Qualification Summary Report

IQ/OQ/PQ Protocol Pack · Template 08 of 09

Report No. _____ **Version** _____

Equipment / area name _____ **Equipment ID / asset No.** _____

Location (building, room) _____ **Department** _____

Manufacturer _____ **Model** _____

Serial No. _____ **URS ref.** _____

Equipment type ☐ Stability chamber ☐ Cold room ☐ Refrigerator ☐ Freezer ☐ Ultra-low freezer ☐ Warehouse ☐ Other: _____

1 Documents executed

Stage	Protocol No.	Report No.	Executed (from – to)	Approved on	Result
DQ					☐ Pass ☐ Fail
IQ					☐ Pass ☐ Fail
OQ					☐ Pass ☐ Fail
PQ					☐ Pass ☐ Fail

2 Results summary

Stage	Tests executed	Passed	Failed	Deviations raised	Deviations closed
IQ					
OQ					
PQ					

3 Key results

Result	Acceptance criterion	Observed
Empty study: min / max across all points		
Loaded study: min / max across all points		
Door-opening recovery (empty)		
Door-opening recovery (loaded)		
Power failure: holdover time		
Power failure: recovery time		

Result	Acceptance criterion	Observed
Seasonal studies (hot / cold)		
Alarm tests: all channels and contacts reached		

4 Deviations

Dev. No.	Stage	Summary	Classification	Status

5 Conclusion

Status ☐ Qualified for routine use ☐ Qualified with restrictions (state below) ☐ Not qualified

Restrictions / conditions of use _____

_____

Next periodic review / requalification due _____

Monitoring in routine use (system and sensor IDs) _____

Prepared by	Independent reviewer	Approved and released by (QA)
Name _____	Name _____	Name _____
Designation _____	Designation _____	Designation _____
Signature _____	Signature _____	Signature _____
Date _____	Date _____	Date _____