PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

Document Name: Performance Qualification Test Data sheet # 4 for Lyophilizer

Equipment/System ID:	**Document Number:**
Effective Date:-	**Version Number:** 00

Verification of measures identified in Risk Analysis

Acceptance Criteria	**RA Ref. No.**	**Compliance**	**Document Reference (if applicable)**		**Comment Ref No.**
		Yes/No/NA	**Document name/type**	**Document no &/or location**	
System Functions					
Loading scheme has to be defined and validated during PQ.	8 (29)				
Proper process designing to have optimum and reproducible heat up time	8 (30)				
• Appropriate sterilization cycles shall be design. • Sterilization cycles should be validated.	8 (33)				
• Pre-sterilization vacuum cycle. • Temperature mapping of empty chamber, identification of "cold spot" • "Mobile/external" temperature sensors within chamber for local temperature measurement at cold spot during sterilization cycle.	8 (37)				
Basis for cycle development for porous goods	8 (40)				

Checked By (Signature/Date):	**Verified By (Signature/Date):**