

TERMINAL STERILIZATION

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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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 #: 138		Room #:		Room #:	
	Performed By/Date	Verified By/Date	Performed By/Date	Verified By/Date	Performed By/Date	Verified By/Date
1. Check Room and Equipment Logs to ensure equipment / room is clean and ready for use.	BKP 07Jul23	ALP 07Jul23		<input checked="" type="checkbox"/> N/A		<input checked="" type="checkbox"/> N/A
2. Room and equipment are visibly clean.	BKP 07Jul23	ALP 07Jul23				
3. Required calibrations for equipment are current and daily balances checks have been performed, per applicable SOP.	BKP 07Jul23	ALP 07Jul23				
4. NO foreign batch material is in the room.	BKP 07Jul23	ALP 07Jul23				
5. Remove or cover any equipment in the room that is not required for the current process.	BKP 07Jul23	ALP 07Jul23				
6. Appropriate room status signs have been posted.	BKP 07Jul23	ALP 07Jul23				

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Terminal Sterilization		
Component	Parameter	Specification
Terminal Sterilization	Cycle Name	P5-NICARD
	Temperature Set Point	121.1°C (Range: 121.1°C – 122.6°C)
	Sterilization Time	18 minutes (Range: 17 – 19 minutes)
	Asset #	OP4004 (SOP-OP-000011)

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## Load A

Operation	Performer Result	Performed By/ Date	Verifier Result	Verified By/ Date
1. Prepare trays to be loaded into autoclave.		BKP 07JUL23		ALP 07JUL23
2. Select Recipe. Record Recipe selected.	PS-NICARD		PS-NICARD	
3. Record tray numbers to be loaded into autoclave.	Tray 1 to 32		Tray 1 to 32	
4. Record total number of vials to be loaded into autoclave.	9600		9600	
5. Place cart in the autoclave and Start the autoclave per SOP. Record cycle start time and cycle number.	Cycle Start Time Cycle Number	BKP 07JUL23	1212 13191	ALP 07JUL23
6. Unload and verify that all trays/units have been removed from the autoclave.		BKP 07JUL23		
7. Record total number of acceptable vials.	Acceptable Vials		9598	TRD 07JUL23
8. Record total number of damaged units.	Damaged Units		2	
9. Document total number of vials unloaded from autoclave. (Step 7) + (Step 8)	Total Vials		9600	
10. Print a hardcopy of the cycle data and review to ensure all parameters were met and cycle was successful. Attach to the batch record.		BKP 07JUL23		TRD 07JUL23

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## Load B

Operation	Performer Result	Performed By/ Date	Verifier Result	Verified By/ Date
1. Prepare trays to be loaded into autoclave.				
2. Select Recipe. Record Recipe selected.	P5-NICARD	BKP 07JUL23	P5-NICARD	ALP
3. Record tray numbers to be loaded into autoclave.	Tray 33 to 62		Tray 33 to 62	07JUL23
4. Record total number of vials to be loaded into autoclave.	<del>8859</del> 8859		8859	
5. Place cart in the autoclave and Start the autoclave per SOP. Record cycle start time and cycle number.	Cycle Start Time Cycle Number	BKP 07JUL23	1452 13192	ALP 07JUL23
6. Unload and verify that all trays/units have been removed from the autoclave.				
7. Record total number of acceptable vials.	Acceptable Vials	EMB 07JUL23	8857	SMA
8. Record total number of damaged units.	Damaged Units		2	07JUL23
9. Document total number of vials unloaded from autoclave. (Step 7) + (Step 8)	Total Vials		8859	
10. Print a hardcopy of the cycle data and review to ensure all parameters were met and cycle was successful. Attach to the batch record.		EMB 07JUL23		SMA 07JUL23

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## Post-Production Activities per SOP-OP-000005

Operation	First Session		Second Session		Third Session	
	Room #: 138		Room #:		Room #:	
	Performed By / Date	Verified By / Date	Performed By / Date	Verified By / Date	Performed By / Date	Verified By / Date
1. Log books have been completed and dirty equipment has been cleaned or removed to be clean.	EmB 07 JUL 23	SMA 07 JUL 23				
2. All batch specific materials have been removed from the room.			<input checked="" type="checkbox"/> N/A		<input checked="" type="checkbox"/> N/A	

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### Post Terminal Sterilization Accountability

Instruction	Result	Performed By/Date	Verified By/Date
1. Total Vials Pre-Terminal Sterilization (Capping Tray Count Table)	18459 Vials	EMB 07JUL23	SMA 07JUL23
2. Total Vials Accounted Post Terminal Sterilization (Load A, Step 9 + Load B, Step 9)	18459 Vials	EMB 07JUL23	SMA 07JUL23
3. Post Terminal Sterilization Accountability (Step 2 ÷ Step 1) x 100 = <u>18459</u> ÷ <u>18459</u> x 100	100 %	EMB 07JUL23	SMA 07JUL23

Specification: 98 – 100%

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#### Theoretical Yield

Instruction	Result	Performed By/Date	Verified By/Date
1. Total Vials Pre-Terminal Sterilization (Capping, Total Vial Count)	18459 Vials	EmB 07JUL23	SMA 07JUL23
2. Total Sum of Acceptable Terminally Sterilized Vials (Load A, Step 7 + Load B, Step 7)	18455 Vials	EmB 07JUL23	SMA 07JUL23
3. Percentage Theoretical Yield (Step 2 ÷ Step 1) x 100 = $\frac{18455}{18459} \times 100$	100 %	EmB 07JUL23	SMA 07JUL23

Specification: 95 – 100%

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Notes: ☒ N/A

Operations Reviewed By: Brendy Key Date: 12 JUL 23  
Quality Reviewed By: Tranhera Poteet Date: 27 JUL 23

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Tiffany Quick  
07JUL23

10001288 T.S

LOAD A

SIGNATURE: .....

PROCESS OK

HIGHEST TEMP 122.3C

LOWEST TEMP 121.2C

01:17:14 14.15 43.7 46.6 75.7

PROCESS COMPLETE

01:16:34 21.77 48.1 44.4 76.1

01:15:46 44.96 57.6 57.6 76.8

EQUALIZATION

01:15:34 44.92 57.3 57.7 76.9

01:14:34 44.91 56.1 55.7 78.1

01:13:34 44.93 57.6 59.7 79.4

01:12:34 45.02 58.5 60.7 80.7

01:11:34 44.98 58.3 61.7 82.1

01:10:34 45.06 60.2 63.1 83.6

01:09:34 45.01 63.9 64.2 85.3

01:08:34 44.96 63.6 65.5 87.2

01:07:34 45.07 64.2 66.9 89.1

01:06:34 45.09 62.8 68.4 91.3

01:05:34 45.07 64.0 70.1 93.8

01:04:34 45.00 66.5 71.9 96.4

01:03:34 45.07 67.9 74.4 99.6

01:02:34 45.08 71.1 77.0 102.9

01:01:34 44.91 74.2 79.8 106.6

01:00:34 45.28 74.1 83.9 110.9

00:59:34 39.56 83.2 89.9 115.6

00:58:34 42.80 86.1 96.3 119.1

00:57:34 44.51 77.4 100.0 121.1

00:56:34 45.25 82.1 105.6 121.9

00:55:40 45.14 122.1 121.8 121.9

FAN COOLING

00:55:34 45.46 122.1 121.8 121.9

POSTTREATMENT

00:55:04 45.22 122.1 121.9 121.9

00:54:34 45.16 122.2 122.0 121.9

00:54:04 45.36 122.1 121.9 122.0

00:53:34 45.49 122.1 121.9 122.0

00:53:04 45.19 122.1 121.8 121.9

00:52:34 45.18 122.1 121.8 122.0

00:52:04 45.22 122.1 121.9 121.9

00:51:34 45.36 122.1 121.8 121.9

00:51:04 45.19 122.1 121.9 121.9

00:50:34 45.10 122.1 121.9 122.0

00:50:04 45.26 122.1 121.9 121.9

00:49:34 45.30 122.0 121.8 121.9

00:49:04 45.32 122.0 121.8 122.0

00:48:34 45.11 122.1 121.9 122.0

00:48:04 45.21 122.2 121.9 122.0

00:47:34 45.36 122.1 121.9 121.9

00:47:04 45.31 122.1 122.0 121.9

00:46:34 45.09 122.1 121.8 121.9

00:46:04 45.22 122.1 121.8 121.9

00:45:34 45.37 122.1 121.9 121.9

00:45:04 45.40 122.2 122.0 121.9

00:44:34 45.34 122.2 121.9 121.9

00:44:04 45.07 122.2 122.0 121.9

00:43:34 45.53 122.1 121.9 121.9

00:43:04 45.32 122.2 122.0 121.9

00:42:34 45.15 122.2 122.0 121.9

00:42:04 45.39 122.2 122.0 121.9

00:41:34 45.38 122.1 121.9 121.9

00:41:04 45.24 122.2 121.9 121.9



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00:41:34 45.38 122.1 121.9 121.9
00:41:04 45.24 122.2 121.9 121.9
00:40:34 45.23 122.0 121.9 121.9
00:40:04 45.05 122.1 122.0 121.8
00:39:34 45.26 122.0 121.9 121.8
00:39:04 45.04 122.1 121.9 121.7
00:38:34 44.85 121.8 121.6 121.5
00:38:04 44.94 121.9 121.6 121.4
00:37:34 44.59 122.1 121.8 121.2
FAN STERILIZING
00:37:00 43.88 121.5 121.2 120.7
00:36:00 42.80 120.5 120.2 119.6
00:35:00 41.66 119.4 119.1 118.3
00:34:00 40.79 118.2 117.9 117.0
00:33:00 39.41 116.8 116.6 115.6
00:32:00 38.41 115.4 115.3 114.2
00:31:00 37.44 114.0 113.9 112.7
00:30:00 36.01 112.5 112.5 111.0
00:29:00 35.03 111.0 111.1 109.4
00:28:00 33.69 109.5 109.6 107.7
00:27:00 32.70 107.8 108.1 105.9
00:26:00 31.65 106.5 106.5 104.1
00:25:00 30.70 104.9 104.9 102.2
00:24:00 29.46 103.5 103.5 100.6
00:23:00 28.72 102.4 102.4 99.0
00:22:00 27.92 101.4 101.3 97.2
00:21:00 27.08 100.4 99.8 95.4
00:20:00 26.41 99.0 98.6 93.4
00:19:00 25.30 97.7 97.4 91.5
00:18:00 24.62 96.2 96.3 89.4
00:17:00 23.91 94.6 95.2 87.3
00:16:00 22.98 93.1 93.7 85.1
00:15:00 22.32 91.6 92.5 83.1
00:14:00 21.73 90.1 90.7 80.9
00:13:00 21.27 88.5 89.0 78.6
00:12:00 20.89 87.1 86.8 76.4
00:11:00 20.67 85.7 84.1 73.8
00:10:00 15.93 85.1 81.8 70.9
00:09:00 14.79 83.2 73.9 68.0
00:08:00 14.76 80.1 73.0 64.5
00:07:00 14.75 77.3 71.7 60.4
00:06:00 14.72 75.2 68.6 55.5
00:05:00 14.69 73.4 64.4 50.0
00:04:00 14.72 71.0 64.0 43.7
00:03:00 14.77 67.5 57.4 37.0
00:02:00 14.73 64.0 55.3 30.4
00:01:00 14.80 57.1 46.9 24.7
00:00:12 14.05 31.8 27.9 23.7
FAN HEAT UP
00:00:00 14.05 31.8 27.9 23.6

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START
PROGTIME AI03 AI00 AI02 AI04
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PROGRAM: P5 NICARD

```

AI04 LOAD TEMP. 04
AI02 DRAIN TEMP.
AI00 CHAMBER TEMP.
AI03 CHAMBER PRESSURE
SIGNALS

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```

COOLING TEMP      80.0    C
PRESSURE COOLING  45.00  PSI
SUPPORT PRESSURE  14.49  PSI
STERILIZING TEMP  121.1    C
STERILIZING TIME  00:18:00
FO LIMIT          99.9
OVER TEMP         1.0    C
HEAT UP TIMEOUT   01:30:00
PARAMETERS

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```

CYCLE COUNTER      : 13191
MACHINE NAME       : V30259
PROCESS START      : 12:12:28
DATE               : 07/07/2023

```

EXELA







10001288  
Load B  
07JUL23  
Emily Billings

SIGNATURE: .....

PROCESS OK

HIGHEST TEMP 122.3C

LOWEST TEMP 121.2C

01:14:10 14.12 46.8 48.5 78.1

PROCESS COMPLETE

01:13:30 21.00 49.0 44.5 78.5

01:12:42 44.04 58.2 59.7 79.2

EQUALIZATION

01:12:30 44.89 58.2 60.0 79.4

01:11:30 44.92 57.5 61.0 80.6

01:10:30 44.93 59.6 61.8 81.9

01:09:30 45.05 57.4 62.7 83.3

01:08:30 45.02 56.6 63.7 84.7

01:07:30 45.07 57.3 64.6 86.4

01:06:30 45.09 61.0 65.8 88.1

01:05:30 45.06 59.9 66.9 90.0

01:04:30 44.98 60.0 67.9 91.9

01:03:30 45.02 61.4 69.4 94.2

01:02:30 45.07 62.8 70.8 96.6

01:01:30 45.07 61.2 72.3 99.1

01:00:30 44.97 66.5 74.0 101.9

00:59:30 45.01 70.4 76.4 105.0

00:58:30 44.95 74.2 78.9 108.2

00:57:30 45.23 76.6 82.9 111.8

00:56:30 39.68 81.1 87.1 115.3

00:55:30 42.43 86.9 94.2 118.4

00:54:30 44.62 77.5 100.2 121.0

00:53:30 45.10 81.3 104.8 121.9

00:52:36 45.00 122.0 121.8 122.0

FAN COOLING

00:52:30 45.27 122.1 122.0 122.0

POSTTREATMENT

00:52:00 45.18 122.1 121.9 122.0

00:51:30 45.19 122.0 121.8 122.0

00:51:00 45.21 122.2 122.0 122.0

00:50:30 45.14 122.1 121.9 122.0

00:50:00 45.28 122.1 121.8 122.0

00:49:30 45.14 122.1 121.9 122.0

00:49:00 45.41 122.1 121.9 122.0

00:48:30 45.14 122.3 122.0 122.0

00:48:00 45.42 122.1 121.9 122.0

00:47:30 45.23 122.2 122.0 122.0

00:47:00 45.06 122.0 121.8 122.0

00:46:30 45.19 122.2 122.0 122.0

00:46:00 45.35 122.1 122.0 122.0

00:45:30 45.45 122.1 121.9 122.0

00:45:00 45.23 122.1 122.0 122.0

00:44:30 45.05 122.1 121.9 122.0

00:44:00 45.61 122.1 121.9 122.0

00:43:30 45.53 122.2 121.9 122.0

00:43:00 45.35 122.2 122.0 122.0

00:42:30 45.21 122.1 122.0 122.0

00:42:00 45.38 122.1 122.0 122.0





```
00:42:30 45.21 122.1 122.0 122.0
00:42:00 45.38 122.1 122.0 122.0
00:41:30 45.38 122.1 121.9 122.0
00:41:00 45.39 122.1 122.0 122.0
00:40:30 45.24 122.2 122.1 122.0
00:40:00 45.10 122.2 122.1 122.0
00:39:30 45.27 122.1 122.0 122.0
00:39:00 45.24 122.2 122.1 122.0
00:38:30 45.09 122.2 122.1 122.0
00:38:00 45.23 122.2 122.1 122.0
00:37:30 45.47 122.2 122.1 121.9
00:37:00 45.39 122.1 122.0 121.9
00:36:30 45.01 122.1 122.1 121.9
00:36:00 45.05 122.0 122.0 121.8
00:35:30 44.95 122.0 121.9 121.6
00:35:00 44.83 121.8 121.9 121.6
00:34:30 44.38 122.1 122.1 121.3
FAN STERILIZING
00:34:00 43.95 121.6 121.5 120.7
00:33:00 42.78 120.5 120.5 119.5
00:32:00 41.90 119.3 119.5 118.3
00:31:00 40.56 118.0 118.1 116.8
00:30:00 39.10 116.5 116.7 115.2
00:29:00 37.94 115.0 115.2 113.6
00:28:00 36.85 113.4 113.7 111.8
00:27:00 35.38 111.6 112.1 110.0
00:26:00 33.99 110.0 110.6 108.2
00:25:00 32.91 108.2 109.0 106.3
00:24:00 31.79 106.4 107.5 104.3
00:23:00 30.53 104.2 105.6 102.4
00:22:00 29.62 102.9 104.3 100.8
00:21:00 28.89 101.6 103.1 99.0
00:20:00 27.98 99.9 101.6 97.1
00:19:00 27.16 98.3 100.2 95.2
00:18:00 25.89 96.5 98.8 93.1
00:17:00 24.99 94.4 97.3 91.0
00:16:00 24.60 93.1 96.0 88.9
00:15:00 23.48 93.3 94.4 86.6
00:14:00 22.79 92.1 92.7 84.4
00:13:00 22.10 90.6 91.1 82.1
00:12:00 21.51 89.0 89.6 79.7
00:11:00 20.93 87.3 87.6 77.2
00:10:00 20.93 85.9 84.8 74.7
00:09:00 16.03 84.9 82.2 71.9
00:08:00 14.75 82.9 75.4 68.6
00:07:00 14.77 80.9 70.0 64.5
00:06:00 14.74 78.9 69.9 59.7
00:05:00 14.78 77.5 63.9 53.9
00:04:00 14.73 75.5 65.1 47.0
00:03:00 14.76 72.5 61.2 40.0
00:02:00 14.69 68.2 58.6 33.0
00:01:00 14.76 61.0 49.5 27.3
00:00:12 14.04 35.0 33.5 26.4
FAN HEAT UP
00:00:00 14.04 34.8 33.5 26.3
START
PROGTIME AI03 AI00 AI02 AI04
-----
PROGRAM: P5 NICARD

AI04 LOAD TEMP. 04
AI02 DRAIN TEMP.
AI00 CHAMBER TEMP.
AI03 CHAMBER PRESSURE
SIGNALS

COOLING TEMP      80.0  C
PRESSURE COOLING  45.00 PSI
SUPPORT PRESSURE  14.49 PSI
STERILIZING TEMP  121.1  C
STERILIZING TIME  00:18:00
FO LIMIT          99.9
OVER TEMP         1.0  C
HEAT UP TIMEOUT  01:30:00
PARAMETERS

CYCLE COUNTER      : 13192
MACHINE NAME       : V30250
PROCESS START      : 14:52:04
DATE               : 07/07/2023

EXELA
```