

COMPOUNDING

Nicardipine HCl Injection (2.5 mg/mL), 25 mg, 10 mL Vial, 203 Liters, Line 2, Michelle Master Batch Record # : MBR-000618	Lot Number: 10001288
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Exela Pharma Sciences

Nicardipine HCl Injection (2.5 mg/mL), 25 mg, 10 mL Vial, 203 Liters, Line 2, Michelle

Exela Catalog Number: 1020TS003

BATCH RECORD ISSUED BY:

Winter J. Tugman

QUALITY ASSURANCE SIGNATURE

DATE

14 JUN, 2023

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SPECIAL INSTRUCTIONS

Safety Requirements:

Personal Protective Equipment: Eye Protection (Safety Glasses or Goggles), Particulate Mask, and Gloves.

Finished Product Storage: 20° - 25°C with excursions allowed between 15° - 30°C

ALLOWABLE HOLD TIME	
Status	Hold Time
Start of Compounding to Start of Filling	NMT 48 hours (2012-PV-099)
End of Filling to Start of Final Terminal Sterilization Load	NMT 72 hours (2012-PV-099)

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Pre-Line Clearance per SOP-OP-000005

Operation	First Session		Second Session		Third Session	
	Room#: <u>102</u>	Room#:	Performed By/Date	Verified By/Date	Performed By/Date	Verified By/Date
1. Check Room Cleaning and Equipment History Logs to ensure equipment/room is clean and ready for use.	<u>MM/DD/23</u> <u>WED JUL 26</u>	<u>JULY 23</u> <u>2023</u>				
2. Room and equipment are visibly clean.	<u>MM/DD/23</u> <u>WED JUL 26</u>	<u>JULY 23</u> <u>2023</u>				
3. NO foreign batch material is in the room.	<u>MM/DD/23</u> <u>WED JUL 26</u>	<u>JULY 23</u> <u>2023</u>				
4. Verify product components and document on Compounding Dispensing page.	<u>MM/DD/23</u> <u>WED JUL 26</u>	<u>JULY 23</u> <u>2023</u>				
5. Required calibrations for equipment are current. Document on Compounding Equipment List.	<u>MM/DD/23</u> <u>WED JUL 26</u>	<u>JULY 23</u> <u>2023</u>				
6. Remove or cover any equipment in the room that is not required for the current process.	<u>MM/DD/23</u> <u>WED JUL 26</u>	<u>JULY 23</u> <u>2023</u>				

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Operation	First Session		Second Session		Third Session	
	Room#:	162	Room#:	162	Performed By/Date	Verified By/Date
				<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A
7. Verify applicable balance/scale check has been performed, if the equipment is to be used, per SOP-OP-000019 or SOP-OP-000034.		2023-06-23 JAS/OLIVER				
8. Appropriate room status signs have been posted.		2023-06-23 JAS/OLIVER				

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PRODUCT COMPOSITION

Material Name	Exela Part #	Function	Quantity per L	Quantity per Batch
Nicardipine HCl, USP	1030	Active	2.5 g	507.5 g
Benzoic Acid, USP	1238	Excipient	0.305 g	61.915 g
Sodium Hydroxide, NF	1004	pH adjust	N/A	Variable to adjust pH to 3.6
Sodium Chloride, USP	1008	Excipient	7.5 g	1,522.5 g
Water for Injection, USP	1013	Solvent	q.s. to 1.0 L	q.s. to 203.0 L

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Lot Number:
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Compounding Dispensing

Attach Exela COA for each raw material used.

Spec. Number	Lot Number	Exp./Retest Date	Amount Required	Amount Dispensed	Performed By/Date	Dispensed Amount / Verified By/Date	Lot Number / Exp./Retest Date / Verified By/Date
1030 Nicardipine HCl, USP	20K004	22 DEC 24		509.54g	JAS 06JUL23	<input checked="" type="checkbox"/> Printout 509.54g AUT 06JUL23 Ann 06JUL23	20K004 22DEC24 AUT 06JUL23 Ann 06JUL23 ② 20K004 22DEC24 AUT 06JUL23 Ann 06JUL23 ③
					N/A JAS 07JUL23		
1238 Benzoic Acid, USP	22F119	23 JUN 24		61.92g	JAS 06JUL23	<input checked="" type="checkbox"/> Printout 61.92g AUT 06JUL23 Ann 06JUL23	22F 01JUL24 22JUN24 AUT 06JUL23 Ann 06JUL23 N/A JAS 06JUL23 ③
				61.92 g	N/A JAS 07JUL23		
1004 Sodium Hydroxide, NF	22F224	08 NOV 23		8.00g	JAS 07JUL23	<input checked="" type="checkbox"/> Printout 8.00g AUT 07JUL23 Ann 07JUL23	22F224 08NOV23 Ann 07JUL23 N/A JAS 07JUL23 ③
				8 g	N/A JAS 07JUL23		

① mistakenly wrote wrong lot number AUT 06JUL23

② information not needed AUT 06JUL23

③ Clarify exp. / retest date AUT 07JUL23 FOR GMP USE ONLY

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Spec. Number	Lot Number	Exp./Retest Date	Amount Required	Amount Dispensed	Performed By/Date	Dispensed Amount / Verified By/Date	Lot Number / Exp./Retest Date / Verified By/Date
1008 Sodium Chloride, USP	22G099	23AUG23		1522.50g 1522.50g	JAS 07JUL23 N/A JAS 07JUL23	<input checked="" type="checkbox"/> Printout 1522.5g (2) AUT 07JUL23 1522.50g AUT 07JUL23	22G099 23AUG23 AUT 07JUL23 1522.50g AUT 07JUL23
1013 Water for Injection, USP			1522.5 g		JAS 07JUL23		
				no expiry			WFI-5 no expiry 07OCT2023 AUT 07JUL23 07OCT2023 07JUL23 N/A 07JUL23

① documented wrong lot number JAS 07JUL23

② clarifying amount dispensed 1522.50g AUT 07JUL23
 ③ clarifying amount dispensed JAS 07JUL23

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Component Check-In

Attach Exela COA for each component used.

Spec. Number	Lot Number	Exp. Date	Recorded By/Date	Lot Number / Exp. Date / Verified By/Date
2101 / 2118 (Circle One) 200 L Mixing Bag	00E114	31MAR24	ACT 00JUL23 Anmagesu23	22E116 31MAY14 JAGI 06JUL23
2076 (2309) (Circle One) Hopper Funnel	18L15Q	10OCT23	ACT 00JUL23 Anmagesu23	18L152 06JUL23 10OCT23

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Benzac Acid USP OP4124	Balance/Scale Printout Attachments	
Nicardipine HCl, USP OP4124	Sodium Hydroxide NF OP4124	
tare weight	0.00 g	0.00 g
	16.68 g	tare weight 335.27 g
H	0.00 g	H 0.00 g
H lot#	61.92 g	H 509.54 g
	2013	H 165.5 g
		AUT 07JUL23
		AUT 07JUL23
Sodium Chloride, USP OP4124		
tare weight	0.00 g	0.00 g
	335.26 g	ALT 07JUL23
H	0.00 g	
H	1522.95 g	
Balance	873.23 g	
21st ap	1522.50 g	FOR GMP USE ONLY

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NIA
JAN 23
G7.11.23

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Batch Calculations	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
1. If one raw material lot, perform the following calculation:	% Assay ⊕	99.7 % 06JUL23	99.7 % JAS 06JUL23	% 06JUL23
	% LOD	0.1 % 06JUL23	0.1 % ALT 06JUL23	% 06JUL23
$\frac{2.5 \text{ g}}{\text{L}} \times 203 \text{ Liters} \times \frac{100}{\underline{99.7} \% \text{ Assay}} \times \frac{100\%}{100\% - \underline{0.1} \% \text{ LOD}}$ = <u>509.54</u> g required for batch	API Required (g)	<u>509.54</u> g	509.54 g	g

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Batch Calculations	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
2. If two raw material lots, perform the following calculations:	Amount of Material (Lot 1)	g	g	g
Lot 1:	% Assay (Lot 1) ①	%	%	%
$\frac{\text{actual g in lot}}{2.5 \text{ g}} \times \frac{1 \text{ Liter}}{2.5 \text{ g}} \times \frac{\% \text{ Assay}}{100\%} \times \frac{100\% - \% \text{ LOD}}{100\%}$	% LOD (Lot 1)	%	%	%
= _____ (Lot 1)	Lot 1 (Liters)	L	L	L
Lot 2:	% Assay (Lot 2) ①	%	%	%
$\frac{2.5 \text{ g}}{2.5 \text{ g}} \times (203 \text{ Liters} - (L1)) \times \frac{100\%}{\% \text{ Assay}} \times \frac{100\%}{100\% - \% \text{ LOD}}$	% LOD (Lot 2)	%	%	%
= _____ grams required (Lot 2)	Lot 2: Amount required	g	g	g
Total:	Lot 1 (g) + Lot 2 (g)	Total (g)	Total (g)	Total (g)

① Note: If API assay value is $\geq 100\%$, Use 100% as Assay Value.

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Compounding Equipment List

Note: List all equipment used for this compounding process. Record additional equipment as required.

Item	Asset #, Unique Identifier, or Lot #	Calibration Due/Expiration Date
200 L Xcellerex Mixing System	OP4085	31JAN04
WFI Port	WF1-5	No expirY
Analytical Balance(s)	OP4124	31AUG23
Floor Scale	OP4541	29FEB24
Temperature Probe(s)	22D031	16 NOV 23
pH Meter ID	OP4065	31JUL23

Equivalent Mix Speeds per 2014-IOQ-117:

Displayed Set Point						
10	20	30	40	50	60	70
1.1	13.1	36.4	61.4	84.1	103.8	126.5

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Compounding

Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
Mixer ID	OP4085	JAS 06Jul23	OP4085 06Jul23	AT 06Jul23 Ann 06Jul23
Date Cleaned	06Jul23		06Jul23	
1. Inspect compounding mixer for cleanliness.				
2. Inspect the compounding mixing bag, and then install and complete set up with funnel as per SOP-OP-000007. Obtain tare weight of compounding mixer.	Tare Weight 79.1 kg	JAS 06Jul23	79.1 kg	AT 06Jul23 Ann 06Jul23
3. Tare scale or load cells. Add 180 ± 1.0 kg of WFI at a target temperature of 55°C (range 50° - 65°C) to the compounding mixing bag. Record time WFI is added to the Mixer.	WFI added 180.1 kg	JAS 06Jul23	180.1 kg	AT 06Jul23 Ann 06Jul23
	Addition Temp 52 °C		52 °C	
	Addition Time 0853		0853	
4. Maintain temperature at a target of 55°C (range: 50° - 65°C) throughout WFI addition using heat exchanger. Begin mixing at SET SPEED 80 or equivalent per Equivalent Mix Speeds per 2014-IOQ-117 chart.	Mixing Start Time 0859	JAS 06Jul23	0859 06Jul23	AT 06Jul23 Ann 06Jul23
	Mixer Speed 154		154	

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Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
Solution Temp	50 °C		50 °C	AUT 06JUL23
Addition Start Time	0917	JAS	0917	AMM 06JUL23
Addition End Time	0917	06JUL23	0917	
Total Addition Time	< 1 min	17451 06JUL23	17455 06JUL23	1 min Aut 06JUL23
Mix Start Time	0917		0917	
Mix End Time	1102		1102	
Solution Weight	180.3 kg		180.3 kg	
Sampling Time	1102	JAS	1102	AUT 06JUL23
Sample Volume	10 mL	06JUL23	10 mL	AMM 06JUL23
Additional Mix Time		<input checked="" type="checkbox"/> N/A		<input type="checkbox"/> N/A
Dissolution Confirmed	YES / NO		YES / NO	

① not needed AUT 06JUL23

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Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
7. Verify temperature of solution is NLT 45°C. With continued mixing, add the required amount of Nicardipine HCl, USP, into the mixing bag. Rinse all containers and funnel following the addition with WFI (range 30° - 55°C). Remove addition funnel, cap the mixing bag, and continue mixing for a minimum of 45 minutes or until complete dissolution is observed. Record solution temperature and weight.	Solution Temp 47 °C 1104	JAS 07JUL23 1104	47 °C 1109	AUT 07JUL23 Ann 07JUL23
	Addition Start Time 1109	JAS 07JUL23 1109		
	Addition End Time 1109	JAS 07JUL23 1109		
	Total Addition Time 5 min		5 min	
	Mix Start Time 1109		1109	
	Mix End Time 0428	JAS 07JUL23 1109	0428	AUT 07JUL23 Ann 07JUL23
	Solution Weight 198.0 kg		198.0 kg	
8. Confirm Nicardipine HCl, USP dissolution by collecting a sample into a clear, colorless container. If dissolution is not observed, continue mixing until complete dissolution is achieved.	Sampling Time 0428	JAS 07JUL23 1109	0428	AUT 07JUL23 Ann 07JUL23
	Sample Volume 10 mL		10 mL	
	Additional Mix Time <input checked="" type="checkbox"/> N/A		<input checked="" type="checkbox"/> N/A	
	Dissolution Confirmed <input checked="" type="radio"/> YES / NO		<input checked="" type="radio"/> YES / NO	

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Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
Initial pH	3.40	JAS 07JUL23	3.40	AJ 07JUL23
Time	0431		0431	AMM 07JUL23
10. With continued mixing at speed setting 80 or equivalent per Equivalent Mix Speeds per 2014-10Q-117 chart, remove cap and attach funnel. Adjust pH to a target of 3.65 (range: 3.60 to 3.70) with 0.1 N NaOH Solution (approximately 3 mL of 0.1 N NaOH per liter is required). Mix for not less than 10 minutes after each addition. Prepare 0.1 N NaOH according to the instructions below. Record pH adjustment information in the pH adjustment table.		JAS 07JUL23	JAS 07JUL23	AJ 07JUL23

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Preparation of Solutions for pH Adjustment

0.1 N Sodium Hydroxide Solution

This solution is used to increase pH. If pH solution previously prepared, document lot number and expiry of prepared solution. N/A preparation tables and attach copy of preparation documentation. If pH adjustment is not required, N/A page.

Material	Lot Number	Expiration	Documented By/Date	Lot Number / Verified By/ Date	Expiration / Verified By/Date
0.1 N Sodium Hydroxide, NF				JAS 07/01/23	JAS 07/01/23

Material	Theoretical Quantity	Measured Quantity	Performed By/Date	Verified By/Date
Sodium Hydroxide, NF EXELA Spec #: 1004	8.0 g	8.00 g	JAS 07/01/23	JAS 07/01/23
Water for Injection, USP EXELA Spec #: 1013	q.s. to 2 L			Ann 07/01/23

Note: Solution may be volumetrically scaled

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Operation	Performed By/Date	Verified By/Date
1. Place approximately 2,000 mL room temperature WFI into a 2,000 mL volumetric beaker.	JAS 07JUL23 JAS 07JUL23	AUT 07JUL23 Aut 07JUL23
2. Add weighed amount of Sodium Hydroxide to the beaker; mix by manual stirring.	JAS 07JUL23 JAS 07JUL23	AUT 07JUL23 Aut 07JUL23
3. Label with solution name, batch number, date prepared and initials of preparer.	JAS 07JUL23 JAS 07JUL23	AUT 07JUL23 Aut 07JUL23
4. Hold solution until completion of the compounding activities. Discard remaining solution after use.	JAS 07JUL23 JAS 07JUL23	AUT 07JUL23 Aut 07JUL23

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pH Adjustment Table

NOTE: Mix for NLT 10 minutes after each adjustment addition. If initial pH is within acceptable pH range and does not require adjustment, 'N/A' table.

Sample	pH Pre Adjustment	Solution Added	Volume Added (mL)	Mixer Speed (rpm)	Time of Addition	Mix Time (minutes)	pH Post Adjustment	pH Adjustment
Initial	3.40	NaOH	820mL	154	0434	10min	3.45	NaOH 820mL ACT 07JUL23
2		NaOH						
3		NaOH						
4		NaOH						
5		NaOH						
6		NaOH						
7		NaOH						
Total Volume Added NaOH (mL)								Recorded By/Date
820mL								ACT 07JUL23
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Compounding (continued)

Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
11. Verify the solution temperature prior to proceeding to Step 12 (specification = 30° - 50°C).	Solution Temp 32	°C JAS 07JUL23	32	°C AUT 07JUL23 Ann 07JUL23
Addition Start Time	0500	JAS 07JUL23	0500	AUT 07JUL23 Ann 07JUL23
Addition End Time	0504	JAS 07JUL23	0504	AUT 07JUL23 Ann 07JUL23
Total Addition Time	4	min 07JUL23	4	min
Mix Start Time	0504		0504	
Mix End Time	0521		0521	
Solution Weight	202.0	kg	202.0	kg

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Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
Sampling Time	0521	JKS 07/07/23	0521	ALT 07/07/23
Sample Volume	10 mL		10 mL	
Additional Mix Time		<input checked="" type="checkbox"/> N/A		<input type="checkbox"/> N/A
Dissolution Confirmed	YES / NO		YES / NO	

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Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
Mix Start Time	0523	JAS 07/01/23	0523 07/01/23	AJT 07/01/23
Mix End Time	0535		0535	MM 07/01/23
Mixer Speed	154		154	
Solution Weight	204.2 kg		204.2 kg	
Final Solution Temp	32 °C	JAS 07/01/23	32 °C	AJT 07/01/23
Solution pH	3.56		3.56	MM 07/01/23

① Wrong TIME AJT 07/01/23
② error code not needed AJT 07/01/23

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16. From the sample port collect the specified In-Process samples. Record the sample volumes.
Prior to lab submission, label each container with Product Name, Catalog Number, Lot Number, Time and
Date Sampled, and Sampler Initials. Complete Part A of FORM-000653.

Description	Number of samples	Amount of each sample	Total amount sampled	Sampling Time(s)	Performed By/Date	Verified Total Amount Sampled	Verified Sampling Time	Verified By/Date
Chemistry in-process bulk sample(s): use sterile pyrogen free syringe(s)	1	60 mL	60	0539	JAS 07JUL23	60	0539	JAS 07JUL23
Microbiology bioburden sample(s): Use sterile, pyrogen free syringe(s) Collect sample immediately prior to initiation of filtration.	1	60 mL	60	0708	AT 07JUL23 JAS 07JUL23	60	0708	JAS 07JUL23
Filtration Start Time: <u>0115</u>								
Bulk retain sample(s): use Type 1 glass bottle.	1	400 mL	400	0540	JAS 07JUL23	400	0540	JAS 07JUL23
Additional Sample Volume① Description: <u>pH</u>	1	10 mL	10		JAS 07JUL23	10		JAS 07JUL23

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Description	Number of samples	Amount of each sample	Total amount sampled	Sampling Time(s)	Performed By/Date	Verified Total Amount Sampled	Verified Sampling Time	Verified By/Date
Total Sampled Volume			530 mL		AUT 07JUL23 JAS 07JUL23	530 mL		JAS 07JUL23
Calculate the total weight of samples using the density: Sample Volume x Density (1.01 g/mL) x 1 kg/1000 g =			0.5 kg		AUT 07JUL23 JAS 07JUL23	0.5 kg		JAS 07JUL23

① Provide description of additional samples. (Ex. Deviation number, Protocol number, etc.)

Compounding Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
17. Record Solution Weight after samples.	Actual Bulk Yield	203.6 kg	JAS 07JUL23	203.6 kg JAS 07JUL23

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Post Production Activities per SOP-OP-000005

Operation	First Session		Second Session		Third Session	
	Performed By/Date	Verified By/Date	Performed By/Date	Verified By/Date	Performed By/Date	Verified By/Date
1. Documentation in log books has been completed and dirty equipment has been cleaned and removed.	JAS 07JUL23		JAS 07JUL23			
2. All batch specific materials have been removed from the room.	ALT 07JUL23				<input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> N/A

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Compounding Accountability – Must be completed prior to beginning Sterile Filtration and Filling

Operation	Performer Result	Performed By/Date	Verifier Result	Verified By/Date
1. Theoretical Bulk Yield	204.2 kg		204.2 kg	
2. Actual Bulk Yield (Step 17):	<u>203.6</u> kg		<u>203.6</u> kg	
3. Losses – Total Sample Weight (Step 16)	<u>0.5</u> kg	JAS 07JUL23	<u>0.5</u> kg	
4. Percent Accountability: ① (Actual Bulk Yield (kg) + Total Losses (kg)) ÷ Post q.s. weight (kg) × 100 = (Step 17 + Step 16) ÷ Step 14 × 100 = (<u>203.6</u> kg + <u>0.5</u> kg) ÷ <u>204.2</u> kg × 100 =	<u>100</u> %	AUT 07JUL23	<u>100</u> %	JAS 07JUL23
5. Percent Theoretical Yield: ② (Actual Bulk Yield (kg) ÷ Theoretical Yield (kg) × 100 = (Step 17 ÷ 204.2 kg) × 100 = (<u>203.6</u> ÷ 204.2 kg) × 100 =	<u>100</u> %		<u>100</u> %	

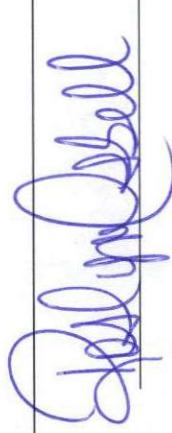
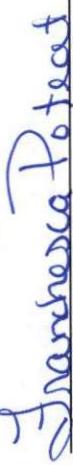
- ① Acceptable results 97% - 103%;
- ② Acceptable results 90% -102%;

Contact Quality Assurance / Production Management if results are not acceptable.
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COMPOUNDING

Nicardipine HCl Injection (2.5 mg/mL), 25 mg, 10 mL Vial, 203 Liters, Line 2, Michelle	Lot Number:	10001288
Master Batch Record # : MBR-000618		

NOTES: N/A

Operations Reviewed by:	 John Baker	Date: 11 Jul 23
Quality Assurance Reviewed by:	 Francisco Poteat	Date: 31 Jul 23

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