| **Document Name:** Performance Qualification Appendix 3.6.1 for Lyophilizer | |
|---|---|
| **Equipment/System ID:** | **Document Number:** |
| **Effective Date:-** | **Version Number:** 00 |

Trial Run #: _____

## Appendix 3.6.1

## Process Simulation with Mannitol

**Equipment Name :** Lyophilizer
**Equipment ID :** .....

**Contents**

### LYOPHILIZATION CYCLE OBSERVATION

| Date | Pack Size | Run No | No of Vials load | No of vials found lyophilized | Result Complies Yes/No | Checked by |
|---|---|---|---|---|---|---|
| | | | | | | |

**Moisture Content Observation in Lyophilization cycle:**

| Date | Shelf | Location of Vial | Observed Moisture content | Result Complies Yes/No | Checked by |
|---|---|---|---|---|---|
| | Shelf No-1 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-2 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

**Document Name:** Performance Qualification Appendix 3.6.1 for Lyophilizer

| **Equipment/System ID:** | **Document Number:** |
|---|---|
| **Effective Date:-** | **Version Number:** 00 |

Trial Run #: _____

| Date | Shelf | Location of Vial | Observed Moisture content | Result Complies Yes/No | Checked by |
|---|---|---|---|---|---|
| | Shelf No-3 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-4 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-5 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-6 | | | | |
| | | | | | |
| | | | | | |

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

| **Document Name:** Performance Qualification Appendix 3.6.1 for Lyophilizer | |
|---|---|
| **Equipment/System ID:** | **Document Number:** |
| **Effective Date:-** | **Version Number:** 00 |

Trial Run #: _____

| Date | Shelf | Location of Vial | Observed Moisture content | Result Complies Yes/No | Checked by |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | Shelf No-7 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-8 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-9 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-10 | | | | |

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

| **Document Name:** Performance Qualification Appendix 3.6.1 for Lyophilizer | |
|---|---|
| **Equipment/System ID:** | **Document Number:** |
| **Effective Date:-** | **Version Number:** 00 |

Trial Run #: _____

| Date | Shelf | Location of Vial | Observed Moisture content | Result Complies Yes/No | Checked by |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-11 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-12 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | Shelf No-13 | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

| **Document Name:** Performance Qualification Appendix 3.6.1 for Lyophilizer | |
|---|---|
| **Equipment/System ID:** | **Document Number:** |
| **Effective Date:-** | **Version Number:** 00 |

Trial Run #: _____

| Date | Shelf | Location of Vial | Observed Moisture content | Result Complies Yes/No | Checked by |
|---|---|---|---|---|---|
| | | | | | |

**Stoppering:**

| Date | Run No | Total No of Vial Loaded | No of vials with stopper | No of vials without Stoppering | Result Complies Yes/No | Checked by |
|---|---|---|---|---|---|---|
| | | | | | | |

**Remarks:**

_____
_____
_____
_____
_____
_____

| Checked By (Sign. /Date) | Verified By (Sign. /Date) |
|---|---|
| | |