PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification test datasheet # 3.6 for Lyophilizer	
Equipment/System ID:	**Document Number:**
Effective Date:	**Version Number:** 00

Test ID #3.6: Process simulation with Mannitol	**Test Run: ____**
Target:	The objective of this test is to: • To ensure that the lyophilizer is capable of carrying the lyophilization process and condensing the ice as per the predefined specification. • To verify the performance of Lyophilization process and stoppering activity of the system with dummy batches.
Necessary materials:	• 2 % Mannitol solution • 10 ml Glass vials • Rubber stopper • Seal • Filling/Sealing machine
Preconditions:	Equipment should be normal operational mode

Test ID	Test Description
1.	Before the study ensures that the lyophilizer is at ambient temperature.
2.	For Lyophilization simulation the following parameter is to be considered for taking a dummy cycle with Mannitol solution. • Maximum Batch Size. • Largest pack size of the product among the entire product. • Highest fill volume among the entire product.
3.	Prepare 2% solution of Mannitol
4.	Weigh and take the required quantity of Mannitol for 10 ml pack size.
5.	Measure and take the required quantity of WFI in vessel for 10 ml pack size.
6.	Add and dissolve Mannitol in WFI for 10 ml pack size.
7.	Calculate the wt/ml of the solution and use this value during filling operation.
8.	Open the loading side door of Lyophilizer.
9.	Load the vials and run the recipe as below for 10 ml pack size.
10.	After loading of vials insert the product probes in one vial per each shelf and place on the shelf.
11.	Set the recipe and record the details in the datasheet.
12.	Run the cycle as per the SOP and observe the cycle on SCADA.
13.	After Lyophilization do the stoppering activity as per the SOP.
14.	After the stoppering activity is completed do the unloading of vials as per the SOP during unloading ensure that the vials of each tray should be kept separately.
15.	Visually verify the cake formation in all vials.

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16.	During unloading of vials visually check the vials for proper stoppering. During the unloading mark 5 vials as four from each corner and one from centre of each shelf. The marking should be with marker and the numbering should be with continuous numbering. Record the details of vial numbering in the datasheet.	
17.	After stoppering checking do the sealing of vials as per the SOP.	
18.	During sealing ensure that vials of each tray should be sealed separately.	
19.	Visually inspect all the vials for any melt back vials or cake collapse as per the SOP.	
20.	Sample the marked vials and send the vials to QC for checking the moisture content and cake appearance.	
21.	Visually check the formation of ice on condenser coil.	
22.	After the cycle is over take the printout of report generated.	
23.	Compare the report generated with the recipe feed.	
24.	Record the observation and results as per **Appendix-3.6.1**	
25.	Attach the reports along with this data sheet.	
	Acceptance criteria	**Acceptance criteria fulfilled? (Y/N)**
1.	The cake formation shall be observed in all vials.	
2.	The stoppering should be satisfactory in all vials.	
3.	The moisture content of the lyophilized cake should not more than 2%.The test for moisture will be performed only for information purpose to check the Lyophilization occurrence. There will be no deviation if moisture not coming in limit considering PQ trial run with dummy for Lyophilization.	
4.	The cake appearance should be uniform without any collapse.	
5.	Ice should be observed on the coil of condenser.	
6.	The report should be generated as per the recipe.	
7.	The cycle should run in a similar sequence as per the recipe.	
Measures after test execution:	NA	
Comment Ref. No	**Comment**	**Deviation Ref No**

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Checked by (Signature/ date)		**Verified by (Signature/ date)**	