



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**Document Name:** Performance Qualification test datasheet # 3.2 for Lyophilizer

**Equipment/System ID:**

**Document Number:**

**Effective Date:**

**Version Number:**

**Test ID #3.2: Coverage Study (Clean in Place Cycle)**

**Test Run:** \_

**Target:** Coverage study is to be carried out for verification of efficiency of cleaning process (CIP cycle) in Lyophilizer.

**Necessary materials:**

- Riboflavin
- Sprayer
- Ultraviolet Light
- WFI

**Preconditions:**

- Equipment should be normal operational mode
- Chamber should be empty.

**Test ID**

**Test Description**

1

Before carrying out the CIP cycle make the necessary connection of water for CIP.

2

Dissolve 0.02% of Riboflavin (Vitamin B<sub>2</sub>) (i.e. 0.2 gm in 1 litre of water). This is a concentration where fluorescence can be seen using an ultraviolet light.

3

Spray the whole interior of the chamber being sure to coat all exposed surfaces – especially those areas which may be masked by the system appurtenances (i.e. ports, chamber roof & underneath shelves).

4

The locations are selected considering the most difficult part to clean.

5

Prior to the test commencing verify the following:

- Chamber door(s) are closed, and all valves are at their no cycle normal state.
- The utility supplies of compressed air, cooling water and purified water are normal.
- Ensure CIP water is ready when the washing starts.
- Lyophilizer is in Auto mode

6

Close the main door of lyophilizer as per the SOP.

7

Feed the recipe for CIP cycle in the SCADA of lyophilizer as per the SOP.

8

Record the recipe parameter in the Appendix 3.2.1.

9

Initiate a CIP cycle using ambient temperature water to simulate CIP test as per the SOP.

10

During running cycle check the cycle sequence with the recipe.

11

Observe manually through the view port for water flow in condenser and chamber during CIP as per the recipe.

12

At the completion of the cycle, inspect the interiors of the chamber using an ultraviolet light. Look for locations in the chamber, which have Vitamin B<sub>2</sub> fluorescence at a level, which is indicative that the spray ball coverage failed to contact the surface in that location.

13

Visually observe the total surface area where it appears that CIP fluid coverage has failed to contact the chamber surface.

14

Record the observations & data as per Appendix 3.2.1.

15

Attach the cycle printout along with this data sheet.



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Test ID	Acceptance criteria	Acceptance criteria fulfilled? (Y/N)
11&12	After completion of CIP cycle the entire surface area of the inner side of chamber and condenser should be visually clean and dry.	
11	The flow of water should be observed both in condenser and chamber during CIP as per the recipe.	
12	No fluorescence should be observed.	

**Measures after test execution:**

Comment Ref. No	Comment	Deviation Ref No

**Checked by (Signature/Date)**

**Verified by (Signature/Date)**

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