Thermal Mapping Protocol Template

[Protocol Number: XXXX]

[Revision: XXXX]

[Protocol Author: XXXXXXXX]

[Prepared Date: XXXXXXXX]

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1.0 PURPOSE

This protocol provides instructions to perform the thermal mapping activities according to the design specifications of the following area.

AREA DESCRIPTION:
AREA DESIGN SPECIFICATIONS DESCRIPTION REFERENCE DOCUMENT NUMBER:

The following monitoring paramenters are considered as part of this protocol:

- ☐ Temperature (T)
- ☐ % Relative Humidity (R/H)

In addition, this protocol brings the instructions for the identification, execution, documentation, and evaluation of the thermal mapping results.

2.0 SCOPE

This protocol can applies to the following areas and equipments:

Area Name	Location	Dimensions (L x W x H), Number of Racks, Shelfs, etc	Intended Use, and Classification	Maximum Capacity of Persons or Products
Stability Room				
Retain Samples				
Refrigerator				
Oven				
Warehouse				
Incoming Area				
Autoclave				
Clean room				
Gowning room				
Freezer				
Lyophilizer				
Storage Room				
Tanks				

3.0 ASSOCIATED DOCUMENTS

3.1 Internal Documents

The following Internal documents are referenced in this protocol:

Document Number	Document Title

3.2 External Documents

The following external documents are referenced in this protocol since it applies to the FDA regulated industries and others entities.

Doc Number	Document Title (as applicable)
21, Part 820	Quality System Regulations, Good Manufacturing Practice for the Medical Devices (current revision)
Part 807	Establishment Registration And Device Listing For Manufacturers And Initial Importers Of Devices
Part 610	General Biological Products Standards
Part 606	Current Good Manufacturing Practice For Blood And Blood Components
Part 600	Biological Products: General
Part 320	Bioavailability And Bioequivalence Requirements
Part 314	Applications For FDA Approval To Market A New Drug
Part 225	Current Good Manufacturing Practice For Medicated Feeds
Part 212	Current Good Manufacturing Practice For Positron Emission Tomography Drugs
Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals
Part 210	Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding Of Drugs; General
Part 111	Current Good Manufacturing Practice In Manufacturing, Packaging, Labelling, Or Holding Operations For Dietary Supplements
Part 110	Current Good Manufacturing Practice In Manufacturing, Packing Or Holding Human Food
Part 11	Electronic Records; Electronic Signatures
ISO 13485	Medical Devices Quality Management Systems Requirements for Regulatory Purposes (current revision)
MDD 93/42/EEC	Medical Device Directive (current revision)

4.0 DEFINITIONS AND ACRONYMS

The following key terms, definitions, and acronyms apply to this protocol:

Word or Acronym	Definition
Critical Area:	Area where the products forms containers and closures are exposed directly to the environment.
Controlled Area:	Area where product, in-process materials, and containers / closures are prepared. These areas will include but are not limited to: staging; assembly, transport; and storage areas of containers and in-process products in protected packages or bags; including processing rooms from which critical areas are accessed.
Room / Area Certification	Process executed by a testing agency that a clean room has been tested in accordance with the latest revision of ISO Standard 14644 and that the cleanliness class requirements have been achieved.
Clean Zone:	Critical Area in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class per ISO 14644.
Clean room	Room (facility) in which the concentration of airborne particles is controlled and which contains one or more Clean Zones.
As Built Room	A room (facility) that is completed and ready for operation with all services connected and functional, but without equipment and operating personnel in the facility.
At-Rest/Static Conditions	Testing performed in a holded room, which is completed and has the production equipment installed and operable, but has no personnel within the room.
Operational / Dynamic Conditions	A room in normal operation, including production equipment and personnel.

5.0 ROLES AND RESPONSIBILITIES

5.1 It is the responsibility of all personnel involved in this protocol to be trained on it. Also, to be familiar and understand the company policies for operation and safety.

5.2 All persons involved in this protocol must complete the training form and Validation Signature Log in Attachment A. They are responsible for carrying out the verification tasks in accordance with the procedures in effect.

5.3 The Engineering Department is responsible to bring the applicable room(s) and equipment in operational working conditions before initiate this protocol.

5.4 Final disposition of the approved qualification protocol will be in accordance with company policies and procedure.

6.0 GENERAL REQUIREMENTS- SAFETY

6.1 During the operation of any equipment related to this qualification, it is imperative that signs and warnings are adhered to equipment and room at all times to prevent serious injury or death to personnel and damage to equipment.

6.2 Ensure that all company policies regarding operational safety are followed at all times.

6.3 Ensure that proper safety precautions are adhered to when working around high voltage circuits.

6.4 Ensure that proper lifting techniques are used when lifting heavy equipment.

6.5 Wear safety glasses at all times while using equipment.

7.0 PRE-REQUISITES

The pre-requisites to this protocol are defined as:

7.1 The procedures or test method to be used as part of by this protocol must be completed, approved, effective and released.

7.2 All personnel involved must be trained in this protocol and the corresponding procedures. Attach training records in **Attachment 1**. Register the signature of each person involved in the execution of this protocol, attach evidence in **Attachment 2**.

7.3 Verify that all measuring instruments and equipment associated with this protocol are properly calibrated before been used and contain an approved NIST-traceable calibration certificate in **Attachment 3**.

7.4 Verify that the area was properly cleaned according to Company procedures, document the cleaning activities in **Attachment 4**.

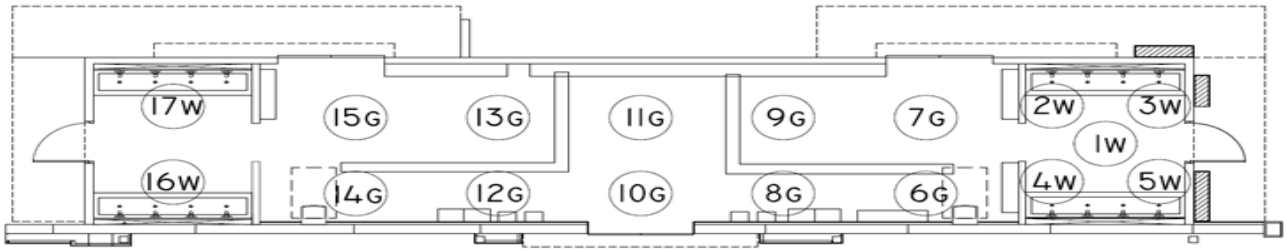
8.0 TEST ATTRIBUTES AND CALIBRATIONS CERTIFICATED

Calibrated Temperature data loggers or equivalent instruments of measurement to be used during this thermal mapping study shall be documented in the following table. All certificates of calibration will be documented in the **Attachment 3.**

Instrument ID	Instrument Name	Calibration Expiration Date

9.0 AREAS COVERED BY THERMAL MAPPING – AREA DIAGRAM

Areas that should be covered in this protocol are include in this diagram:



IMPORTANT NOTE: Describe the in the above diagram the dimensions of the area and the location of each calibrated data logger, chart recorders or equivalent measuring instruments used during this protocol. Place a calibrated data logger(s) or equivalent instrument(s) near to the permanent chart recorder(s) or sensor(s) on the area. Also, describe the location of each rack, shelves, materials, products, machines, etc.