



100 Majestic Way, Bangor, PA 18013 / [www.biospectra.us](http://www.biospectra.us)

## SUPPLY CHAIN CENTER MAPPING STUDY REPORT

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

**TABLE OF CONTENTS**

1. INTRODUCTION:.....3

2. OBJECTIVE: .....3

3. SCOPE:.....3

4. REFERENCES:.....3

5. RESPONSIBILITIES: .....4

6. WAREHOUSE DESCRIPTION/LAYOUT: .....4

7. EXECUTIVE SUMMARY:.....4

8. CONCLUSION: .....6

TABLE 1: TABLE OF LIMITS FOR THE SUPPLY CHAIN CENTER MAPPING STUDY ..... 7

## 1. INTRODUCTION:

This Report is intended for the Mapping Study of the Monroe Plaza warehouse, now called Supply Chain Center (BSI08) located at BioSpectra's 51 North 3<sup>rd</sup> street Stroudsburg, PA facility. The purpose of this report is to summarize the results of the executed Supply Chain Center Mapping Study, formerly known as Monroe Plaza Mapping Study, DCN: BSI-PRL-0472. This report will detail the temperature distribution and humidity within a controlled warehouse area for Raw Materials, Process Materials, Components, and Finished Goods.

## 2. OBJECTIVE:

The objective of this Report is to provide the results of the Supply Chain Center Mapping Study. The executed mapping study conformed to the requirements established by the Equipment Qualification Master Plan, FDA Guidelines, and ICH Q7 Guidelines.

## 3. SCOPE:

This Report applies to the execution of the Supply Chain Center Mapping Study Protocol DCN: BSI-PRL-0472. This Report applies to the warehouse conditions for the Supply Chain Center storage area of Raw Materials, Process Materials, Components, and Finished Goods.

## 4. REFERENCES:

### 4.1. Reference Documents

- 4.1.1. BSI-MEM-1135, Monroe Plaza Preliminary Mapping Study Report
- 4.1.2. BSI-PRL-0472, Monroe Plaza Mapping Study
- 4.1.3. BSI-SOP-0010, Documentation Entry and Error Correction
- 4.1.4. BSI-SOP-0137, Discrepancy Investigation Procedure
- 4.1.5. BSI-SOP-0155, Lockout / Tagout Program
- 4.1.6. BSI-SOP-0194, Personal Protective Equipment SOP
- 4.1.7. BSI-SOP-0435, Equipment Qualification Master Plan
- 4.1.8. BSI-SOP-0552, Supply Chain Center Warehousing Plan

### 4.2. Reference Codes and Standards

- 4.2.1. The Joint IPEC-PQG Good Manufacturing Practice Guide for Pharmaceutical Excipients
- 4.2.2. ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
- 4.2.3. World Health Organization, Supplement 8 "Temperature Mapping of Storage Areas"
- 4.2.4. NIST National Institute for Standards and Technology

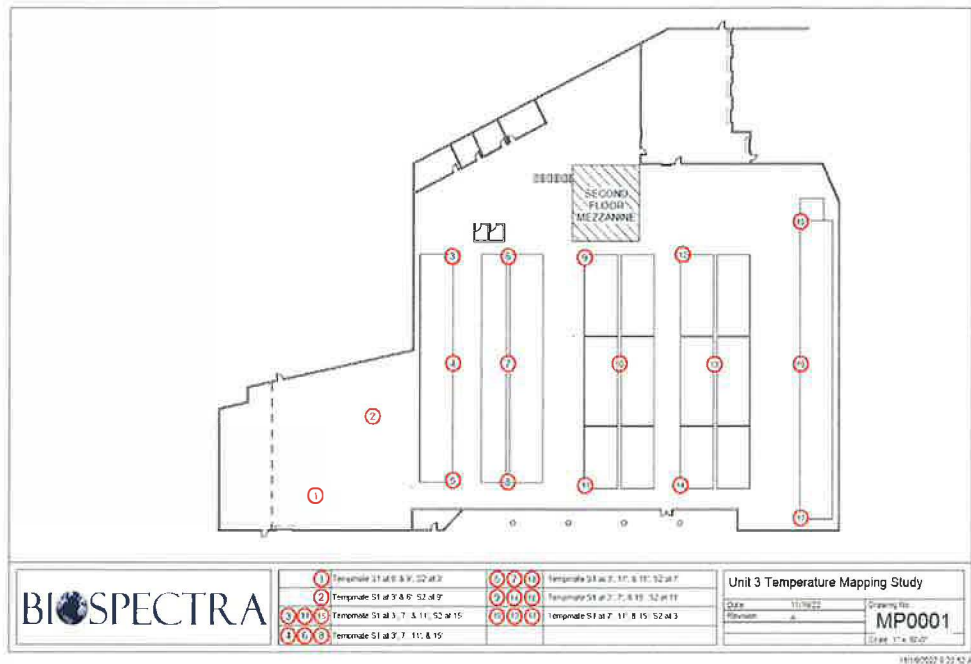
The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

**5. RESPONSIBILITIES:**

It is the responsibility of the personnel listed in the approval section of the Mapping Study Protocol to approve the executed Mapping Study report via the DMS and provide an adequate conclusion regarding the suitability of the storage area conditions. It is the responsibility of the Qualification Team as listed in the approval section of this Mapping Study Report to ensure that this Report meets the requirements as stated in the BioSpectra Equipment Qualification Master Plan.

**6. WAREHOUSE DESCRIPTION/LAYOUT:**

The drawing below, “MP0001” details the warehouse layout and data logger placement during the time of execution.



**7. EXECUTIVE SUMMARY:**

7.1. Mapping Study

7.1.1. Training Verification

Test Purpose: The purpose of this Appendix was to verify the completion of personnel training regarding the associated Mapping Study Protocol.

Test Results: Personnel recording data and/or reviewing the Protocol was identified; documented and training verification forms were attached to the appropriate Appendix. All acceptance criteria for each Training Verification were met. No discrepancies or issues were encountered during this portion of the Mapping Study. All results are accepted for this portion of the Mapping Study.

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

#### 7.1.2. Calibration of Instrumentation

Test Purpose: The purpose of this Appendix was to identify the required critical measuring tools to be used in the appendix and confirm the calibration status of each tool used in the study.

Test Results: There was a total of 52 calibrated Tempmate-S1 data loggers and 14 calibrated Tempmate-S2 data loggers utilized for the completion of this Mapping Study. Their calibration documentation was verified and documented for the completion of this Appendix. A copy of the calibration records are attached to the Appendix. No discrepancies or issues were encountered during this portion of the Mapping Study. All results are accepted for this portion of the Mapping Study.

#### 7.1.3. Change Control Log

Test Purpose: The purpose of this Appendix was to document all changes requested in regards to this Mapping Study.

Test Results: No Change Controls were requested during the execution of the Protocol. All acceptance criteria for the Change Control Log were met. All results are accepted for this portion of the Mapping Study.

#### 7.1.4. Discrepancy Report Log

Test Purpose: The purpose of this Appendix was to document Discrepancy Investigation Report(s) that may have occurred during the execution of the Protocol.

Test Results: One Discrepancy Investigation was requested during the execution of the Protocol. SDI23-54 was requested to investigate logger at location 6 at a height of 11' not recording temperature data during the execution of this Mapping Study. Tempmate was contacted to investigate this discrepant Tempmate S-1 data logger. After Tempmate's internal investigation, they discovered that the logger S/N: S122070669-04 was a test unit, started by Tempmate after calibration to ensure manufactured units are functioning properly. Typically, these units are not sent to the customer, but this specific logger was accidentally placed to dispatchable goods. All results are accepted for this portion of the Mapping Study as all other loggers in the Supply Chain Center storage area recorded temperatures within the 15°C to 30°C specification.

#### 7.1.5. Mapping Study

Test Purpose: To gather and review information regarding the control of temperature distribution and humidity within a storage area while not being affected by seasonal variation.

Test Results: After the 24-hour stabilization period, all of the data loggers' data was collected, analyzed and reported on. The recording duration was 100 days  $\pm$  12 hours. The lowest recorded temperature during the 100-day testing period was 15.0°C. There is no impact to the results of the Mapping Study as the 15.0°C reading is within the temperature specification of 15-30°C for the warehouse. Additionally, this was a single temperature reading, and the temperature readings recorded by this logger returned readings above 16°C twenty minutes later. The humidity distribution within the warehouse was recorded as reference only via the Tempmate-S2 data loggers. All results were accepted and approved for this portion of the Mapping Study.

### 8. CONCLUSION:

The execution of the Supply Chain Center Mapping Study showed one deviation from the Protocol due to a logger not recording temperature data during the duration of the Mapping Study. The data logger locations were arranged in a grid fashion and distanced in a manner that maps the entire storage area including the aisles between the storage racking where material may be staged during receiving and shipping operations. The data logger locations followed the World Health Organization; Supplement 8: Temperature Mapping of Storage Areas guidelines. The execution of the Mapping Study determined that there are no observed cold spots remaining within the warehouse as previously reported in the preliminary study report, DCN: BSI-MEM-1135. Lastly, the long-term monitoring locations as detailed in the Supply Chain Center Warehousing Plan, DCN: BSI-SOP-0552 were selected based on the results of this executed Mapping Study. The Mapping Study of the Supply Chain Center is considered complete and approved for use in storage in all areas including the storage racks, staging area, and aisles between the storage racks as of 3/17/23. Additionally, the executed protocol and associated attachments are attached as supporting documentation to this mapping study report.

**Table 1: Table of Limits for the Supply Chain Center Mapping Study**

Table of Limits							
Appendix	Parameter/Component	Result			Parameter Limit		
E: Mapping Study	Supply Chain Center Warehouse	The Supply Chain Center Warehouse Mapping step started at 0925 on 11/22/22. The data logger installation check was completed by the Qualification Lead at 1220 on 11/22/22. The 24-hour stabilization period start time also began at 1220 on 11/22/22 and ended at 1220 on 11/23/22. After the stabilization period, a 100-day ± 12-hours testing period started. The study ended at 0952 on 3/3/23. The Tempmate-S1 and Tempmate-S2 data was then analyzed and detailed below.			After the 24-hour stabilization period, the data loggers will be started and record for 100 consecutive days ± 12-hours. The Tempmate-S1 and Tempmate-S2 data loggers' temperature and humidity data will be collected and analyzed to verify that the maximum and minimum temperatures fall within 15°C-30°C. The humidity distribution within the warehouse will be recorded as reference only via the Tempmate-S2 data loggers.		
		Tempmate – S1					
		Location	Height (ft)	Maximum Temp(°C)		Minimum Temp (°C)	Mean Temp (°C)
		1	6	22.1		16.6	19.2
		1	9	22.4		16.9	19.4
		16	15	22.0		18.0	20.9
		2	3	21.0		15.9	19.0
		2	6	21.5		17.6	19.8
		17	7	22.1		18.4	21.1
		3	3	22.2		19.0	21.1
		3	7	22.0		19.1	21.2
		3	11	22.2		19.2	21.3
		17	11	21.9		18.2	20.9
		4	3	21.4		17.8	20.2
		4	7	21.8		18.5	21.0
		4	11	22.0		18.6	21.2
		4	15	22.6		19.0	21.5
		5	3	22.4		17.8	21.3
		5	11	22.0		18.6	21.1
		5	15	22.2		18.9	21.3
		17	15	21.6		17.8	20.6
		6	3	21.7		18.7	20.8
		6	7	22.0		18.9	21.2
		6	11	Refer to SDI23-54		Refer to SDI23-54	Refer to SDI23-54
		6	15	22.6		19.1	21.6
		7	3	21.5		18.3	20.7
		7	11	22.4		18.9	21.4
		7	15	22.7		19.0	21.6
		8	3	22.3		18.9	21.2
		8	7	22.0		18.9	21.2
8	11	23.3	18.6	21.0			
8	15	22.2	18.8	21.2			
9	3	22.3	19.0	21.0			
9	7	22.9	19.1	21.3			
9	15	22.6	19.1	21.5			
10	7	22.1	18.5	21.1			
10	11	22.4	18.7	21.3			
10	15	22.3	18.6	21.3			
11	3	21.5	18.0	20.7			
11	7	21.8	18.5	21.0			
11	11	24.7	18.7	21.1			
12	7	22.5	19.1	21.2			

The information contained herein is the confidential property of BioSpectra. The recipient is responsible for its safe-keeping and the prevention of unauthorized appropriation, use, disclosure and copying.

**Table of Limits**

Appendix	Parameter/ Component	Result				Parameter Limit																																																																																							
E: Mapping Study	Supply Chain Center Warehouse	<b>Tempmate – S1</b>				<p>After the 24-hour stabilization period, the data loggers will be started and record for 100 consecutive days ± 12-hours. The Tempmate-S1 and Tempmate-S2 data loggers' temperature and humidity data will be collected and analyzed to verify that the maximum and minimum temperatures fall within 15°C-30°C. The humidity distribution within the warehouse will be recorded as reference only via the Tempmate-S2 data loggers.</p>																																																																																							
		<table border="1"> <thead> <tr> <th data-bbox="386 321 532 380">Location</th> <th data-bbox="532 321 646 380">Height (ft)</th> <th data-bbox="646 321 833 380">Maximum Temp(°C)</th> <th data-bbox="833 321 1019 380">Minimum Temp (°C)</th> <th data-bbox="1019 321 1206 380">Mean Temp (°C)</th> </tr> </thead> <tbody> <tr><td>12</td><td>11</td><td>22.1</td><td>18.9</td><td>20.9</td></tr> <tr><td>12</td><td>15</td><td>22.4</td><td>19.1</td><td>21.2</td></tr> <tr><td>13</td><td>3</td><td>21.3</td><td>17.9</td><td>20.6</td></tr> <tr><td>13</td><td>11</td><td>22.0</td><td>18.4</td><td>21.2</td></tr> <tr><td>13</td><td>15</td><td>22.6</td><td>18.5</td><td>21.4</td></tr> <tr><td>14</td><td>3</td><td>22.2</td><td>18.4</td><td>21.1</td></tr> <tr><td>14</td><td>7</td><td>22.1</td><td>18.0</td><td>20.9</td></tr> <tr><td>14</td><td>15</td><td>22.3</td><td>18.4</td><td>21.0</td></tr> <tr><td>15</td><td>3</td><td>21.4</td><td>17.8</td><td>20.3</td></tr> <tr><td>15</td><td>7</td><td>22.2</td><td>17.8</td><td>20.3</td></tr> <tr><td>15</td><td>11</td><td>21.6</td><td>17.9</td><td>20.6</td></tr> <tr><td>16</td><td>3</td><td>21.1</td><td>17.8</td><td>20.4</td></tr> <tr><td>16</td><td>7</td><td>21.6</td><td>18.0</td><td>20.8</td></tr> </tbody> </table>	Location	Height (ft)	Maximum Temp(°C)		Minimum Temp (°C)	Mean Temp (°C)	12	11	22.1	18.9	20.9	12	15	22.4	19.1	21.2	13	3	21.3	17.9	20.6	13	11	22.0	18.4	21.2	13	15	22.6	18.5	21.4	14	3	22.2	18.4	21.1	14	7	22.1	18.0	20.9	14	15	22.3	18.4	21.0	15	3	21.4	17.8	20.3	15	7	22.2	17.8	20.3	15	11	21.6	17.9	20.6	16	3	21.1	17.8	20.4	16	7	21.6	18.0	20.8																				
		Location	Height (ft)	Maximum Temp(°C)	Minimum Temp (°C)		Mean Temp (°C)																																																																																						
		12	11	22.1	18.9		20.9																																																																																						
		12	15	22.4	19.1		21.2																																																																																						
		13	3	21.3	17.9		20.6																																																																																						
		13	11	22.0	18.4		21.2																																																																																						
		13	15	22.6	18.5		21.4																																																																																						
		14	3	22.2	18.4		21.1																																																																																						
		14	7	22.1	18.0		20.9																																																																																						
		14	15	22.3	18.4		21.0																																																																																						
		15	3	21.4	17.8		20.3																																																																																						
		15	7	22.2	17.8		20.3																																																																																						
		15	11	21.6	17.9		20.6																																																																																						
		16	3	21.1	17.8		20.4																																																																																						
		16	7	21.6	18.0		20.8																																																																																						
		<table border="1"> <thead> <tr> <th data-bbox="386 831 532 890">Location</th> <th data-bbox="532 831 646 890">Max (°C)</th> <th data-bbox="646 831 760 890">Min (°C)</th> <th data-bbox="760 831 873 890">Mean (°C)</th> <th data-bbox="873 831 1019 890">Maximum Humidity (%RH)</th> <th data-bbox="1019 831 1206 890">Minimum Humidity (%RH)</th> </tr> </thead> <tbody> <tr><td>1</td><td>21.5</td><td>15.0</td><td>18.6</td><td>43.0</td><td>21.2</td></tr> <tr><td>2</td><td>21.9</td><td>17.8</td><td>20.1</td><td>50.3</td><td>14.0</td></tr> <tr><td>3</td><td>22.6</td><td>19.5</td><td>21.7</td><td>44.8</td><td>14.8</td></tr> <tr><td>5</td><td>22.2</td><td>18.6</td><td>21.2</td><td>45.6</td><td>15.5</td></tr> <tr><td>7</td><td>22.0</td><td>18.6</td><td>21.1</td><td>46.6</td><td>13.0</td></tr> <tr><td>9</td><td>22.6</td><td>19.3</td><td>21.6</td><td>47.4</td><td>13.3</td></tr> <tr><td>10</td><td>21.6</td><td>18.4</td><td>21.0</td><td>49.5</td><td>12.5</td></tr> <tr><td>11</td><td>22.2</td><td>18.9</td><td>21.3</td><td>48.8</td><td>13.0</td></tr> <tr><td>12</td><td>22.9</td><td>19.3</td><td>21.2</td><td>48.5</td><td>12.0</td></tr> <tr><td>13</td><td>21.6</td><td>18.1</td><td>20.9</td><td>49.9</td><td>13.1</td></tr> <tr><td>14</td><td>22.2</td><td>18.2</td><td>21.0</td><td>49.1</td><td>14.2</td></tr> <tr><td>17</td><td>21.9</td><td>18.2</td><td>20.9</td><td>49.6</td><td>13.7</td></tr> <tr><td>16</td><td>21.7</td><td>18.0</td><td>20.8</td><td>49.1</td><td>14.6</td></tr> <tr><td>15</td><td>21.7</td><td>17.9</td><td>20.6</td><td>50.0</td><td>12.9</td></tr> </tbody> </table>	Location	Max (°C)	Min (°C)		Mean (°C)	Maximum Humidity (%RH)	Minimum Humidity (%RH)	1	21.5	15.0	18.6	43.0	21.2	2	21.9	17.8	20.1	50.3	14.0	3	22.6	19.5	21.7	44.8	14.8	5	22.2	18.6	21.2	45.6	15.5	7	22.0	18.6	21.1	46.6	13.0	9	22.6	19.3	21.6	47.4	13.3	10	21.6	18.4	21.0	49.5	12.5	11	22.2	18.9	21.3	48.8	13.0	12	22.9	19.3	21.2	48.5	12.0	13	21.6	18.1	20.9	49.9	13.1	14	22.2	18.2	21.0	49.1	14.2	17	21.9	18.2	20.9	49.6	13.7	16	21.7	18.0	20.8	49.1	14.6	15	21.7	17.9	20.6	50.0	12.9
		Location	Max (°C)	Min (°C)	Mean (°C)		Maximum Humidity (%RH)	Minimum Humidity (%RH)																																																																																					
		1	21.5	15.0	18.6		43.0	21.2																																																																																					
		2	21.9	17.8	20.1		50.3	14.0																																																																																					
		3	22.6	19.5	21.7		44.8	14.8																																																																																					
		5	22.2	18.6	21.2		45.6	15.5																																																																																					
		7	22.0	18.6	21.1		46.6	13.0																																																																																					
		9	22.6	19.3	21.6		47.4	13.3																																																																																					
		10	21.6	18.4	21.0		49.5	12.5																																																																																					
		11	22.2	18.9	21.3		48.8	13.0																																																																																					
		12	22.9	19.3	21.2		48.5	12.0																																																																																					
		13	21.6	18.1	20.9		49.9	13.1																																																																																					
14	22.2	18.2	21.0	49.1	14.2																																																																																								
17	21.9	18.2	20.9	49.6	13.7																																																																																								
16	21.7	18.0	20.8	49.1	14.6																																																																																								
15	21.7	17.9	20.6	50.0	12.9																																																																																								