2020
Quality Assurance Representative		10/26/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative	Alex Schwarz 28DE1555A70442B...	Alex Schwarz	VP, CMC	10/26/2020
Representative	Ashanti Mathai E70636F912E9449...	Ashanti Mathai	CEO	10/26/2020



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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 Bartron Jr.	Scientist II	<i>Troy A Bartron Jr.</i>	TB	10/21/2020
David M. St. Fort	Sr. Manager, Form Dev	<i>David M. St. Fort</i>	DSF	23 OCT 2020
Devin Gerson	QA Specialist	<i>Devin Gerson</i>	DG	10/26/20
James Hahn	Formulation Technician	<i>James Hahn</i>	JH	10/28/20
Peter Filoon	Formulation Specialist	<i>Peter Filoon</i>	PF	10/28/20
Rami Dargi	QA specialist	<i>Rami Dargi</i>	RD	10/28/2020
Merlin Davis	Formulation technician	<i>Merlin Davis</i>	MD	10/28/20
Jason Connelly	Formulation Technician	<i>Jason Connelly</i>	JC	10/29/20
William Hahn	QA Specialist	<i>William Hahn</i>	WH	10/30/20
Patrice Collow	Formulation Technician	<i>Patrice Collow</i>	PC	11/9/20

① LE for 10/29/20 PC 11/9/20



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Date Executed: 10/28/20 Initials: POF

III. Materials / Formulation:

Step	Description				Done By	Checked By															
1	The following represents approximate batch size requirements to manufacture and package 8 mg Naloxone HCl Nasal Swabs.																				
	Formulation Component	mg/unit ³	%w/w	g/batch ¹																	
	Filtered Naloxone Solution	150.0	100.0	139.5																	
	Total	150.0	100.0	139.5																	
	<table border="1"><thead><tr><th>Device Assembly Components</th><th>Quantity / unit</th><th>Quantity / batch ¹</th></tr></thead><tbody><tr><td>6 Sock 1/8ZF/WHT EXT HDL Swab</td><td>1</td><td>930</td></tr><tr><td>Pro-fax PF511 Natural Caps</td><td>1</td><td>930</td></tr><tr><td>A3333 2 3/4" X 10" Peelable Foil Pouches</td><td>1</td><td>960 ²</td></tr><tr><td>Clinical Pouch Label</td><td>1</td><td>930</td></tr></tbody></table>						Device Assembly Components	Quantity / unit	Quantity / batch ¹	6 Sock 1/8ZF/WHT EXT HDL Swab	1	930	Pro-fax PF511 Natural Caps	1	930	A3333 2 3/4" X 10" Peelable Foil Pouches	1	960 ²	Clinical Pouch Label	1	930
Device Assembly Components	Quantity / unit	Quantity / batch ¹																			
6 Sock 1/8ZF/WHT EXT HDL Swab	1	930																			
Pro-fax PF511 Natural Caps	1	930																			
A3333 2 3/4" X 10" Peelable Foil Pouches	1	960 ²																			
Clinical Pouch Label	1	930																			

¹ To be dispensed in excess to account for potential processing losses.

² Includes overage to account for equipment setup.

³ Equivalent to 147.5 µl based on a solution density of 1.017 g/mL.



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Initials: *JL*

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	<u>538.21</u>	g	
B	6 Sock 1/8ZF/WHT EXT HDL (For M4097-12)	SuperBrush LLC	R200724-01A	IAQ8Z-2020-05-07	7/24/2025	<u>980</u>	ct	
C	Pro-fax PF511 Natural Caps (For M4097-12, Bag 1 of 2)	Seaway Plastic Engineering	R200902-01B	235665	9/2/2021	<u>914</u>	ct	
D	Pro-fax PF511 Natural Caps (For M4097-12, Bag 2 of 2)		R200902-01C			<u>66</u>	ct	
E	Total Quantity of Pro-fax PF511 Natural Caps Provided (For M4097-12) (C + D)					<u>980</u>	ct	
F	A3333 2 3/4" X 10" Peelable Foil Pouches (For M4097-12, Bag 1 of 2)	Beacon Converters, Inc	R200825-01A	1092933	8/25/2025	<u>872</u>	ct	<i>RSF</i>
G	A3333 2 3/4" X 10" Peelable Foil Pouches (For M4097-12, Bag 2 of 2)	Beacon Converters, Inc	R200825-01B			<u>163</u>	ct	<i>JL</i>
H	Total Quantity of A3333 2 3/4" X 10" Peelable Foil Pouches (For M4097-12) (F + G)					<u>1035</u>	ct	
I	Clinical Pouch Labels	ClinSys	R200924-02A	03997-0005	9/24/2025	<u>2000</u>	ct	
J	Clinical Box Labels	Emerson	n/a	n/a	n/a	<u>5</u>	ct	



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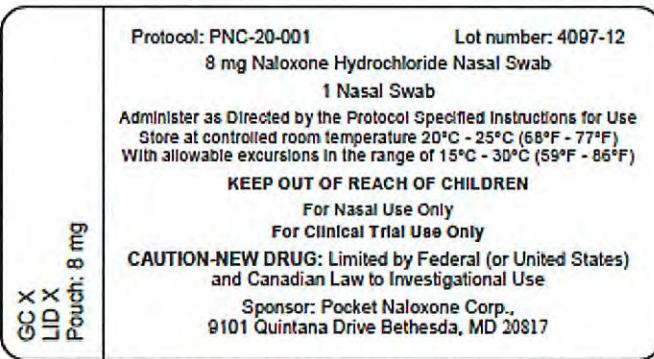
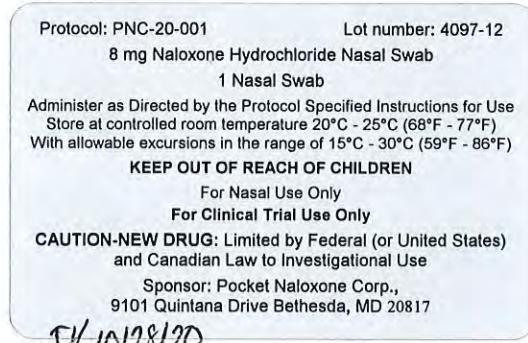
M4097-12

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Date Executed: 10/28/20

Initials: JK

Step	Description			Done By	Checked By
3	Affix a copy of all approved label sheets to this batch record and update the attachments list in Step 47.	Component	Copy Attached (✓)	Attachment List Updated (✓)	<i>JK</i> <i>BF</i>
	Clinical Box Labels		✓	✓	
4	Clinical Pouch Labels: With QA present affix a sample label in the space provided. Ensure the sample label text is identical to the printed text below:  Protocol: PNC-20-001 Lot number: 4097-12 8 mg Naloxone Hydrochloride Nasal Swab 1 Nasal Swab 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) KEEP OUT OF REACH OF CHILDREN For Nasal Use Only For Clinical Trial Use Only CAUTION-NEW DRUG: Limited by Federal (or United States) and Canadian Law to Investigational Use Sponsor: Pocket Naloxone Corp., 9101 Quintana Drive Bethesda, MD 20817  Protocol: PNC-20-001 Lot number: 4097-12 8 mg Naloxone Hydrochloride Nasal Swab 1 Nasal Swab 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) KEEP OUT OF REACH OF CHILDREN For Nasal Use Only For Clinical Trial Use Only CAUTION-NEW DRUG: Limited by Federal (or United States) and Canadian Law to Investigational Use Sponsor: Pocket Naloxone Corp., 9101 Quintana Drive Bethesda, MD 20817 <i>JK 10/28/20</i>	<i>JK</i> <i>BF</i>			
	QA Label Inspection: Label text above and sample label affixed are identical (✓) (<i>✓</i>). QA Release (Initials / Date): <u>RD 10/28/2020</u>				



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Date Executed: 10/28/2020 Initials: RD

Step	Description	Done By	Checked By
5	<p>QA Packaging Component Release: Components listed in Step 2 are acceptable for use per SOP R-07 (✓) (<u>✓</u>). Quantities issued in Step 2 fulfill the required quantities outlined in Step 1 (✓) (<u>✓</u>). All raw material containers are visually clean and free of foreign material (✓) (<u>✓</u>). QA Release (Initials / Date): <u>RD 10/28/2020</u></p>		



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Initials: JL

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>JL</u>	<u>HD</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		



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Date Executed: 10/28/20 Initials: JH

Step	Description					Done By	Checked By
8	Equipment List:						
	Name	ID	PM Due Date	Cal. Due Date	SOP		
	Chart Recorder	L581		2/21	E-23		
	Top Loading Balance (≥3,000g, 2g minimum weight)	A145 ①	11/20	11/20	Q-15		
	Analytical Balance 1 (20mg minimum weight)	A301	11/20	11/20	Q-15		
	Analytical Balance 2 (20mg minimum weight)	A394	11/20	11/20	Q-15		
	FisherBrand Elite Pipette, 100 – 1000 µL (2)	For Project 4097		4/21 7/21	n/a		
	Pipette Tips (1000 µL)	For Project 4097			n/a		
	FisherBrand Elite Pipette, 20 – 200 µL (2)	For Project 4097		2/21	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	7/21	7/21	E-100		
	Pneumatic Air Gun with Regulator	N/A			n/a		
	2 Gal HDPE Container with Lid	For Project 4097			n/a		

①For clarity A145 ①(10/28/20 14D +4 10/28/20
HD 10/28/20



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Initials: SJ

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)	Exxon Mobil / Univar Solutions		MV20878218	4/20/21	SJ
	70% Saturated IPA Wipes	Berkshire		2004000132	6/26/21	HD
	Lint-Free Cloths	Berkshire		0830181	5/17/25	
		DMS 06 Nov 2020				
11	QA Room and Equipment Release: The release of the room and equipment has been executed and documented in appropriate logbook(s) (✓) (✓). Expiry dates for cleaning materials and equipment have been verified for continued use (✓) (✓). QA's visual inspection of the room and equipment has been performed and documented in appropriate logbook(s) (✓) (✓). QA Release (Initials / Date): RD 10/28/2020					



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Initials: JK

Step	Description		Done By	Checked By										
12	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.	<table border="1"><tr><td>Chart Recorder ID</td><td>1581</td></tr><tr><td>Chart Paper Type (circle one)</td><td>Daily / Weekly / Monthly</td></tr><tr><td>Chart Recorder Setting (circle one)</td><td>Daily / 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	1581	Chart Paper Type (circle one)	Daily / Weekly / Monthly	Chart Recorder Setting (circle one)	Daily / Weekly / Monthly	Temperature Setting (circle one)	°C °F	Both pens are recording (✓)	/	JK	HD
Chart Recorder ID	1581													
Chart Paper Type (circle one)	Daily / Weekly / Monthly													
Chart Recorder Setting (circle one)	Daily / Weekly / Monthly													
Temperature Setting (circle one)	°C °F													
Both pens are recording (✓)	/													



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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				<u>JL</u> <u>10/28/20</u>	Checked by / Date <u>JL</u> <u>10/28/20</u>
	Gauge ID	<u>F0072</u>	<u>F0071</u>	<u>F0070</u>					
	Cal Due Date	<u>4/30/20</u>	<u>4/30/21</u>	<u>4/30/21</u>					
Step #	Time	Temperature	Relative Humidity	Chart recording matches digital display (✓)	Pressure Reading (inches of water)			Done by / Date	Checked by / Date
		(°C)	(%)		Room	Ante Room	Gowning Room		
13	11:06 AM	20.7	45	✓	0.050	0.045	0.050	<u>JL</u> <u>10/28/20</u>	<u>JL</u> <u>10/28/20</u>
19	11:32 AM	20.4	47	✓	0.050	0.045	0.050	<u>JL</u> <u>10/28/20</u>	<u>JL</u> <u>10/28/20</u>
21	1:05 PM	20.3	47	✓	0.050	0.040	0.050	<u>JL</u> <u>10/28/20</u>	<u>JL</u> <u>10/28/20</u>
21	3:25 PM	20.5	48	✓	0.050	0.040	0.050	<u>PSF</u> <u>10/28/20</u>	<u>JL</u> <u>10/28/20</u>
21	5:34 PM	20.5	46	✓	0.050	0.040	0.050	<u>JL</u> <u>10/28/20</u>	<u>JL</u> <u>10/28/20</u>
21	9:04 AM	20.5	52	✓	0.050	0.050	0.050	<u>PSF</u> <u>10/29/20</u>	<u>JL</u> <u>10/29/20</u>
21	10:40 AM	20.5	51	✓	0.050	0.050	0.050	<u>PSF</u> <u>10/29/20</u>	<u>JL</u> <u>10/29/20</u>
21	11:31 AM	20.4	51	✓	0.050	0.050	0.050	<u>JL</u> <u>10/29/20</u>	<u>PSF</u> <u>10/29/20</u>
21	12:30 PM	20.3	54	✓	0.050	0.050	0.050	<u>PSF</u> <u>10/29/20</u>	<u>JL</u> <u>10/29/20</u>

QEE 4/30/21 JL 10/28/20 HD 10/28/20



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Step	Description							Done By	Checked By
13	(Continued) 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.								
Step #	Time	Temperature (°C)	Relative Humidity (%)	Chart recording matches digital display (✓)	Pressure Reading (inches of water) Room	Ante Room	Gowning Room	Done by / Date	Checked by / Date
21	3:23 PM	20.5	50	✓	0.050	0.040	0.050	<i>JH 10/29/20</i>	<i>QC 10/29/20</i>
21	5:38 PM	20.6	48	✓	0.050	0.045	0.050	<i>JH 10/29/20</i>	<i>QC 10/29/20</i>
21	8:35 AM	20.5	34	✓	0.050	0.050	0.045	<i>PJF 10/30/20</i>	<i>JL 10/30/20</i>
21	11:19 AM	20.7	31	✓	0.050	0.050	0.045	<i>PSF 10/30/20</i>	<i>JL 10/30/20</i>
21	11:30 AM	20.7	31	✓	0.050	0.050	0.045	<i>PSF 10/30/20</i>	<i>JL 10/30/20</i>
21	12:50 PM	20.5	30	✓	0.055	0.050	0.045	<i>PSF 10/30/20</i>	<i>JL 10/30/20</i>
21	2:40 PM	20.5	31	✓	0.055	0.050	0.045	<i>PSF 10/30/20</i>	<i>JL 10/30/20</i>
23	2:48 PM	20.5	33	✓	0.050	0.050	0.050	<i>JL 10/30/20</i>	<i>PSF 10/30/20</i>
25	4:28 PM	20.3	33	✓	0.050	0.045	0.050	<i>JB 10/30/2020</i>	<i>HJ 10/30/20</i>
25	9:33 AM	20.4	13	✓	0.050	0.045	0.050	<i>JH 11/2/20</i>	<i>PSF 11/2/20</i>
44	11:55 AM	20.3	12	✓	0.050	0.050	0.045	<i>PSF 11/2/20</i>	<i>JH 11/2/20</i>
					<i>DMS on Nov 2020</i>				



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V. Manufacturing/Packaging Procedure:

Step	Description	Done by	Checked by												
14	<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#: M4097-12 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 (✓) (<u>✓</u>). Update the affixed duplicate label in the in-process section of the batch record (✓) (<u>✓</u>).</p>	<i>JK</i>	<i>HD</i>												
15	<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> <table border="1"> <tr> <td>Batch Record#: M4097-12 Material: Naloxone Solution Waste Receiving Number: N/A Lot Number: N/A Tare Weight: Net Quantity: Initials/Date:</td> <td>Tare weight (with lid)</td> <td><i>548.80</i></td> <td>grams</td> </tr> <tr> <td></td> <td>Balance Minimum Weight</td> <td><i>2g</i></td> <td></td> </tr> <tr> <td></td> <td>Balance ID</td> <td><i>A145</i></td> <td></td> </tr> </table> <p>Update the container label with tare weight (✓) (<u>✓</u>). Update the affixed duplicate label in the in-process section of the batch record (✓) (<u>✓</u>).</p>	Batch Record#: M4097-12 Material: Naloxone Solution Waste Receiving Number: N/A Lot Number: N/A Tare Weight: Net Quantity: Initials/Date:	Tare weight (with lid)	<i>548.80</i>	grams		Balance Minimum Weight	<i>2g</i>			Balance ID	<i>A145</i>		<i>JK</i>	<i>HD</i>
Batch Record#: M4097-12 Material: Naloxone Solution Waste Receiving Number: N/A Lot Number: N/A Tare Weight: Net Quantity: Initials/Date:	Tare weight (with lid)	<i>548.80</i>	grams												
	Balance Minimum Weight	<i>2g</i>													
	Balance ID	<i>A145</i>													

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Step	Description	Done by	Checked by										
16	<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#: M4097-12 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>	<u>JK</u>	<u>HD</u>										
17	<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>130 °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	130 °C	Sealing Pressure	80 PSI	<u>JK</u>	<u>HD</u>
Setting	Recommendation												
Sealing Temperature	190 °C												
Sealing Time	2.0 sec												
Cooldown Temperature	130 °C												
Sealing Pressure	80 PSI												



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

JK OCT 27 2020

Date Executed: 10/28/20

Initials: JK

Step	Description					Done by	Checked by																					
18	<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></td><td>2.0 sec</td></tr> <tr> <td>Cooling Temperature</td><td>Report</td><td></td><td></td><td>130 °C</td></tr> <tr> <td>Sealing Pressure</td><td>Report</td><td></td><td></td><td>80 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																								
19	<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

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

OC OCT 27 2020

Date Executed: 10/28/2020 Initials: RD

Step	Description	Done by	Checked by
20	<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: RD 10/28/2020</p>		

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12*DC OCT 27 2020*Date Executed: 10/28/20 Initials: JL

Step	Description	Done by	Checked by
21	<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> <p>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.</p> <p>B. Place a Pro-fax PF511 Natural Cap on an analytical balance. Zero the balance.</p> <p>C. Setup a FisherBrand Elite 20 – 200 µL pipette with 200µL tip. Dial in 147.5 µL on the handle. Wipe the tip down with a lint free wipe wetted with IPA prior to extraction.</p> <p>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.</p> <p>E. Dispense the extracted solution into the cap on the analytical balance.</p> <p>F. Verify that the weight of solution dispensed is between 150.0 mg ± 7.5 mg (Acceptable Range: 142.5 – 157.5 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.</p> <p>a. Two operators may conduct Steps B – F simultaneously.</p> <p>b. Operators must confirm each other's dispensed weight for each swab.</p> <p>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.</p> <p>H. Place the completed swab cap-side down into a 400 mL beaker for packaging.</p> <p>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 22.</p> <p>I. Repeat steps B – H in sets of 10 until not less than 930 swabs have been prepared.</p> <p>J. Pausing for end of day:</p> <p>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.</p> <p>b. All prepared swabs must complete the pouching and labeling operation.</p> <p>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)	<i>JL 10/28/20</i> <i>HD 10/28/20</i> <i>JF 10/28/20</i> <i>PF 10/29/20</i> <i>JL 10/29/20</i> <i>DC 10/29/20</i> <i>PF 10/30/20</i> <i>JL 10/30/20</i> <i>HD 11/6/20</i> <i>HD 11/6/20</i>
	Analytical Balance 1: Balance ID: <u>A301</u> Minimum Weight: <u>20 mg</u>	Analytical Balance 2: Balance ID: <u>A394</u> Minimum Weight: <u>20 mg</u>	<u>JL</u> <u>PF</u>

*① HD 11/6/20 L.E to R 10/24/20 HD 11/6/20 DMS 09 Nov 2020
② L.E to R 10/30/20 HD 10/30/20 DMS 09 Nov 2020*



MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 10/28/20 Initials: SL

Step	Description	Done by	Checked by
22	<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 19. 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 16 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 930 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><i>SL 10/28/20 PSF 10/28/20 HD 10/28/20 PSF 10/29/20 HD 10/29/20 JK 10/29/20 PC 10/29/20 POF 10/30/20 JC 10/30/20 HD 11/4/20</i></p>	

① HD 11/4/20 L.Et=12/10/30/20 HD 11/6/20 DMS 09 Nov 2020



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 10/28/20

Initials: SJL

Packaging Worksheet (for Steps 21 & 22):

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)	150.0	Acceptable Range (mg):		142.5 – 157.5	Done By:	PJF	Check By:	SJL
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All operators have reviewed and understood instructions found in Steps 21 & 22 (initial/date, daily) <i>PJF 10/28/20 SJL 10/28/20 HD 10/28/20</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	10/28/20	Yos	PJF	HD	HD	SJL	SJL	POT	10	N/A	PJF	SJL
	2	10/28/20	N/A	PJF	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	3	10/28/20	N/A	PJF	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	4	10/28/20	N/A	PJF	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	5	10/28/20	N/A	POT	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	6	10/28/20	N/A	POT	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	7	10/28/20	N/A	POT	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	8	10/28/20	N/A	PJF	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	9	10/28/20	N/A	POT	HD	HD	SJL	SJL	POT	10	N/A	POT	SJL
	10	10/28/20	N/A	POT	HD	HD	SJL	SJL	POT	10	N/A	SJL	POT
	11	10/28/20	N/A	POT	HD	HD	POT	POT	SJL	10	N/A	SJL	POT
	12	10/28/20	N/A	SJL	HD	HD	POT	POT	SJL	10	N/A	SJL	POT
	13	10/28/20	N/A	SJL	HD	HD	POT	POT	SJL	10	N/A	SJL	POT
	14	10/28/20	N/A	SJL	HD	HD	POT	POT	SJL	10	N/A	SJL	POT
	15	10/28/20	N/A	SJL	HD	HD	POT	POT	SJL	10	N/A	SJL	POT

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



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 10/28/20 Initials: POF

Packaging Worksheet (for Steps 21 & 22, 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)	150.0	Acceptable Range (mg):			142.5 – 157.5	Done By:	<i>POF</i>	Check By:	<i>SH</i>
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All operators have reviewed and understood instructions found in Steps 21 & 22 (initial/date, daily) <i>POF 10/28/20 HD 10/28/20 JK 10/28/20 POF 10/29/20 HD 10/29/20 DC 11/9/20</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	10/28/20	Yes	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>POF</i>	<i>POF</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>POF</i>
	17	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>POF</i>	<i>POF</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	18	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	19	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	20	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	21	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	22	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	23	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	24	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	<i>N/A</i>	<i>SH</i>	<i>HD</i>
	25	10/28/20	N/A	<i>SH</i>	<i>HD</i>	<i>HD</i>	<i>SH</i>	<i>HD</i>	<i>SH</i>	10	Yes	<i>SH</i>	<i>HD</i>
	26	10/29/20	Yes	<i>POF</i>	<i>HD</i>	<i>HD</i>	<i>POF</i>	<i>HD</i>	<i>POF</i>	10	<i>N/A</i>	<i>POF</i>	<i>HD</i>
	27	10/29/20	N/A	<i>POF</i>	<i>HD</i>	<i>HD</i>	<i>POF</i>	<i>HD</i>	<i>POF</i>	10	<i>N/A</i>	<i>POF</i>	<i>HD</i>
	28	10/29/20	N/A	<i>POF</i>	<i>HD</i>	<i>HD</i>	<i>POF</i>	<i>HD</i>	<i>POF</i>	10	<i>N/A</i>	<i>POF</i>	<i>HD</i>
	29	10/29/20	N/A	<i>POF</i>	<i>HD</i>	<i>HD</i>	<i>POF</i>	<i>HD</i>	<i>POF</i>	10	<i>N/A</i>	<i>POF</i>	<i>HD</i>
	30	10/29/20	N/A	<i>POF</i>	<i>HD</i>	<i>HD</i>	<i>POF</i>	<i>HD</i>	<i>POF</i>	10	<i>N/A</i>	<i>POF</i>	<i>HD</i>

① L/E for 10/29/20

DC 11/9/20

DMS 09 Nov 2020

# of units	Done by	Checked by
150	<i>POF</i>	<i>HD</i>



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

PC

OCT 27 2020

Date Executed: 10/29/20 Initials: POF

Packaging Worksheet (for Steps 21 & 22, 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)	150.0	Acceptable Range (mg):		142.5 – 157.5	Done By:	POF	Check By:	<i>STC</i>
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All operators have reviewed and understood instructions found in Steps 21 & 22 (initial/date, daily) <i>POF 10/29/20 HD 10/29/20 STC 10/29/20 PC 11/9/20</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
	31	10/29/20	Yes	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	32	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	33	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	34	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	35	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	36	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	37	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	38	10/29/20	N/A	POF	HD	HD	POF	POF	HD	10	N/A	POF	HD
	39	10/29/20	N/A	POF	HD	HD	POF	POF	HD	10	N/A	POF	HD
	40	10/29/20	N/A	POF	HD	HD	POF	POF	HD	10	N/A	POF	HD
	41	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	42	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	43	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	44	10/29/20	N/A	POF	HD	HD	POF	HD	POF	10	N/A	POF	HD
	45	10/29/20	N/A	POF	HD	HD	POF	HD	STC	10	N/A	STC	HD

OLE for 10/29/20

PC 11/9/20

DMS 09 Nov 2020

# of units	Done by	Checked by
150	<i>STC</i>	<i>HD</i>



MANUFACTURING BATCH RECORD

EMERSON
RESOURCES INC

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 10/29/20 Initials: JH

Packaging Worksheet (for Steps 21 & 22, 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)	150.0	Acceptable Range (mg):		142.5 – 157.5	Done By:	JH	Check By:	PC
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All operators have reviewed and understood instructions found in Steps 21 & 22 (initial/date, daily) <i>JH 10/29/20 PC 10/29/20 HD 10/29/20 JC 10/30/20 PTF 10/30/20 HD 10/30/20</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
	46	10/29/20	Yes	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	47	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	48	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	49	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	50	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	51	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	52	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	53	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	54	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	55	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	56	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	57	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	58	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	N/A	JH	HD
	59	10/29/20	N/A	PC	HD	HD	JH	JH	PC	10	Yes	JH	HD
	60	10/30/20	Yes	PTF	HD	HD	JC	JC	PTF	10	N/A	PTF	JC

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



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 10/30/20 Initials: POF

Packaging Worksheet (for Steps 21 & 22, 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)	150.0	Acceptable Range (mg):			142.5 – 157.5	Done By:	POF	Check By:	JC
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All operators have reviewed and understood instructions found in Steps 21 & 22 (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
POF 10/30/20 JC 10/30/20 ① 10/30 HD 10/30/20	61	10/30/20	YCS	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	62	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	63	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	64	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	65	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	66	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	67	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	68	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	69	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	70	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	71	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	72	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10 ^②	N/A	POF	JC
	73	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	74	10/30/20	N/A	POF	JC	JC	POF	JC	POF	10	N/A	POF	JC
	75	10/30/20	N/A	POF	JC	JC	POF	JC	POF	20 ^③	N/A	POF	JC

① L.E for C.R. 09/27
H.D 11/10/20 for HD 10/30/20
D.M.S 09 Nov 2020

E.E HD 11/6/20 L.E for 10/30/20 D.M.S 09 Nov 2020

# of units	Done by	Checked by
150	POF	JC

② For clarity, 10 POF 11/9/20 D.M.S 09 Nov 2020



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

JC OCT 27 2020

Date Executed: 10/30/20 Initials: POF

Packaging Worksheet (for Steps 21 & 22, 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)	150.0	Acceptable Range (mg):			142.5 – 157.5	Done By:	POF	Check By:	JC
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All operators have reviewed and understood instructions found in Steps 21 & 22 (initial/date, daily) <i>JL 10/30/20 POF 10/30/20</i> <i>(2)</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	10/30/20	Yes	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
77	10/30/20	Yes	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
78	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
79	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
80	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
81	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
82	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
83	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
84	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
85	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
86	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
87	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
88	10/30/20	N/A	POF	JL	JL	POF	JL	POF	POF	10	N/A	POF	JC
89	10/30/20	N/A	POF	JL	JL	POF	POF	POF	JL	10	N/A	POF	JC
90	10/30/20	N/A	POF	JL	JL	POF	POF	POF	JL	10	N/A	POF	JC

F	Total # of units packaged (sum of 76-90):	# of units	Done by	Checked by
		150	POF	JC

① Yes POF 10/30/20 JL 10/30/20 ② N/A 11/6/20 L.E for 10/30/20 HD 11/6/20 DMS 09 Nov 2020



MANUFACTURING BATCH RECORD

Batch Record Number:

Issued By/ Date:

8 mg Naloxone HCl Nasal Swabs

M4097-12

De OCT 27 2020

Date Executed: 10/30/20 Initials: POF

Packaging Worksheet (for Steps 21 & 22, 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)	150.0	Acceptable Range (mg):		142.5 – 157.5	Done By:	<u>POF</u>	Check By:	<u>JL</u>
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All operators have reviewed and understood instructions found in Steps 21 & 22 (initial/date, daily) <i>POF 10/30/20 JC 11/10/20 JL 11/14/20</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
	91	10/30/20	Yes	POF	JL	JL	POF	POF	JL	10	N/A	POF	JL
	92	10/30/20	N/A	POF	JL	JL	POF	POF	JL	10	N/A	POF	JL
	93	10/30/20	N/A	POF	JL	JL	POF	POF	JL	10	N/A	POF	JL

	# of units	Done by	Checked by
G Total # of units packaged (sum of 91-93):	30	POF	JL

(1) L.E for 10/30/20 HD 11/14/20 DMS or normal (2) L.E for 10/30/20 JL 11/10/20 DC 11/14/20



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 10/30/20 Initials: POF

Step	Description	Done by	Checked by																														
23	Number of units packaged: <u>930</u> units (Sum of Totals on Packaging Worksheet(s), Steps 21 & 22, A + B + C + D + E + F + G)	<i>PJF</i>	<i>JL</i>																														
24	QA Inspection of Packaging: 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. 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.																																
	<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>930</u></td> <td></td> <td></td> <td><i>DC RD</i></td></tr> <tr> <td>B Initial number of units accepted</td> <td><u>929</u></td> <td></td> <td></td> <td><i>DC RD</i></td></tr> <tr> <td>C Initial number of units rejected</td> <td><u>1</u></td> <td></td> <td></td> <td><i>DC RD</i></td></tr> <tr> <td>D Number of repackaged/relabelled units accepted</td> <td><u>1</u></td> <td><i>TB</i></td> <td><i>HD</i></td> <td><i>DC RD</i></td></tr> <tr> <td>E Total number of units accepted (B + D)</td> <td><u>930</u></td> <td></td> <td></td> <td><i>DC RD</i></td></tr> </tbody> </table>		Number of Units	Done By	Checked By	QA Initials	A Number of pouch seals & labels checked	<u>930</u>			<i>DC RD</i>	B Initial number of units accepted	<u>929</u>			<i>DC RD</i>	C Initial number of units rejected	<u>1</u>			<i>DC RD</i>	D Number of repackaged/relabelled units accepted	<u>1</u>	<i>TB</i>	<i>HD</i>	<i>DC RD</i>	E Total number of units accepted (B + D)	<u>930</u>			<i>DC RD</i>		
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E Total number of units accepted (B + D)	<u>930</u>			<i>DC RD</i>																													
	Place empty pouches and removed/damaged labels into Device Assembly Waste (✓ or N/A) (<u>✓</u>). Place units from rejected pouches not successfully repackaged or relabeled into the poly bag labeled Device Assembly Waste (✓ or N/A) (<u>✓</u>).	<i>TB</i>	<i>HD</i>																														
25	Determine the quantity of pouch labels remaining and return to QA for GMP storage. Quantity remaining: <u>1056</u> pouch labels	<i>51C</i> <i>11/2/20</i>	<i>POF</i> <i>11/2/20</i>																														
26	Determine and record the number of pouch labels in Device Assembly Waste . Quantity: <u>13</u> waste pouch labels	<i>51C</i> <i>11/2/20</i>	<i>POF</i> <i>11/2/20</i>																														



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 11/2/20

Initials: *JHC*

Step	Description	Done by	Checked by																																				
27	QA verification of remaining pouch label quantity: Quantity received: <u>1056</u> pouch labels QA Initials / Date: <u>RD 11/02/2020</u>																																						
28	Determine and record the number of waste swabs in Device Assembly Waste . Quantity: <u>1</u> waste swabs	<i>JHC</i>	<i>POF</i>																																				
29	Prepare 2 boxes (12 x 12 x 12") lined with poly bags with attached label for 8 mg Naloxone HCl Nasal Swabs (Finished Product Retain) . Ensure the box labels includes the following: Batch Record#: M4097-12 Material: 8 mg Naloxone HCl Nasal Swabs (Finished Product Retain) Receiving #: N/A Lot #: 4097-12 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 (✓) (<i>✓</i>).	<i>JHC</i>	<i>POF</i>																																				
30	With QA present, neatly place the required quantity of units into the boxes prepared in Step 29 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><u>✓</u></td> <td><u>/</u></td> <td><u>/</u></td> <td><i>JHC</i></td> <td><i>POF</i></td> <td><i>RD</i></td> </tr> <tr> <td>2</td> <td>100</td> <td><u>100</u></td> <td><u>✓</u></td> <td><u>✓</u></td> <td><u>✓</u></td> <td><i>JHC</i></td> <td><i>POF</i></td> <td><i>RD</i></td> </tr> <tr> <td>Total</td> <td>200</td> <td><u>200</u></td> <td></td> <td></td> <td></td> <td><i>JHC</i></td> <td><i>POF</i></td> <td><i>RD</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>	<u>✓</u>	<u>/</u>	<u>/</u>	<i>JHC</i>	<i>POF</i>	<i>RD</i>	2	100	<u>100</u>	<u>✓</u>	<u>✓</u>	<u>✓</u>	<i>JHC</i>	<i>POF</i>	<i>RD</i>	Total	200	<u>200</u>				<i>JHC</i>	<i>POF</i>	<i>RD</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>	<u>✓</u>	<u>/</u>	<u>/</u>	<i>JHC</i>	<i>POF</i>	<i>RD</i>																															
2	100	<u>100</u>	<u>✓</u>	<u>✓</u>	<u>✓</u>	<i>JHC</i>	<i>POF</i>	<i>RD</i>																															
Total	200	<u>200</u>				<i>JHC</i>	<i>POF</i>	<i>RD</i>																															



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

K OCT 27 2020

Date Executed: 11/21/20

Initials: JH

Step	Description						Done by	Checked by																																																																								
31	<p>Prepare 6 boxes (12 x 12 x 12") lined with poly bags with attached label for 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability). Ensure the box label(s) includes the following:</p> <p>Batch Record#: M4097-12 Material: 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability) Receiving #: N/A Lot #: 4097-12 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 (✓) (<u> </u>).</p>						<i>JH</i>	<i>POF</i>																																																																								
32	<p>With QA present, neatly place the required quantity of units into the boxes prepared in Step 31 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>POF</i></td> <td><i>JH</i></td> <td><i>RD</i></td> </tr> <tr> <td>2</td> <td>107</td> <td>107</td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>POF</i></td> <td><i>JH</i></td> <td><i>RD</i></td> </tr> <tr> <td>3</td> <td>107</td> <td>107</td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>POF</i></td> <td><i>JH</i></td> <td><i>RD</i></td> </tr> <tr> <td>4</td> <td>107</td> <td>107</td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>POF</i></td> <td><i>JH</i></td> <td><i>RD</i></td> </tr> <tr> <td>5</td> <td>107</td> <td>107</td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>POF</i></td> <td><i>JH</i></td> <td><i>RD</i></td> </tr> <tr> <td>6</td> <td>105</td> <td>105</td> <td>✓</td> <td>✓</td> <td>✓</td> <td><i>POF</i></td> <td><i>JH</i></td> <td><i>RD</i></td> </tr> <tr> <td>Total</td> <td>640</td> <td>640</td> <td></td> <td></td> <td></td> <td><i>POF</i></td> <td><i>JH</i></td> <td><i>RD</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>POF</i>	<i>JH</i>	<i>RD</i>	2	107	107	✓	✓	✓	<i>POF</i>	<i>JH</i>	<i>RD</i>	3	107	107	✓	✓	✓	<i>POF</i>	<i>JH</i>	<i>RD</i>	4	107	107	✓	✓	✓	<i>POF</i>	<i>JH</i>	<i>RD</i>	5	107	107	✓	✓	✓	<i>POF</i>	<i>JH</i>	<i>RD</i>	6	105	105	✓	✓	✓	<i>POF</i>	<i>JH</i>	<i>RD</i>	Total	640	640				<i>POF</i>	<i>JH</i>	<i>RD</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																																																																								
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4	107	107	✓	✓	✓	<i>POF</i>	<i>JH</i>	<i>RD</i>																																																																								
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EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 11/2/20 Initials: BD

Step	Description	Done by	Checked by																								
33	<p>Clinical Box Labels must contain the following information. Affix a sample label in the space provided.</p> <p><i>PF 11/2/20</i></p> <div style="border: 1px solid black; width: 150px; height: 150px; margin-bottom: 10px;"></div> <p>Box _____ of _____ Batch Record: M4097-12 Material: 8 mg Naloxone HCl Nasal Swabs Lot: 4097-12 Storage Condition: Controlled Room Temperature Net Quantity: _____ units (1 swab/pouch) Initials/date: _____ Caution - Limited by federal (US) law to investigational use</p> <p>Box _____ of _____ Batch Record: M4097-12 Material: 8 mg Naloxone HCl Nasal Swabs Lot: 4097-12 Storage Condition: Controlled Room Temperature Net Quantity: _____ units (1 swab/pouch) Initials/date: _____ Caution - Limited by federal (US) law to investigational use</p>	<i>BD</i>	<i>ST</i>																								
34	<p>With QA present, neatly place the required quantity of units into a 12 x 12 x 12 box lined with a poly bag. Affix a box label as shown in Step 33 onto the box. 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 boxes in the below table:</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <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>90</td> <td>90</td> <td>✓</td> <td>✓</td> <td><i>BD</i></td> <td><i>PL</i></td> <td><i>RD</i></td> </tr> <tr> <td>Total</td> <td>90</td> <td>90</td> <td></td> <td></td> <td><i>BD</i></td> <td><i>PL</i></td> <td><i>RD</i></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	90	90	✓	✓	<i>BD</i>	<i>PL</i>	<i>RD</i>	Total	90	90			<i>BD</i>	<i>PL</i>	<i>RD</i>		
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	90	90	✓	✓	<i>BD</i>	<i>PL</i>	<i>RD</i>																				
Total	90	90			<i>BD</i>	<i>PL</i>	<i>RD</i>																				



MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

JL OCT 27 2020

Date Executed: 11/2/20 Initials: PJF

Step	Description					Done by	Checked by															
35	With QA present, seal the cardboard box from Step 34 with security tape across both top and bottom of tape seals on the box.																					
	<table border="1"> <thead> <tr> <th>Box number</th> <th>Security Tape Serial Number (Top Seal)</th> <th>Security Tape Serial Number (Bottom Seal)</th> <th>Done By</th> <th>Checked By</th> <th>QA Verified By</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>A7436520</td> <td>A7436521</td> <td><i>PJF</i></td> <td><i>JL</i></td> <td><i>RD</i></td> </tr> </tbody> </table>		Box number	Security Tape Serial Number (Top Seal)	Security Tape Serial Number (Bottom Seal)	Done By	Checked By	QA Verified By	1	A7436520	A7436521	<i>PJF</i>	<i>JL</i>	<i>RD</i>								
Box number	Security Tape Serial Number (Top Seal)	Security Tape Serial Number (Bottom Seal)	Done By	Checked By	QA Verified By																	
1	A7436520	A7436521	<i>PJF</i>	<i>JL</i>	<i>RD</i>																	
36	Determine and record the number of clinical box labels remaining: <u>3</u> box labels																					
37	Determine and record the number of box labels in Device Assembly Waste .																					
	Quantity: <u>0</u> waste box labels																					
38	Determine the net quantity of Filtered Naloxone Solution remaining.																					
	<table border="1"> <tbody> <tr> <td>Gross Weight (includes bottle and cap)</td> <td><u>968.09</u></td> <td>grams</td> </tr> <tr> <td>Tare weight of container (from label)</td> <td><u>587.09</u></td> <td>grams</td> </tr> <tr> <td>Net Quantity (gross - tare)</td> <td><u>381.00</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> </tbody> </table>		Gross Weight (includes bottle and cap)	<u>968.09</u>	grams	Tare weight of container (from label)	<u>587.09</u>	grams	Net Quantity (gross - tare)	<u>381.00</u>	grams	Balance Minimum Weight	<u>2g</u>		Balance ID	<u>A145</u>		<i>PJF</i>		<i>JL</i>		
Gross Weight (includes bottle and cap)	<u>968.09</u>	grams																				
Tare weight of container (from label)	<u>587.09</u>	grams																				
Net Quantity (gross - tare)	<u>381.00</u>	grams																				
Balance Minimum Weight	<u>2g</u>																					
Balance ID	<u>A145</u>																					
	Update the bottle label with the new net quantity (✓) (<u>✓</u>).																					



EMERSON
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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 11/2/20 Initials: PJF

Step	Description	Done by	Checked by																				
39	<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>538.68</u></td><td>grams</td></tr> <tr> <td>Tare Weight (with lid)</td><td><u>548.80</u>⁽¹⁾</td><td>grams</td></tr> <tr> <td>Net Quantity (gross – tare)</td><td><u>2.46</u></td><td>grams</td></tr> <tr> <td>Balance Minimum Weight</td><td><u>2,</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>538.68</u>	grams	Tare Weight (with lid)	<u>548.80</u> ⁽¹⁾	grams	Net Quantity (gross – tare)	<u>2.46</u>	grams	Balance Minimum Weight	<u>2,</u>		Balance ID	<u>A145</u>		<i>PJF</i>	<i>JH</i>					
Gross Weight	<u>538.68</u>	grams																					
Tare Weight (with lid)	<u>548.80</u> ⁽¹⁾	grams																					
Net Quantity (gross – tare)	<u>2.46</u>	grams																					
Balance Minimum Weight	<u>2,</u>																						
Balance ID	<u>A145</u>																						
40	<p>Packaged Swab Reconciliation:</p> <table border="1"> <tr> <td>A</td><td>Number of swabs packaged (Step 24E)</td><td><u>930</u></td><td>swabs</td></tr> <tr> <td>B</td><td>Number of Finished Product Retain swabs packaged (Step 30, Total)</td><td><u>200</u></td><td>swabs</td></tr> <tr> <td>C</td><td>Number of Release/Micro/Stability swabs packaged (Step 32, Total)</td><td><u>640</u></td><td>swabs</td></tr> <tr> <td>D</td><td>Number of Clinical swabs packaged (Step 34, Total)</td><td><u>90</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 24E)	<u>930</u>	swabs	B	Number of Finished Product Retain swabs packaged (Step 30, Total)	<u>200</u>	swabs	C	Number of Release/Micro/Stability swabs packaged (Step 32, Total)	<u>640</u>	swabs	D	Number of Clinical swabs packaged (Step 34, Total)	<u>90</u>	swabs	E	% Accountability (B + C + D) / A × 100 Note: Accountability should be 100%. If not 100%, notify QA.	<u>100</u>	%	<i>PJF</i>	<i>JH</i>
A	Number of swabs packaged (Step 24E)	<u>930</u>	swabs																				
B	Number of Finished Product Retain swabs packaged (Step 30, Total)	<u>200</u>	swabs																				
C	Number of Release/Micro/Stability swabs packaged (Step 32, Total)	<u>640</u>	swabs																				
D	Number of Clinical swabs packaged (Step 34, Total)	<u>90</u>	swabs																				
E	% Accountability (B + C + D) / A × 100 Note: Accountability should be 100%. If not 100%, notify QA.	<u>100</u>	%																				

⁽¹⁾ 551.26 PJF 11/2/20 JH 11/2/20

⁽²⁾ For clarity, 548.80 PJF 11/9/20 JH 11/9/20



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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

OC OCT 27 2020

Date Executed: 11/2/20 Initials: POF

Step	Description				Done by	Checked by
41	Swab Label Reconciliation:					
A	Number of pouch labels issued (Step 2I)	2000	labels			
B	Number of pouch labels affixed to the batch record (Step 4)	1	labels			
C	Number of pouch labels on acceptable pouches (Step 24E)	930	labels			
D	Number of pouch labels remaining (Step 25)	1056	labels			
E	Number of waste pouch labels (Step 26)	13	labels			
F	% Accountability $(B + C + D + E) / A \times 100$	100	%			
	Note: Accountability should be 100%. If not 100%, notify QA.					
42	Clinical Box Labels Reconciliation:					
A	Number of clinical box labels issued (Step 2J)	5	labels			
B	Number of box labels affixed to the batch record (Step 33)	1	labels			
C	Number of box labels on box(es) (Step 34)	1	labels			
D	Number of box labels remaining (Step 36)	3	labels			
E	Number of waste box labels (Step 37)	0	labels			
F	% Accountability $(B + C + D + E) / A \times 100$	100	%			
	Note: Accountability should be 100%. If not 100%, notify QA.					



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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

Date Executed: 11/2/20 Initials: BJF

Step	Description				Done by	Checked by
43	Naloxone Solution Reconciliation:					
	A Net quantity of solution issued (Step 2A)	538.21	grams			
	B Net quantity of solution packaged (Step 24E x 0.150g)	139.5	grams			
	C Net quantity of solution on waste swabs (Step 28 x 0.150g)	0.150	grams			
	D Net quantity of remaining solution (Step 38)	381.00	grams			
	E Net quantity of waste solution (Step 39)	2.46	grams			
	F % Accountability $(B + C + D + E) / A \times 100$	97	%			
	Note: Accountability should be $\geq 90\%$ and $\leq 101\%$. Notify QA if < 90% or > 101%.					
	G % Yield (For Informational Purposes Only) $(B) / (A - D) \times 100$	89	%			
44	Record the current room temperature, relative humidity, and Magnehelic pressure reading in the table in Step 13 (✓) (<u>✓</u>).				<i>BJF</i>	<i>JL</i>
45	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>BJF</i>	<i>JL</i>
46	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 11/2/20</u>					



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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

VI. In-Process Section:

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: Device Assembly Waste

Receiving#: N/A

Lot#: N/A

Tare Weight: N/A

Net Quantity: N/A

Initials/Date: JK 10/28/20

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

JK 10/28/20

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: Naloxone Solution Waste

Receiving#: N/A

Lot#: N/A

Tare Weight: 548.80g

Net Quantity: 2.465 g OF 11/2/20

Initials/Date: JK 10/28/20

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

JK 10/28/20

DMS 06 Nov 2020

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: In-process Swabs, Box ___ of ___

Receiving#: N/A

Lot#: N/A

Tare Weight: N/A

Net Quantity: N/A

Initials/Date: JK 10/28/20

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

JK 10/28/20

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Finished Product Retain)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Retain Box 1 of 2

Net Quantity: 100 units

Retain Exp: 11/2/2030

Initials/Date: JK 11/2/20

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

JK 11/2/20

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Finished Product Retain)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Retain Box 2 of 2

Net Quantity: 100 units

Retain Exp: 11/2/2030

Initials/Date: JK 11/2/20

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

JK 11/2/20



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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

OC OCT 27 2020

VI. In-Process Section (Continued):

Clinical Batch In Process Label

PSF 11/2/20

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Release/Micro/Stability Box 1 of 6

Net Quantity: 107 units

Initials/Date: PSF 11/2/20

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

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Release/Micro/Stability Box 2 of 6

Net Quantity: 107 units

Initials/Date: PSF 11/2/20

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

PSF 11/2/20

DM 06 Nov 2020

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Release/Micro/Stability Box 3 of 6

Net Quantity: 107 units

Initials/Date: PSF 11/2/20

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

PSF 11/2/20

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Release/Micro/Stability Box 4 of 6

Net Quantity: 107 units

Initials/Date: PSF 11/2/20

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

PSF 11/2/20

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Release/Micro/Stability Box 5 of 6

Net Quantity: 107 units

Initials/Date: PSF 11/2/20

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

PSF 11/2/20

Clinical Batch In Process Label

Batch Record#: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs (Release/Micro/Stability)

Receiving#: N/A

Lot#: 4097-12

Tare Weight: N/A

Net Quantity: 107 units

Initials/Date: PSF 11/2/20

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

PSF 11/2/20



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

M4097-12

Issued By/ Date:

OK OCT 27 2020

VI. In-Process Section (Continued):

DMJ 06 Nov 2020



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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

M4097-12

Issued By/ Date:

DC OCT 27 2020

VI. In-Process Section (Continued):

DMS 06 Nov 2020



**EMERSON
RESOURCES INC**

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

OCT 27 2020

VII. Comments:

A hand-drawn graph on lined paper showing a straight line with a positive slope. The line passes through points labeled A, B, C, and D. The slope is labeled as $1/1/2$ or $1/1/2^o$.



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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

M4097-12

Issued By/ Date:

OCT 27 2020

VII. Comments (Continued):



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MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

JL OCT 27 2020

VIII. Technical Review:

Step	Description	Reviewed by/Date
47	<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><i>Copy of Clinical Box Label Sheet</i> 1 <i>J/10/28/20</i></p> <p><i>Chart Recorder Paper</i> 1 <i>P07 11/2/20</i></p> <p><i>DMS</i> <i>06 Nov 2020</i></p>	<i>DMS</i> <i>11 Nov 2020</i>



EMERSON
RESOURCES INC

MANUFACTURING BATCH RECORD

8 mg Naloxone HCl Nasal Swabs

Batch Record Number:

Issued By/ Date:

M4097-12

DC OCT 27 2020

IX. 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		11/11/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative				
Representative				

100% Review
Page | 1 of 1

TB 10/21/2020

Label Author (Initials/Date)

Dus 27 oct 2020

Technical Reviewer (Initials/Date)

DC 10/27/20

QA Representative (Initials/Date)

TrueBlock Shipping Labels
Completely covers everything underneath

Box ____ of ____

Batch Record: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs

Lot: 4097-12

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: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs

Lot: 4097-12

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: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs

Lot: 4097-12

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: M4097-12

Material: 8 mg Naloxone HCl Nasal Swabs

Lot: 4097-12

Storage Condition: Controlled Room Temperature

Net Quantity: _____ units (1 swab/pouch)

Initials/date: _____

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

