



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification Test Datasheet # 2.2 for Lyophilizer

Equipment/System ID:

Document Number:

Effective Date:-

Version Number: 00

Test ID #2.2: Availability of Documents

Test Run: ____

Target: Required documents are available

Necessary materials: None

Preconditions: None

Test ID **Test Description**

1 Check the calibration certificates of Data logger & temperature sensor to be used for temperature mapping of Lyophilizer.

2 Check the certificates & total viable spore count report (Quantification) of Biological Indicator.

3 Check that the certificates of chemical indicator are available and they are within their expiry period.

Test ID	Acceptance criteria:	Acceptance criteria fulfilled? (Y/N)
1	Full-loop calibration certificate is available for temperature sensor. Copy is added to this test sheet.	
1	Full-loop calibration certificates are available for Data logger. Copy is added to this test sheet.	
2	Certificates are available for Biological Indicator. Copy is added to this test sheet	
2	Spore calculation report of Biological Indicator. Copy is added to this test sheet	
3	Chemical indicators certificate are available and they are within their expiry period.	

Measures after test execution: NA

Comment Ref. No

Comment

Deviation Ref No

Checked by (Signature/Date)

Verified by (Signature/Date)