VALIDATION SUMMARY REPORT

FOR

COMPUTER SYSTEM

OF

FTIR

System Name	**FTIR**
System ID	
Location	**Instrument Lab**
Effective Date	

VALIDATION SUMMARY REPORT FOR COMPUTER SYSTEM

System Name: FTIR **System ID:**

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1. PREPARATION AND APPROVALS:

The signature listed below indicates the preparation and approval of this Validation summary report. This approval is joint responsibility of listed functional areas.

REPORT DEVELOPMENT	SIGN / DATE
Name : _____ **Designation** : _____	

REPORT REVIEW AND APPROVAL (M/S……)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Engineering**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **IT**
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Control**

REPORT AUTHORIZATION (M/S……)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Assurance**

2. REVISION HISTORY:

Date	Supersedes	Reason for Revision

3. OBJECTIVE AND SCOPE:

The objective of this summary report is to collect sufficient data and the qualification executed pertaining to the Computer system of FTIR at …….

Successful completion of this document will provide the successfully validated of the computer system of FTIR.

This document is applicable to environment monitoring systemat …….This report describes the successful validation qualification for the control system.

4. REFERENCES:

The publication listed below form part of this report's reference documents. Each publication shall be the latest revision in effect on the date this report is approved for execution unless noted otherwise. Except as modified by the requirements specified herein or the details of the drawings, work included in this report shall conform to the applicable provisions of these publications.

GAMP 5	Good Automated Manufacturing Practices, Version 5, Guideline document for Automated Systems from International Society of Pharmaceutical Engineering
21 Code of Federal Regulations (CFR), Part 210	Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding off Drugs; General
21 Code of Federal Regulations (CFR), Part 211	Current Good Manufacturing Practice for finished Pharmaceuticals
WHO	Appendix 5, validation of computerized systems.
VP	-
SRS	-
RA	-
IQ	-
OQ	-
PQ	-
TM	-

5. ROLE AND RESPONSIBILITY:

The Validation team comprising of representative from each of the following departments should be responsible for overall compliance with this validation plan.

Department	Responsibilities
Validation Agency (……..)	➢ To collect data necessary for the generation, execution of this report from M/s. …….. ➢ To prepare the validation summary report. ➢ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle. ➢ To submit validation documents for approval.
Engineering (M/s. ……)	➢ Project Management and Planning. ➢ To provide the necessary data for qualification activities. ➢ To co-ordinate during execution of qualification activities. ➢ To review and approve the validation documents.
IT (M/s. ……..)	➢ To provide the necessary data for qualification activities. ➢ To co-ordinate during execution of qualification activities. ➢ To review and approve the validation documents.
Quality Control (M/s…….)	➢ To provide the necessary data for qualification activities. ➢ To co-ordinate during execution of qualification activities. ➢ To review the validation documents.
Quality Assurance (M/s. ……..)	➢ To approve and authorize the validation documents.

6. DELIVERABLE DOCUMENTS:

- Validation Plan
- System Requirement Specification
- Gap and Risk Assessment
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceability Matrix
- Validation Summary Report

7. INSTALLATION QUALIFICATION TEST STATUS:

S.No.	Critical Feature	Pass/Fail	Discrepancy (Y / N)	Checked By / Date
1.	Identification of System Details			
2.	Verification of Master Documents			
3.	Verification of Capacity Requirement			
4.	Verification of Hardware Components			
5.	Verification of Software Components			
6.	Verification of Physical and Logical Security Control			
7.	Verification of Test Instruments Calibration and Traceability			
8.	Verification of Power Utility			
9.	Verification of Environmental Condition			
10.	Verification Of Communication Link Between Server To Computer System			
11.	Verification of General System Installation			
12.	Verification of Standard Operating Procedures			

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8. OPERATION QUALIFICATION TEST STATUS:

S.No.	Critical Feature	Pass / Fail	Discrepancy? (Y/N)	Checked By / Date
1.	Verification of Field Instruments Calibration			
2.	Verification of Windows Security			
3.	Verification of System Start-up & Shutdown.			
4.	Verification of Password Security			
5.	Verification of User Level and Rights			
6.	Verification of Application software Screens.			
7.	Verification of System Response Failure.			
8.	Verification of Electronic Data Security.			
9.	Verification of Audit Trail .			
10.	Verification of Report Generation.			
11.	Verification of User Prevented From Alternating Date and Time			
12.	Verification of Data Back Up			
13.	Verification of system software as per 21 CFR part 11 Clauses			

9. PERFORMANCE QUALIFICATION TEST STATUS:

S.No.	Critical Feature	Pass / Fail	Discrepancy? (Y/N)	Checked By / Date
1.	Verification of Control Loop Test			

10. ABBREVIATION:

Abbreviations	Description
GMP	Good Manufacturing Practices
IS	Information Services
IQ	Installation Qualification
OQ	Operation Qualification
QA	Quality Assurance
PQ	Performance Qualification
TM	Traceability Matrix
SOP	Standard Operating Procedure
SRS	System Requirement and Specification
TS	Technical Services
WHO	World Health Organization

11. SUMMARY & CONCLUSION:

Compiled by: _____ **Date:**_____