



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification test datasheet # 3.1 for Lyophilizer

Equipment/System ID:

Document Number:

Effective Date:

Version Number: 00

Test ID #3.1: Steam Quality Test

Test Run: _

Target: Objective if this test is to demonstrate that the steam being introduced into the chamber is of requisite physical, chemical & microbiological quality.

Necessary materials:

- Steam quality test kit
- Sampling Bottles
- Tube
- SOP for steam quality testing

Preconditions:

- Equipment should be normal operational mode

Test ID

More than Test Description

1

Check the quality of steam for non condensable gases as per the SOP

2

Check the quality of steam for superheat gases as per the SOP

3

Check the quality of steam for dryness value as per the SOP

4

Record the observations & data as per Appendix 3.1.1.

Test ID

Acceptance criteria

Acceptance criteria fulfilled? (Y/N)

1

The fraction of non-condensable gases should not exceed 3.5%.

2

The superheat measured in the expansion tube should not exceed 25°C

3

The Dryness value should not be less than 0.95. The steam temperature should be within $\pm 3^{\circ}\text{C}$ of the value measured during superheat test

Measures after test execution:

Comment Ref. No

Comment

Deviation Ref. No

Checked By (Signature/Date)

Verified By (Signature/Date)