| **Document Name:** Installation and Operational Qualification Protocol for Infrared Ray Dryer | |
|---|---|
| **Identification No.:** | **Document Number:** |
| **Effective Date:** | **Revision No.:** 00 |

# Installation, Operational Qualification Protocol

# Infrared Ray Dryer

# Equipment ID: .....

| Revision | Date | Reason for revision |
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## 1.0 Pre-Approval:

This document is prepared by the validation team of ……. for the project "Oral Solid Dosage Formulation Facility" of ……. under the authority of their Project Manager. Hence this document before being effective shall be approved by the head QA of ……..

| **PREPARED BY** | | |
|---|---|---|
| **NAME/ FUNCTIONAL AREA** | **SIGNATURE** | **DATE** |
| | | |
| **Validation & QA** | | |

| **CHECKED BY** | | |
|---|---|---|
| **NAME/ FUNCTIONAL AREA** | **SIGNATURE** | **DATE** |
| | | |
| **Validation & QA** | | |
| | | |
| **Production** | | |
| | | |
| **Engineering** | | |
| | | |
| **Quality Assurance** | | |

| **APPROVED BY** | | |
|---|---|---|
| **NAME/ FUNCTIONAL AREA** | **SIGNATURE** | **DATE** |
| | | |
| **Head -Quality Assurance** | | |

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## 2.0 Objective:

The purpose of carrying out Installation, Operational Qualification is to verify/ demonstrate with documented evidence that,

a) The equipment and its critical components are installed correctly and in accordance with installation plan and as per the supplier installation instructions.

b) The equipment is functioning properly.

c) The equipment is performing satisfactorily.

## 3.0 Scope:

The document includes the installation, operational qualification procedure of the equipment as per details given below:

| | |
|---|---|
| In-house name of the equipment | Infrared Ray Dryer |
| Equipment identification number | ..... |
| Purchase Order Reference | …….. |
| Supplier Name and address | …….. |
| **Installation location** | |
| Facility | Hormone Block |
| Floor | ……. |
| Room name and number (if applicable) | Drying Room |

This protocol is generated to qualify the installation & operation of the equipment. In case of further modification or relocation, some part of the same protocol can be used or separate protocol or addendum can be generated.

## 4.0 Reference Document:

Following documents are referred during preparation of the protocol

| Document Name | Document Number |
|---|---|
| Validation Master Plan | |
| Project Validation Plan | |
| Risk Assessment Document | |
| Supplier design document | |
| Drawings | GA Drawing |
| Equipment Manual | Instructional manual of Infrared Dryer |

## 5.0 Equipment description:

### 5.1 Use

Infrared Ray Dryer is an ideal machine to dry the washed equipment in the shortest possible time without particulate contamination during drying process. The working of Infrared Ray Dryer is based on the basic principle of exposing the equipment to be dried to the human friendly Infrared Rays. When the Infrared Rays fall on SS surface, the light energy gets converted into heat energy by virtue of which the traces of water get evaporated. This results in effective drying of the equipment.

### 5.2 Capacity

Capacity: - 1000W Heaters

### 5.3 Operation & Design Feature

The equipment to be dried is kept underneath the dome of Infrared Ray Dryer Umbrella Type. The Dome of Umbrella type I.R Dryer can be raised or lowered pneumatically by 300 mm with the help of handle provided for it. A Filter is provided to the inlet of the blower. The prevalidated time is set on the LCD display on the control panel. The drying cycle starts with the switching ON of the Infrared Elements & after a lapse of one minute or any set time, the Blower gets switched ON. On completion of set drying time, the Infrared Elements get switched OFF & after a lapse of one minute or any set time, the Blower gets switched OFF. This marks the end of Drying Cycle. The most important part of this operation is, it is fully automatic & the operator doesn't have to be engaged continuously with the dryer. Nevertheless dual mode is provided which enables the operator to operate the equipment in either AUTO or MANUAL mode.

## 6.0 Installation-Operational Qualification Test Plan:

Installation-Operational qualification shall include following test:

i) Verification of signatures/participants as per test data sheet #1
ii) Verification of Documents as per test data sheet #2
iii) Verification of components as per test data sheet #3
iv) Verification of Installation as per test data sheet # 4
v) General Function Test as per test data sheet #5
vi) Verification of limiting functions as test per data sheet #6
vii) Performance Evaluation test as per test data sheet #7
viii) Verification of Noise Level as per test data sheet #8

### 6.1 Identification of Components to be tested:

The components taken from the component list or P & ID are listed in the Appendix-I. In every case where the decision for criticality is yes, ("Y"), a test has to be performed. If the decision is "No" ("N") then no test is to be performed. Though all components listed shall be identified and verified for the presence in accordance to P & ID or relevant drawings as per test sheet #2.
Each critical component shall be verified against the checklist given in test sheet #3. Specific test ID number for specific component is mentioned in the following table. After verification of the component the checker and verifier should sign the respective sheet.

The non-compliance should be highlighted in the used document. The annotated document should be identified by a serial number, which should appear in both test sheet and the annotated document. The annotated document must be attached with report, as it is then a raw data.'

## 7.0 Responsibility:

Responsibilities of different department/ personnel involved in different activities related to the installation, operational qualification of the equipment are defined below:

| Functions | Responsible |
|---|---|
| Preparation of IOQ protocol | - |
| Review of the protocol | - |
| Approval of the protocol | - |
| Clearance of the equipment for execution | - |
| Execution of IOQ protocol | - |
| Preparation of IOQ report | - |
| Review of executed IOQ protocol and report | - |
| Approval of the Executed IOQ protocol and report | - |

## 8.0 Test Execution Method:

### 8.1 Pre –Requisites

Prior to conducting/ executing the installation, operational qualification protocol following conditions must be fulfilled:

- Equipment should be safe for execution.
- Facility should be ready for execution.
- Area should be clean.

### 8.2 Signature Registration & Training:

All personnel who are executing or reviewing the protocol must enter his/her name and signature in signature registration page. Provide the location of training record or attach the appropriate training record with the report to indicate that the personnel are trained on the following:

- Execution of IOQ protocol
- Writing GMP critical record

- Deviation handling procedure
- Review of executed validation protocol and GMP critical records

A signature registration page is given as Data sheet # 01

### 8.3 General Recording Instruction:

- Execution will be carried out as per the SOP for Qualification protocol execution.
- Recording of observation will follow good documentation practice as per SOP.
- In the test data sheet test parameter and criteria will be pre-defined. Other cells e.g. observation and signature will be completed by the person manually.
- Where observation is to be recorded as 'Y/N/NA', write 'Y' when the observation is in compliance with acceptance criteria, write 'N' when observation is a non-compliance. If it is not applicable write NA, if unobvious write suitable justification for being not applicable.
- Any mistake in the approved protocol format if identified before or during execution shall be recorded as comment rather canceling it manually. This mistake will be verified during review of executed protocol.
- Comment summary sheet will be available separately as Data sheet # 10. This test sheet should be separate for a specific test sheet. Required number of comment summary sheet shall be issued during execution.
- Comments and deviation will be recorded as per the instruction given in the following section.
- If possible or required a digital photograph may be taken and print of the photograph may be presented as evidence of compliance or deviation from the acceptance criteria.

### 8.4 Deviation Handling:

- During execution the comments if any shall be noted as comment no. in the respective datasheet.
- All comments shall be numbered as "X-YY" where "X" is test sheet no. and "YY" is the sequential serial no. for that particular test sheet; For example in test sheet no. 3, second comment shall be numbered as 3-02. Comment number shall be allotted on the test data sheet and comments shall be written on comment summary sheet.
- During review or execution all comments shall be verified and if any comment is made to specify non-compliance to that test acceptance criteria, comment shall be escalated as "Deviation"
- The deviation will be identified and it will be suitably numbered in the comment section of the comment summary sheet as per SOP of deviation Management.
- The deviation will be assessed whether it has any GMP criticality. GMP non-critical deviations can be justified whereas GMP critical deviation may require investigation and corrective actions.
- All deviations shall be resolved before handing over the equipment for routine use.

### 8.5 General Safety Instruction for Execution:

Safety will be one of the key considerations during the execution of this protocol. The following guidelines must be observed during the execution stage.

- All personnel involved with the execution shall identify hazards associated with performance of IOQ testing and precautions to be taken.
- All personnel involved with the execution shall inform to Company management any hazard, to themselves or others, associated with the materials, equipment, method of working and the precautions to be taken.
- All personnel involved with the execution shall check that utilities are safely isolated when energizing or de-energizing.

## 9.0 Acceptance Criteria:

The individual parameters successfully pass the examination if all responses in the test sheets in the inspection result column are "Y" or those tests with an open response (i.e. because a check was not feasible) are justified, and acceptance of the justification must be recorded by the approvers of the report. The system successfully passes IOQ if all the test specifications are passed or open tests justified and accepted.

Thus, it is shown that the equipment,

- Meets the Specifications and Quality requirements identified by the User
- Is correctly installed and documented
- The equipment operation is in accordance with requirements.

## 10.0 Summary Report and Conclusion:

In order to close the IOQ, the tests results are evaluated and the IOQ report (format enclosed) is formally approved. All results, conclusions and variances will be addressed and final disposition of the equipment will be stated. Successful completion of this protocol and approval of the report will verify that the Infra red Ray Dryer meets all the acceptance criteria and is ready for routine use.

## 11.0 Enclosed Documents:

Following documents are enclosed as part of installation, operational qualification protocol and shall be preapproved as a part of the main protocol.

| S.No. | Document | Document Name | Document No. |
|---|---|---|---|
| 1 | Data Sheet # 1 | Identification of Signatures / Participants | - |
| 2 | Data Sheet # 2 | Document Verification Sheet | - |
| 3 | Data Sheet # 3 | Component verification test* | - |
| 4 | Data Sheet # 4 | Verification of Installation | - |
| 5 | Data Sheet # 5 | General Function Test | - |
| 6 | Data Sheet # 6 | Automated control system verification@ | - |
| 7 | Data Sheet # 7 | Verification of Emergency stop | - |
| 8 | Data Sheet # 8 | Verification of Noise Level | - |

| S.No. | Document | Document Name | Document No. |
|---|---|---|---|
| 9 | Data Sheet # 9 | Performance Evaluation | - |
| 10 | Data Sheet # 10 | Comment Summary Sheet | - |
| 11 | Appendix-I | List of components to be tested | - |
| 12 | Qualification Report | Installation, Operational Qualification report | - |
| 13 | Attached documents | List of attached document | - |

*There are number of data sheets for each test ID of respective component to be verified according to Appendix-I.
@ There are separate datasheets for each critical test of automated control system verification

## 12.0 Abbreviations:

| Abbreviation | Terms |
|---|---|
| cGMP | Current Good Manufacturing Practices |
| QA | Quality Assurance |
| GMP | Good Manufacturing Practices |
| SOP | Standard Operating Procedure |
| IOQ | Installation Operational Qualification |
| PID | Proportionate Integral Derivative |
| EHS | Environment Health and Safety |
| ID | Identification |