M4097-01A

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		10/6/2020
Technical Reviewer		06 OCT 2020
Quality Assurance Representative		10/6/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative	see attached	DC	10/20/20	
Representative				

EMERSON RESOURCES INC

MANUFACTURING BATCH RECORD

Solution Preparation for Naloxone Swabs

Batch Record Number: **M4097-01A**

Issued By/ Date: OC OCT 20 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		10/6/2020
Technical Reviewer		06 OCT 2020
Quality Assurance Representative		10/6/20

Pocket Naloxone Corp. Approval

Approver	Signature	Printed Name	Title	Date
Representative	DocuSigned by: Alex Schwarz 25DE1585A70442B...	Alex Schwarz	VP, CMC	10/20/2020
Representative	DocuSigned by: Ashanthi Mathai E70636F912E9449...	Ashanthi Mathai	CEO	10/20/2020

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. Barbron Jr.	Formulation Scientist		TB	10/6/2020
David M. Slifer	Sr. Manager, Form Dev		DMS	06 OCT 2020
Devin Corson	QA Specialist		DC	10/6/20
Peter Filoon	Formulation Specialist		PJF	10/21/20

N/A DC 11/6/20

III. Materials / Formulation:

Step	Description	Done By	Checked By
1	The following represents the formulation for preparing approximately 1000g of 60 mg/mL Naloxone HCl solution.		

1N Sodium Hydroxide Solution Formulation:

Component	%w/w	g/batch
Sodium Hydroxide Pellets	4.0	20.0
Sterile Water	96.0	480.0
Total	100.0	500.0

1N HCl Solution Formulation:

Component	%w/w	g/batch
12N HCl	9.83	49.17
Sterile Water	90.17	450.83
Total	100.00	500.0

60 mg/mL Naloxone HCl Solution Formulation:

Component	% w/v	g/batch
Naloxone HCl Dihydrate	6.569 [1, 2]	65.69
Citric Acid Anhydrous	0.192	1.92
Benzalkonium Chloride (50% w/w solution)	0.203	2.03
Disodium EDTA Dihydrate	0.055	0.55
Sodium Chloride	0.150	1.50
Sterile Water	QS	QS
Total	100.000	1,000.00

[1] Equivalent to 6.0 % w/v Naloxone HCl.
[2] From COA, the calculated purity = HPLC Assay – Inorganic Impurities – Water content = 100.6 – 0.1 – 9.1 = 91.4 %.

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
2	Raw Material List:	TB	RSF
3	QA Material Release:		

	Component	Manufacturer	Receiving Number	Lot Number	Expiration/ Retest Date	Net Quantity (from label)	
A	Naloxone HCl Dihydrate	Mallinckrodt	R200714-01A	2003000177	2/28/2025	To be dispensed	
B	Citric Acid Anhydrous	ADM	R200807-01A	S006054	6/5/2023		
C	Benzalkonium Chloride (50% w/w solution)	Sigma Aldrich	R200813-01A	BCBZ4386	9/30/2021		
D	Disodium EDTA Dihydrate [2]	EMD Millipore	R180427-02	E300000683	11/30/2022		
E	Sodium Chloride	Avantor	R200203-02A	0000248072	11/5/2024		
F	Sodium Hydroxide Pellets [1]	Avantor	R190627-01	0000231642	10/24/2021		
G	Hydrochloric Acid [1]	Avantor	R160808-02	0000144734	4/24/2021		
H	Sterile Water	HyClone	R200721-01A	AF29424794	3/31/2023	3	L

[1] Required for preparation of pH adjustment solutions.
[2] Equivalent to EDTA diSodium Dihydrate on the raw material dispensing label.

Components listed in Step 2 are acceptable for use per SOP R-07 (✓) (✓).

All containers are visually clean and free of foreign material (✓) (✓).

Quantities issued in Step 2 fulfill the required quantities outlined in Step 1 (✓) (✓).

QA Release (Initials / Date): DC 10/21/20

Date Executed: 10/21/2020 Initials: TK

IV. Room Release and Setup:

Step	Description	Done By	Checked By
4	Room and Equipment Cleaning: Room Number: ~~217~~ 218 ① Cleaning Batch Record(s): C4097-12 Room and equipment were previously cleaned, swabbed, and released.	TK	POF
5	Proper gowning for dispensing and handling of this material is as follows: **NOTE: Please confirm all hair is contained inside hair cover and beard cover (if applicable).** A. Safety glasses/safety goggles B. Hair cover C. Beard cover (if applicable) D. Disposable gowning E. Disposable sleeves (as needed) F. Shoe covers G. Non-latex gloves H. **PAPR required for handling Naloxone HCl Dihydrate in dry form**		

① EE TB 11/6/2020 DC 11/6/20

MANUFACTURING BATCH RECORD

Solution Preparation for Naloxone Swabs

Batch Record Number: **M4097-01A**

Issued By/ Date: DC OCT 20 2020

Date Executed: 10/2/2020 Initials: TB

Step	Description	Done By	Checked By
6	Equipment List:	TB	RGF

Name	ID	PM Due Date	Cal. Due Date	SOP
Chart Recorder	L581		2/2021	E-23
Top Loading Balance (≥ 3,000 g, 2 g minimum Weight)	A145	~~3~~ ① 11/30/2020	11/30/2020	Q-15
Analytical Balance (20 mg minimum Weight)	A301	11/30/2020	11/30/2020	Q-15
Peristaltic Pump	L579			N/A
Magnetic Stir Plate	A340			N/A
Magnetic Stir Plate	L116			N/A
Timer	A388		7/13/2021	N/A
pH Meter with Probe	A185		4/30/2021	A-25
Nalgene Beaker (600 mL) (3)	For Project 4097			N/A
HDPE Container/Lid (2 gal) (2)	For Project 4097			N/A
Stainless Steel Container (~ 1L)	For Project 4097			N/A
Glass Media Bottle with Cap (1L)	For Project 4097			N/A
Stir bars (3)	For Project 4097			N/A
FisherBrand Elite Pipette, 20 – 200 µL	For Project 4097		2/2021	N/A
FisherBrand Elite Pipette, 100 – 1000 µL	For Project 4097		7/2021	N/A
Pipette Tips (1 mL)	For Project 4097			N/A
Pipette Tips (200 µL)	For Project 4097			N/A
Optiscale 47 Capsule Filters (Polysep II, 1.0/0.2 µm, Cat# SGW3A47HH3)	For Project 4097			N/A

① EE TB ~~10/20/2020~~ 10/21/2020 RGF 10/21/20
TB 10/21/2020 DC 11/6/20

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
7	Additional Equipment List: Equipment that may be cleaned, swabbed, released and then introduced to the room after manufacturing has already begun will be documented in this list. This step should be completed at the time of equipment transfer.		

Name	ID	PM Due Date	Cal. Due Date	Cleaning BR#	Done By/Date	Checked By/Date	QA Initials/Date

DMS 26 OCT 2020

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
8	In-Process Cleaning: The following may be used for cleaning throughout the process.	TB	PJF
9	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): OC 10/21/20		

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
	DMS 25 OCT 2020		

Date Executed: 10/21/2020 Initials: TK

Step	Description	Done By	Checked By
10	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.	TB	PJF

Chart Recorder ID	L581
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 (✓)	✓

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
11	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.**		

				Done by / Date	Checked by / Date
Room ID	218			TB 10/21/2020	BJF 10/21/20
Gauge Location	Room	Ante Room	Gowning Room		
Gauge ID	F0072	F0071	F0070		
Cal Due Date	4/30/2021	4/30/2021	4/30/2021		

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
11	11:09 AM	20.6	68	✓	0.050	0.030	0.065	TB 10/21/2020	BJF 10/21/20
13	12:40 PM	20.6	72	✓	0.050	0.030	0.060	BJF 10/21/20	TB 10/21/20
15	1:51 PM	20.6	75	✓	0.050	0.030	0.060	TB 10/21/20	BJF 10/21/20
37	3:14PM	20.5	76	✓	0.050	0.030	0.065	BJF 10/21/20	TB 10/21/20
47	4:06 PM	20.5	79	✓	0.050	0.030	0.060	TB 10/21/2020	BJF 10/21/20
				DMS 26 OCT 2020					

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
11	***(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)			Done by / Date	Checked by / Date
					Room	Ante Room	Gowning Room		

DMS 26 OCT 2020

Date Executed: 10/21/2020 Initials: TB

V. Dispensing Procedure

Step	Description	Reviewed and Understood
12	**Dispensing Instructions:** 1. 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. Note: Cardboard and/or fiber containers should not be placed on the working surface. 2. Attach a label to the poly bag or container, and record the tare weight. Tare the poly bag or container on the balance. Note: An intermediate container may be used when appropriate, which does not require a label. 3. Dispense the required quantity of the raw material into the poly bag or container. Record the net quantity. 4. Ensure that the label contains the following: Batch Record#: **M4097-01A** Material: Receiving #: Lot #: Tare Weight: Net Quantity: Expiration Date: Initials/Date: Note: Additional information can be placed on label where necessary. 5. Affix a duplicate label to the in-process section of the batch record. 6. 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. TB 10/21/2020 BSF 10/21/2020

EMERSON RESOURCES INC

MANUFACTURING BATCH RECORD

Solution Preparation for Naloxone Swabs

Batch Record Number: **M4097-01A**

Issued By/ Date: JC OCT 20 2020

Date Executed: 10/21/2020 Initials: TB

Dispensing Worksheet (for Step 12):

Sample Type	Instructions
For Solution Prep	Dispense Raw Material into a vial with cap
Retain Sample	Include expiration 2 years from current date

	Raw Material	Balance ID	Target Quantity		Acceptable Range		Dispensed Quantity		Recorded By	Checked By	Label Prepared & Checked (✓)	Duplicate Label Prepared & Checked (✓)	Dispensing Label Updated (✓)	Done By	Checked By
A	Citric Acid Anhydrous (For Solution Prep)	A301	1.92	g	1.86 – 1.98	g	1.9582	g	TB	BJF	✓	✓		TB	BJF
B	Citric Acid Anhydrous (Retain Sample)	A145	20.0	g	18.0 – 22.0	g	19.96	g	TB	BJF	✓	✓		TB	BJF
C					Total Dispensed		21.9182	g	TB	BJF			✓	TB	BJF
D	Disodium EDTA Dihydrate (For Solution Prep)	A301	0.55	g	0.52 – 0.58	g	0.5758	g	TB	BJF	✓	✓		TB	BJF
E	Disodium EDTA Dihydrate (Retain Sample)	A145	20.0	g	18.0 – 22.0	g	19.38	g	TB	BJF	✓	✓		TB	BJF
F					Total Dispensed		19.9558	g	TB	BJF			✓	TB	BJF
G	Sodium Chloride (For Solution Prep)	A301	1.50	g	1.45 – 1.55	g	1.5334	g	TB	BJF	✓	✓		TB	BJF
H	Sodium Chloride (Retain Sample)	A145	20.0	g	18.0 – 22.0	g	20.75	g	TB	BJF	✓	✓		TB	BJF
I					Total Dispensed		22.2834	g	TB	BJF			✓	TB	BJF
J	Sodium Hydroxide Pellets (For pH solution)	A145	20.0	g	19.5 – 20.5	g	20.14	g	TB	BJF	✓	✓		TB	BJF
K	Sodium Hydroxide Pellets (Retain Sample)	A145	20.0	g	18.0 – 22.0	g	19.90	g	TB	BJF	✓	✓		TB	BJF
L					Total Dispensed		40.04	g	TB	BJF			✓	TB	BJF

Date Executed: 10/21/2020 Initials: TB

Dispensing Worksheet continued (for Step 12):

Sample Type	Instructions
Retain Sample	Include expiration 2 years from current date

	Raw Material	Balance ID	Target Quantity		Acceptable Range		Dispensed Quantity		Recorded By	Checked By	Label Prepared & Checked (✓)	Duplicate Label Prepared & Checked (✓)	Dispensing Label Updated (✓)	Done By	Checked By
M	Hydrochloric Acid (For pH Solution) [1]	A145	49.17	g	49.00 – 49.34	g	49.18	g	TB	BJF	✓	✓		TB	BJF
N	Hydrochloric Acid (Retain Sample) [1]	A145	20.0	g	18.0 – 22.0	g	19.90	g	TB	BJF	✓	✓		TB	BJF
O	Total Dispensed						69.08	g	TB	BJF			✓	TB	BJF
P	Benzalkonium Chloride (50% w/w solution) (Retain Sample) [1]	A145	20.0	g	18.0 – 22.0	g	20.07	g	TB	BJF	✓	✓	✓	TB	BJF

[1] **Dispense raw material into an appropriate glass container.**

Date Executed: 10/21/20 Initials: BOF

Step	Description	Done By	Checked By
13	Record the end time, room Magnehelic pressure reading, and the current temperature and relative humidity in Step 11.	BOF	TB
14	QA Final In-Process Check: All steps are completed and in-process specifications met (✓) (✓). Content on all labels has been verified (✓) (✓). All quantities dispensed are within specifications (✓) (✓). QA Initials / Date: QC 10/21/20		

Date Executed: 10/21/20 Initials: TB

VI. Solution Preparation Procedure:

Step	Description	Done By	Checked By
15	Prepare a labeled Nalgene beaker (600 mL) for **1N NaOH Solution** preparation. Add a stir bar to the beaker. Obtain the tare weight of the empty beaker with stir bar. Ensure that the label contains the following: Batch Record#: **M4097-01A** Material: **1N NaOH Solution** Receiving Number: **N/A** Lot Number: **N/A** Tare Weight: Net Quantity: **N/A** Initials/Date: Tare weight (with **stir bar**): 88.41 grams Balance Minimum Weight: 2g Balance ID: A145 Update the beaker label with tare weight (✓) (✓). Update duplicate label to the in-process section of the batch record (✓) (✓).	TB	PJF
16	Tare the beaker labeled **1N NaOH Solution** and dispense the required quantity of **Sterile Water** into it. **Required Quantity**: **480.0 (475.0 – 485.0)** **grams** Net Quantity: 481.02 grams Balance Minimum Weight: 2g Balance ID: A145 Place the beaker on the magnetic stir plate and begin mixing to form a gentle vortex (✓) (✓).	TB	PJF

Date Executed: 10/21/20 Initials: TB

Step	Description	Done By	Checked By
17	Slowly add the **Sodium Hydroxide Pellets (For pH solution)** to the vortex. Adjust stirring speed to maintain a vortex during and after pellet addition. Continue mixing until the pellets are fully dissolved and a clear solution has formed. Timer Started (✓) (✓). Mix Time: 3:06 min:sec After mixing is complete, cover the **1N NaOH Solution** with aluminum foil (✓) (✓).	TB	PJF
18	Prepare a labeled Nalgene beaker (600 mL) for **1N HCl Solution** preparation. Add a stir bar to the beaker. Obtain the tare weight of the empty beaker with stir bar. Ensure that the label contains the following: Batch Record#: **M4097-01A** Material: **1N HCl Solution** Receiving Number: **N/A** Lot Number: **N/A** Tare Weight: Net Quantity: **N/A** Initials/Date: Tare weight (with **stir bar**): 88.57 grams Balance Minimum Weight: 2g Balance ID: A145 Update the beaker label with tare weight (✓) (✓). Update duplicate label to the in-process section of the batch record (✓) (✓).	TB	PJF
19	Tare the beaker labeled **1N HCl Solution** and dispense the required quantity of **Sterile Water** into it. **Required Quantity**: **450.8 (445.8 – 455.8)** **grams** Net Quantity: 450.82 grams Balance Minimum Weight: 2g Balance ID: A145 Place the beaker on the magnetic stir plate and begin mixing to form a gentle vortex (✓) (✓).	TB	PJF

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
20	Slowly and carefully add the **Hydrochloric Acid (For pH solution)** to the vortex. Adjust stirring speed to maintain a vortex during and after solution addition. Continue mixing until a clear solution has formed. Timer Started (✓) (✓). Mix Time: 2:00 min:sec After mixing is complete, cover the **1N HCl Solution** with aluminum foil (✓) (✓).	TB	POF
21	Prepare a labeled stainless steel container (~ 1L) for **Unfiltered Naloxone Solution** preparation. Add a stir bar to the container. Obtain the tare weight of the empty container with stir bar. Ensure that the label contains the following: Batch Record#: **M4097-01A** Material: **Unfiltered Naloxone Solution** Receiving Number: **N/A** Lot Number: **N/A** Tare Weight: Net Quantity: Initials/Date: Tare weight (with **stir bar**): 318.40 grams Balance Minimum Weight: 2g Balance ID: A145 Update the container label with tare weight (✓) (✓). Update duplicate label to the in-process section of the batch record (✓) (✓).	TB	POF

Date Executed: 10/21/2020 Initials: TK

Step	Description	Done By	Checked By
22	Place the **Unfiltered Naloxone Solution** container on a balance. Zero the balance. Using a FisherBrand Elite Pipette, 100 – 1000 µL and a 1 mL fresh tip, slowly add the required quantity of **Benzalkonium Chloride (50% w/w solution)** to the container. **Target Quantity** 2.03 **grams** **Required Quantity** 1.98 – 2.08 **grams** Net Quantity Added 2.0480 grams Balance Minimum Weight 20 mg Balance ID A301 Update the dispensing label on the **Benzalkonium Chloride (50% w/w solution)** raw material container (✓) (✓). Remove the **Benzalkonium Chloride (50% w/w solution)** from the room (✓) (✓).	TK	RJT
23	Zero the balance with the labeled **Unfiltered Naloxone Solution** and dispense the required quantity of **Sterile Water** into it. **Required Quantity** 740 - 760 **grams** Net Quantity 751.71 grams Balance Minimum Weight 2g Balance ID A145 Place the container on the magnetic stir plate and begin stirring to form a gentle vortex (✓) (✓).	TK	RJT

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
24	Place a suitable weigh boat on a balance. Tare the balance and dispense the required quantity of **Naloxone HCl Dihydrate** into the weigh boat. Multiple weight boats may be used. Each weigh boat should be tared before dispensing. Record the total quantity of **Naloxone HCl Dihydrate** dispensed.	TB	BOF
25	Slowly add the dispensed **Naloxone HCl Dihydrate** to the **Unfiltered Naloxone Solution** vortex. Adjust stirring speed to maintain a vortex during and after powder addition. Mix for NLT **2** minutes and until a clear solution has formed.	TB	BOF

Required Quantity	**65.69 (65.59 – 65.79)**	**grams**
Net Quantity, Weigh Boat 1	48.97	grams
Net Quantity, Weigh Boat 2	16.80	grams
Net Quantity, Weigh Boat 3	N/A	grams
Total Quantity Dispensed	65.77	grams
Balance Minimum Weight	2g	
Balance ID	A145	

Update the dispensing label on the **Naloxone HCl Dihydrate** raw material container (✓) (✓).
Remove the **Naloxone HCl Dihydrate** raw material container from the room (✓) (✓).

Timer Started (✓) (✓).

Mix Time	2:00	min:sec

Note: The weigh boat may be rinsed into the container with **Unfiltered Naloxone Solution** if needed.

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
26	Slowly add the **Citric Acid Anhydrous (For Solution Prep)** to the **Unfiltered Naloxone Solution** vortex. Adjust stirring speed to maintain a vortex during and after powder addition. Mix for NLT **2** minutes and until a clear solution has formed. Timer Started (✓) (✓). Mix Time: 2:00 min:sec Note: The **Citric Acid Anhydrous (For Solution Prep)** may be rinsed into the container with **Unfiltered Naloxone Solution** if needed.	TB	RJF
27	Slowly add the **Disodium EDTA Dihydrate (For Solution Prep)** to the **Unfiltered Naloxone Solution** vortex. Adjust mixer speed to maintain a vortex during and after powder addition. Mix for NLT **2** minutes and until a clear solution has formed. Timer Started (✓) (✓). Mix Time: 2:00 min:sec Note: The **Disodium EDTA Dihydrate (For Solution Prep)** may be rinsed into the container with **Unfiltered Naloxone Solution** if needed.	TB	RJF
28	Slowly add the **Sodium Chloride (For Solution Prep)** to the vortex. Adjust stirring speed to maintain a vortex during and after powder addition. Mix for NLT **2** minutes and until a clear solution has formed. Timer Started (✓) (✓). Mix Time: 2:00 min:sec Note: The **Sodium Chloride (For Solution Prep)** may be rinsed into the container with **Unfiltered Naloxone Solution** if needed.	TB	RJF

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
29	Place the **1N NaOH Solution** on an appropriate balance and tare the solution. Increase the mixing speed of the **Unfiltered Naloxone Solution** so that a vigorous vortex is formed without splashing the solution. Dropwise, slowly add the required quantity of **1N NaOH Solution** using a FisherBrand Elite Pipette, 100 – 1000 µL with a fresh 1 mL tip until the required quantity of **1N NaOH Solution** has been added. Mix for NLT **2** minutes following the complete addition of **1N NaOH Solution**. (1)	TB	PSF
30	Zero an appropriate balance and place the **Unfiltered Naloxone Solution** container on it. Obtain the gross weight. Calculate the net quantity of **Unfiltered Naloxone Solution** and **Sterile Water** required to Q.S. the solution to a net quantity of **1,000 grams**.	TB	PSF

Required Quantity	16.63 (16.50 – 16.76)	grams
Net Quantity	16.64	grams
Balance Minimum Weight	2g	
Balance ID	A145	

A	Gross weight of solution/container	1157.49	grams
B	Tare weight (from label)	318.40	grams
C	Net quantity of Solution (gross – tare)	839.09	grams
D	Additional Sterile Water required (= 1,000 – C)	160.91	grams
E	Balance Minimum Weight	2g	
F	Balance ID	A145	

(1) Solution mixed for 2:00 min:sec following total addition. TB 10/21/2020 PSF 10/21/20

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
31	Place a Nalgene Beaker (600 mL) on a balance. Tare the balance and dispense the required quantity of **Sterile Water** into the container.	TB	BSF

Required Quantity	Step 30D +/- 1.0	grams
Net Quantity	161.51	grams
Balance Minimum Weight	2g	
Balance ID	A145	

Step	Description	Done By	Checked By
32	Transfer the **Sterile Water** dispensed in the prior Step to the **Unfiltered Naloxone Solution**. Place the solution on the magnetic stir plate. Turn on the stirrer so that a gentle vortex is achieved. Continue stirring for NLT 5 minutes. Timer Started (✓) (✓).	TB	PSF

Mix Time	5:00	min:sec

Step	Description	Done By	Checked By
33	Prepare a labeled HDPE container with lid (2 gal) to collect **Naloxone Waste**. Waste includes in-process pH samples, filter flushes and other discarded solution. Obtain the tare weight of the empty container with lid. Ensure that the label contains the following: Batch Record#: **M4097-01A** Material: **Naloxone Waste** Receiving Number: **N/A** Lot Number: **N/A** Tare Weight: Net Quantity: Initials/Date: Update the container label with tare weight (✓) (✓). Update duplicate label to the in-process section of the batch record (✓) (✓).	TB	PSF

Tare weight (with lid)	550.20	grams
Balance Minimum Weight	2g	
Balance ID	A145	

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
34	Verify that the pH meter has been calibrated. If the calibration has not been done on the current date, perform calibration as instructed in SOP A25. Record the calibration in the equipment logbook. pH Meter ID: A185 Calibration has been performed and passed (✓): ✓	TB	PJ

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
35	**Solution pH Adjustment** Record data in the table below. All samples will be placed into **Naloxone Waste** after measurement is completed. 1. Using a sterile disposable pipette, transfer a sufficient quantity of **Unfiltered Naloxone Solution** into a tared glass scintillation vial. Record the weight of solution sampled. 2. Measure the initial pH of the solution. 3. If the pH is less than 4.40, add additional aliquots of **1N NaOH Solution** as needed to reach target range. a. Mix for NLT 2 minutes before sampling. 4. If the pH is greater than 4.60, add aliquots of **1N HCl Solution** as needed to reach target range. a. Mix for NLT 2 minutes before sampling. **Target pH: 4.50** **Acceptable Range: 4.40 – 4.60**	TB	PJF

Addition #	1N NaOH Solution Added (g)	1N HCl Solution Added (g)	Mixing Time (min:sec)	Sample Quantity (g)	pH
0	n/a	n/a	0:0	7.51	4.40
1					
2					
3					
4					
5					
6					
7					
8					
Total	A: n/a	B: n/a	n/a	C: 7.51	

DMS 26 Oct 2020

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
36	Return the **Unfiltered Naloxone Solution** to a zeroed balance. Obtain the gross weight of the solution/container. Calculate the net quantity of unfiltered solution prepared.	TB	POF

Gross weight of solution/container	1311.31	grams
Tare weight (from label)	318.40	grams
Net quantity of unfiltered solution (gross-tare)	992.91	grams
Balance Minimum Weight	2g	
Balance ID	A145	

Update the in-process label to reflect the current net quantity (✓) (✓).
Update the duplicate label in the in-process section of the batch record (✓) (✓).

37	Record the end time, room Magnehelic pressure reading, and the current temperature and relative humidity in Step 11.	POF	TB
38	QA In-Process Check (Solution Preparation): All steps are completed and in-process specifications met (✓) (✓). All calculations have been verified (✓) (✓). Content on all labels has been verified (✓) (✓). QA Initials / Date: QC 10/21/20		

Date Executed: 10/21/2020 Initials: JB

VII. Filtration:

Step	Description	Done By	Checked By
39	Prepare a labeled glass Media Bottle with Lid (1L) for collection of **Filtered Naloxone Solution.** Record the tare weight of the labeled container with lid. Ensure that the label contains the following: Batch Record#: **M4097-01A** Material: **Filtered Naloxone Solution** Receiving Number: **N/A** Lot Number: **N/A** Tare Weight: Net Quantity: Initials/Date : Tare weight (with label & lid): 587.09 grams; Balance Minimum Weight: 2g; Balance ID: A145 Update the container label with the tare weight (✓) (✓). Update the duplicate label in the in-process section of the batch record (✓) (✓).	JB	POF
40	Setup the peristaltic pump with Tygon 17 tubing. Attach an **OptiScale 47** filter to the outlet side. Place the HDPE Container labeled **Naloxone Waste** on a balance. Tare the balance. Turn on the peristaltic pump and flush the required quantity of **Unfiltered Naloxone Solution** through the filter into the waste container. **Required flush quantity: 300 - 325 grams**; Net quantity of flush: 300.84 grams; Balance Minimum Weight: 2g; Balance ID: A145	JB	POF

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
41	**Filtration Instructions:** 1. Direct the outlet of the filter into the media bottle labeled **Filtered Naloxone Solution.** 2. Turn on the peristaltic pump and filter the entire remaining quantity of **Unfiltered Naloxone Solution** into the media bottle. 3. Place the cap securely on the media bottle. 4. Transfer any unfiltered solution to the **Naloxone Waste** container. 5. Discard the pump tubing and used filter. 6. Update the duplicate label for the **Unfiltered Naloxone Solution** in the in-process section to reflect a net quantity remaining of 0 grams.	TB	JSF
42	Obtain the gross weight (with lid) of the Media Bottle used to collect **Filtered Naloxone Solution.** Calculate the net quantity of filtered solution available. Gross weight (with lid): 1264.33 grams Tare weight (from label): 587.09 grams Net quantity (gross – tare): 677.24 grams Balance Minimum Weight: 2g Balance ID: A145 Update the container label with the net quantity of solution (✓) (✓). Update the duplicate label in the in-process section of the batch record (✓) (✓).	TB	JSF

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
43	Collect any remaining waste in the **Naloxone Waste** container and seal with the lid. Determine the net quantity collected. Gross weight of waste/container/lid: 866.27 grams Tare weight (from label): 550.20 grams Net quantity (gross – tare): ~~36.07~~ ① grams Balance Minimum Weight: 2g Balance ID: A145 Update the label on the container to reflect the current net quantity (✓) (✓). Update the duplicate label in the In-Process Section to reflect net quantity of waste collected (✓) (✓).	TB	PSF
44	Prepare a labeled HDPE container with lid (2 gal) to collect **HCl / NaOH Waste**. Waste includes remaining pH adjustment solutions. Ensure that the label contains the following: Batch Record#: **M4097-01A** Material: **HCl / NaOH Waste** Receiving Number: **N/A** Lot Number: **N/A** Tare Weight: **N/A** Net Quantity: **N/A** Initials/Date: Update duplicate label to the in-process section of the batch record (✓) (✓).	TB	PSF
45	Transfer the **1N HCl** Solution and **1N NaOH Solution** to the **HCl / NaOH Waste** container and seal with the lid.	TB	PSF

① 316.07g - For Clarity. TB 10/26/2020 PSF 10/27/2020

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
46	**Filtered Naloxone Solution Accountability:**	TB	RJF

A	Net quantity of formulation excipients added (Step 12A + Step 12D + Step 12G + Step 22 + Step 24, Total)	71.8854	grams
B	Net quantity of sterile water added (Step 23 + Step 31)	913.22	grams
C	Net quantity of pH adjustment solution added (Step 29 + Step 35A + Step 35B)	16.64	grams
D	Net quantity of all components (A + B + C)	1061.7454	grams
E	Net quantity of pH samples taken (Step 35C)	7.51	grams
F	Net quantity of **Filtered Naloxone Solution** (Step 42)	677.24	grams
G	Net quantity of **Naloxone Waste** (Step 43)	316.07	grams
H	**Accountability (≥ 90 and ≤ 102%):** (E + F + G) / D X 100 Notify QA if accountability is less than 90% or greater than 102%.	100	%
I	**Yield (For Information Only)** F / D x 100	68	%

47	Record the current room temperature, relative humidity, and Magnehelic pressure reading in the table in Step 11 (✓) (✓).	TB	RJF
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 (✓) (✓).	TB	RJF

Date Executed: 10/21/2020 Initials: TB

Step	Description	Done By	Checked By
49	Final QA In-Process Check: All steps are complete and any in-process specifications have been met (✓) (✓). Content on all labels has been verified (✓) (✓). QA Initials / Date: DC 10/21/20		

VIII. In-Process Section:

TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Citric Acid Anhydrous (For Solution Prep)**
Receiving#: **R200807-01A**
Lot#: **S006054**
Tare Weight: 20.3817g
Net Quantity: 1.9582g
Initials/Date: 10/21/2020 TB LE. Gi 10/21/2020 TB 10/21/2020

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TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Citric Acid Anhydrous (Retain Sample)**
Receiving#: **R200807-01A**
Lot#: **S006054**
Tare Weight: 4.32g
Net Quantity: 19.96g
Retain Exp: 10/21/2022
Initials/Date: TB 10/21/2020

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DMS 26 OCT 2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Disodium EDTA Dihydrate (For Solution Prep)**
Receiving#: **R180427-02**
Lot#: **E300000683**
Tare Weight: 20.1595g
Net Quantity: 0.5758g
Initials/Date: TB 10/21/2020

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TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Disodium EDTA Dihydrate (Retain Sample)**
Receiving#: **R180427-02**
Lot#: **E300000683**
Tare Weight: 4.28g
Net Quantity: 19.38g
Retain Exp: ~~TB~~ 10/21/2022 EE TB 10/21/2020
Initials/Date: TB 10/21/2020

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TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Sodium Chloride (For Solution Prep)**
Receiving#: **R200203-02A**
Lot#: **0000248072**
Tare Weight: 20.2921g
Net Quantity: 1.5334g
Initials/Date: TB 10/21/2020

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TB 10/21/2020

2022/12/01 SL

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Sodium Chloride (Retain Sample)**
Receiving#: **R200203-02A**
Lot#: **0000248072**
Tare Weight: 4.34g
Net Quantity: 20.75g
Retain Exp: 10/21/2022
Initials/Date: TB 10/21/2020

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VIII. In-Process Section (Continued):

TB 10/21/20

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Sodium Hydroxide Pellets (For pH solution)**
Receiving#: **R190627-01**
Lot#: **0000231642**
Tare Weight: 4.38g
Net Quantity: 20.14g
Initials/Date: TB 10/21/20

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TB 10/21/20

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Sodium Hydroxide Pellets (Retain Sample)**
Receiving#: **R190627-01**
Lot#: **0000231642**
Tare Weight: 4.34g
Net Quantity: 19.90g Retain Exp: 10/21/2022
Initials/Date: TB 10/21/2020

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DMS 26 Oct 2020

TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Hydrochloric Acid (For pH Solution)**
Receiving#: **R160808-02**
Lot#: **0000144734**
Tare Weight: 246.13g
Net Quantity: 49.18g
Initials/Date: TB 10/21/2020

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TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Hydrochloric Acid (Retain Sample)**
Receiving#: **R160808-02**
Lot#: **0000144734**
Tare Weight: 246.50g
Net Quantity: 19.90g Retain Exp: 10/21/2022
Initials/Date: TB 10/21/20

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Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Benzalkonium Chloride (50% w/w solution) (Retain Sample)**
Receiving#: **R200813-01A**
Lot#: **BCBZ4386**
Tare Weight: 245.36g
Net Quantity: 20.07g Retain Exp: 10/21/2022
Initials/Date: TB 10/21/20

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TB 10/21/20

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **1N NaOH Solution**
Receiving#: **N/A**
Lot#: **N/A**
Tare Weight: 88.41g
Net Quantity: N/A
Initials/Date: TB 10/21/20

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VIII. In-Process Section (Continued):

TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **1N HCl Solution**
Receiving#: **N/A**
Lot#: **N/A**
Tare Weight: 88.57g
Net Quantity: N/A
Initials/Date: TB 10/21/2020

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TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Unfiltered Naloxone Solution**
Receiving#: **N/A**
Lot#: **N/A**
Tare Weight: 318.40g
Net Quantity: 992.91g
Initials/Date: TB 10/21/2020

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DMS 26 OCT 2020

TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Naloxone Waste**
Receiving#: **N/A**
Lot#: **N/A**
Tare Weight: 550.20g
Net Quantity: 316.09g
Initials/Date: TB 10/21/2020

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TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **Filtered Naloxone Solution**
Receiving#: **N/A**
Lot#: **N/A**
Tare Weight: 587.09g
Net Quantity: 677.24g
Initials/Date: TB 10/21/2020

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

TB 10/21/2020

Clinical Batch In Process Label

Batch Record#:**M4097-01A**
Material: **HCl / NaOH Waste**
Receiving#: **N/A**
Lot#: **N/A**
Tare Weight: N/A
Net Quantity: N/A
Initials/Date: TB 10/21/2020

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DMS 26 OCT 2020

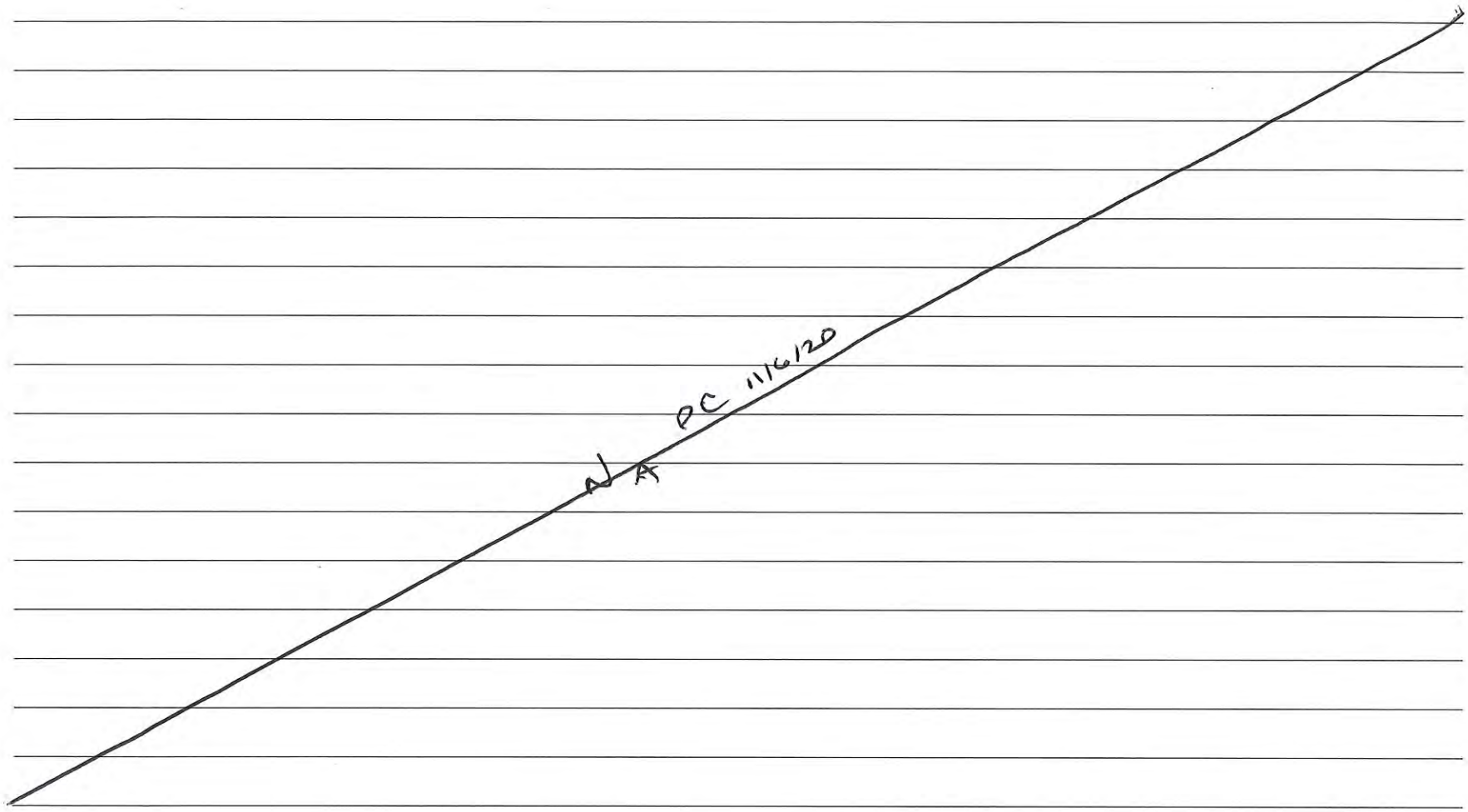
VIII. In-Process Section (Continued):

DHS 26 OCT 2020

IX. Comments:

N/A dc 11/6/20

IX. Comments (Continued):



X. Technical Review:

Step	Description	Reviewed By / Date
50	Technical Review: 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.	DMS 27 Oct 2020

Attachment Name	# of pages	Initials/Date
Daily Chart Recorder Paper	1	TB 10/21/2020

DMS 26 Oct 2020

XI. Final Batch Record Approval:

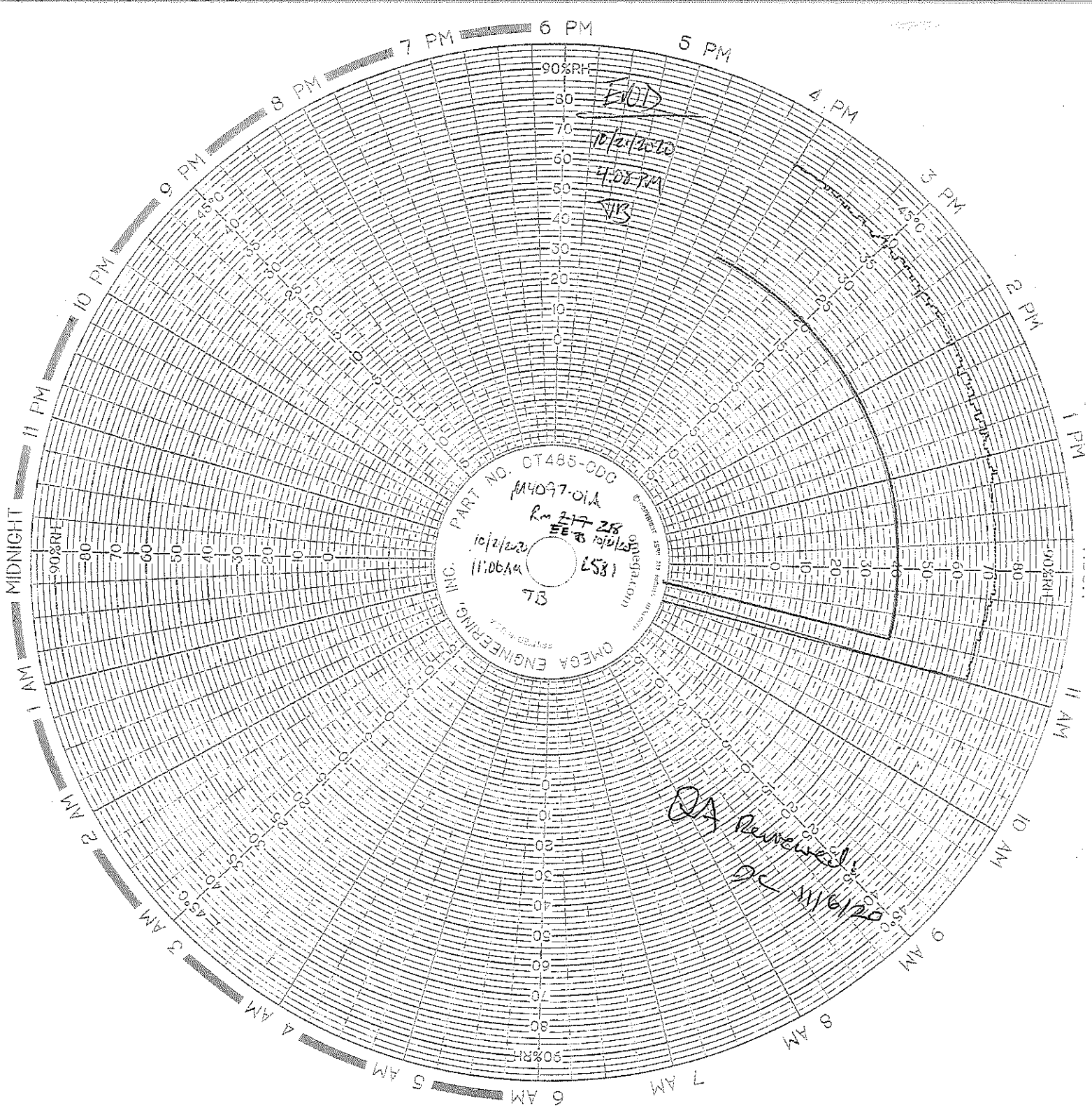
This batch record was reviewed after its execution and was found to be acceptable. The signatures below indicate approval of this batch record as adequate, complete, and correct.

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				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OMEGA ENGINEERING, INC.
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