

12.1 Loop Checks Verification

Objective:

Verify that all Travelers have been completed and all discrepancies have been resolved.

Procedure:

Verify that all loop checks have been completed by reviewing all Travelers that is attached to each component of the TruBio™ Control System. Ensure that all discrepancies have been resolved prior to starting OQ.

Sample
Document

Acceptance Criteria:

Acceptance Verification				
No	Acceptance Criteria	Actual Result	Pass / Fail	Initial/Date
1	All Travelers have been Verified	All Travelers have been _____	Pass Fail	
2	All discrepancies have been Resolved	All discrepancies have been _____	Pass Fail	
3	Copies of all Travelers are attached to the IOQ Package	Copies of all Travelers are _____ to the IOQ Package	Pass Fail	
4	TruBio™ Bioreactor Control System is ready to start Operational Qualification	TruBio™ Bioreactor Control System _____ ready to start Operational Qualification	Pass Fail	

Comments:

Results:

Loop Check Verification					
No	Action	Expected Result	Actual Result	Pass / Fail	Initial / Date
1	Verify all Travelers associated with this TruBio™ Control System	I/O Tower Traveler Completed	I/O Tower Traveler _____	Pass Fail	
		MFC Module Traveler Completed	MFC Module Traveler _____	Pass Fail	
		Pump Tower Traveler Completed	Pump Tower Traveler _____	Pass Fail	
		TruLogic Traveler Completed	TruLogic Traveler _____	Pass Fail	
		Agitator Traveler Completed	Agitator Traveler _____	Pass Fail	
2	Record I/O Tower Model and Serial #	Record Model #	Model #: _____	N/A	
		Record Serial #	Serial #: _____	N/A	
3	Record Pump Tower Model and Serial #	Record Model #	Model #: _____	N/A	

Loop Check Verification					
No	Action	Expected Result	Actual Result	Pass / Fail	Initial / Date
		Record Serial #	Serial #: _____	N/A	
4	Record TruLogic Tower Model and Serial #	Record Model #	Model #: _____	N/A	
		Record Serial #	Serial #: _____	N/A	
5	Record MFC Tower Model and Serial #	Record Model #	Model #: _____	N/A	
		Record Serial #	Serial #: _____	N/A	

Comments:

Section 12.3 has been completed. Your signature below indicates that the results have been reviewed with all discrepancies recorded in Appendix B.

	Printed Name	Signature	Date
Reviewed By			