



PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification test datasheet # 3.7 for Lyophilizer		
Equipment/System ID:	Document Number:	
Effective Date:	Version Number: 00	
Test ID #3.7: Condenser Defrosting		Test Run: ____
Target:	The objective of this test is to: <ul style="list-style-type: none"> To ensure that the lyophilizer is capable of carrying the de-icing process and removing the ice from the condenser. To verify the condenser defrosting cycle as per the set parameter. 	
Necessary materials:	<ul style="list-style-type: none"> All Utilities Ice is formed in the condenser. 	
Preconditions:	Equipment should be normal operational mode	
Test ID	Test Description	
1.	Start the Condenser Defrosting Cycle after the Lyophilization cycle of process simulation study is completed and lyophilizer is unloaded.	
2.	Set the recipe as mentioned in Appendix: 3.7.1.	
3.	Run the cycle as per the SOP and observe the cycle parameters on SCADA.	
4.	After the cycle is over inspect visually for any ice in condenser and dryness of condenser.	
5.	After the cycle is over take the printout of report generated.	
6.	Compare the report generated with the recipe feed.	
7.	Record the observation and results as per Appendix -3.7.1	
8.	Attach the reports along with this data sheet.	
	Acceptance criteria	Acceptance criteria fulfilled? (Y/N)
1.	No Ice should be observed in the condenser.	
2.	The condenser should be dry enough visually.	
3.	The report generation should be as per the recipe.	
4.	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)**