Instrument Name	Computer System
System ID.	.....
System Used For	High Pressure Liquid Chromatography
Make	Waters
HPLC ID.	.....
Application Software Type	Chromatographic☑ Non Chromatographic ☐
Application Software	Empower
Software Version	3.0
Make	Waters
System Type	New System☐ Existing system ☑
Location	Instrument Room

1.0 PURPOSE: This validation plan describes the approach, system deliverables, activities, and deliverables needed to complete validation of the Computerized System (Hardware and Software).

2.0 OBJECTIVE : The objective of this validation effort is to ensure that appropriate procedural and technical controls are implemented and maintained in a controlled and documented manner throughout the life of the computer system and Software

3.0 SCOPE: Computer System and Software for HPLC is implemented for the powerful data analysis capabilities, excellent data presentation and outstanding graphical flexibility in Site It is decided to validate Computer System and Software for HPLC related to GMP critical areas. This plan applies to Computer System and Integrated Software for HPLC and is used in GxP regulated activities. Computer System and Integrated Software for HPLC which may affect the quality of the data generated to support their regulatory submissions will be covered under the scope.

4.0 RESPONSIBILITIES: The validation group comprising of a representative from each of the following departments shall be responsible for the overall compliance with this validation plan.

Role	Responsibility
Validation Agency (M/S. .....)	Validation Agency is responsible for the following activities: ➢ Developing the validation deliverables. ➢ Perform the Qualification Protocols. ➢ Discrepancy Reporting (If required) observed during Execution of Qualification Document. ➢ Mapping of requirement with specification and execution tests in Qualification Document and developing TM. ➢ Summarizing execution of results and preparing VSR.
QC, IT	The System owner of the process or processes being managed should be identified. The system owner is ultimately responsible for ensuring that the Computer System and Software for HPLC and its operation is in compliance and fit for intended use in accordance with applicable procedures. The IT Department is responsible for the availability, support and maintenance of the system and for the security of the data residing on that system (but not limited to), Specific activities may include (but not limited to), ➢ Providing adequate resources to support validation of the system. ➢ Ensuring adequate training for the users.

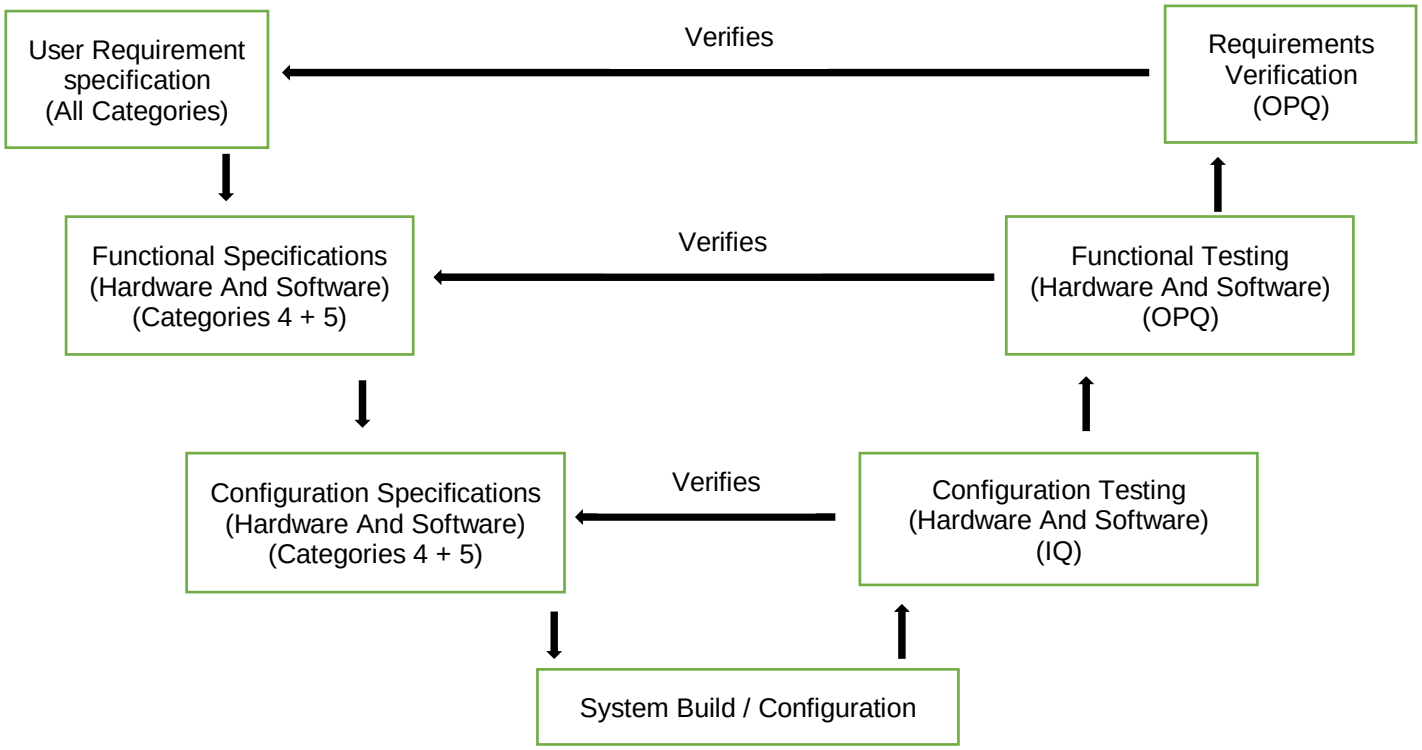
Role	Responsibility
	➢ Assist in preparation of validation protocols and approvals. ➢ Authorization of all validation documentation. ➢ Ensuring changes are tested, approved and managed (via Change Control procedures). ➢ Ensuring that the system as described in scope and its operation is in compliance and fit for the intended use in accordance with applicable procedures. ➢ To review the Validation Plan and Validation deliverables. ➢ Developing and maintaining security controls. ➢ Coordinating during the execution of qualification tests.
QA	This Quality Assurance Team is responsible for (but not limited to), ➢ Ensuring that all appropriate quality procedures are in place to support validation activities. ➢ Ensuring that all validation activities are carried out in accordance with procedures. ➢ Support of life cycle processes such as change control and documentation management. ➢ Assistance in preparation of validation protocols and approvals. ➢ Monitoring compliance with regulations and established standards. ➢ Agreeing on an approach to manage discrepancies with approval of any supporting rationales. ➢ Quality management of external service and application providers. ➢ Review and Approval of all validation documentation.

5.0 REFERENCE: The publications listed below are referred while preparing the Validation Deliverables.

Document	Description
CFR Title 21, Part 11	Code of Federal Regulations : Electronic Records; Electronic Signatures
EU GMP Annexure 11	Good Manufacturing Practice; Medical Products for Human and Veterinary use Annex 11; Computerized Systems; Volume 4
GAMP5	A Risk – Based Approach to Compliant GxP Computerized Systems (Good Automated Manufacturing Practices Version 5.0)
ICH Q9	Quality Risk Management

6.0 VALIDATION APPROACH: GAMP5's approach can be summed up by the V-model diagram. The V-model juxtaposes the specifications produced for a system to the testing performed as part of the verification process. The types of specifications associated with a system are tied to its degree of complexity. For example, for a configured product (Category 4), requirements, functional and configuration testing is conducted to verify the requirements, functional and configuration specifications. However, functional and configuration specifications are not required when using commercial off-the-shelf software (Category 3). As a result, the extent of the testing performed would also be reduced.

The aim of conducting verifications is to demonstrate that the system functions as intended. This is accomplished by using the requirements and specifications as an objective standard to which the system is tested. The test scripts are traced to the requirements and specifications they verify. If the test passes, the executed test script serves as documented evidence that the associated requirements and specifications were met.



The strategies defined in GAMP5: A Risk-Based Approach to Compliant GxP Computerized Systems are guidelines, not regulations. It is, therefore, not mandatory to follow this methodology.

However, the framework outlined in this guidance document provides a comprehensive approach to computer system validation that is generally accepted within the industry. Moreover, the risk-based approach advocated is in line with the application of the European EMA and US FDA regulations governing computer system validation, EU Annex 11 and 21 CFR Part 11, respectively.

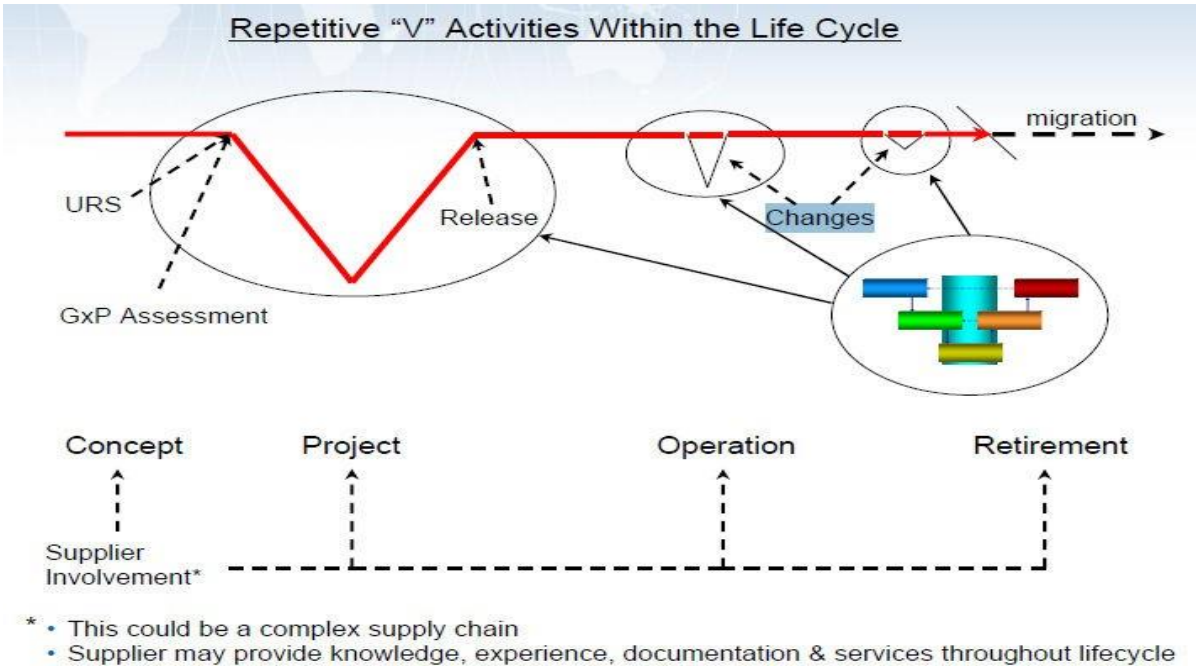
Aside from being an excellent tool to help ensure regulatory compliance, GAMP5 is also useful when determining the scope of testing. The risk-based approach allows you to concentrate your testing efforts on the high-risk areas of the system while aiding in the formulation of a rationale for performing reduced testing on areas deemed low-risk. As a result, testing can be tailored to the system being validated. This makes the validation effort more efficient while still demonstrating that the system works as intended.

Another advantage of implementing GAMP's approach to computer system validation is that ISPE also publishes reference materials that are specific to various systems requiring validation. ISPE's comprehensive series of "Good Practice Guides" focusing on best practices can help you apply the risk-based approach recommended by GAMP5 to the systems utilized by your organization. For additional guidance related to testing, you can consult the GAMP®5 Good Practice Guide: A Risk-Based Approach to Testing of GxP Systems. Good practice guides are also available for just about every type of GxP computerized system, such as GxP process control systems, GxP systems used to apply electronic signatures and GxP laboratory systems.

The approach considered for Computer System Hardware and Software for HPLC as Concurrent Validation approach because of the complexity and the long time span for computerised system validation the process is typically broken down into life cycle phases. The validation exercise will follow the typical 'V' diagram approach for System and Software for HPLC advocated by GAMP5 following Life Cycle Management model. The diagram is shown above as reference.

This model comprises of User Requirement Specifications (URS), GxP Assessment, Validation Plan, Configuration Specification (CS), Risk Assessment, Qualification Document (IQ / OPQ), Requirement Traceability Matrix (RTM) and Validation Summary Report (VSR). A typical life cycle management model is shown in diagram below.

The model suggests that after completion of first validation exercise, the Computer System and Software for HPLC will be governed by formal change control process during operation phase. All changes shall follow the 'V' model depending upon the impact assessment. After completion of use of the system, the same will be retired following a defined retirement plan.



6.1 LIFECYCLE PHASE: The objective of this section is to establish requirements and provide a guideline for the overall validation of the system. A lifecycle approach will be used for validating the Computer System and Software for HPLC.

6.2 PLANNING PHASE.

6.2.1 USER REQUIREMENT SPECIFICATION: The User Requirements Specification (URS) is define the business needs, the intended usage and the required process features of the Computer System And Software for HPLC The approved URS document is available prior to commencing the qualification phase in case of revalidation and to be available before procurement in case of new procurement.

6.2.2 GXP ASSESSMENT: GxP assessment shall be performed based on business processes, System requirements and regulatory requirements will decide whether the system is GxP compliant or not. Each system in scope shall be subjected to a series of questions with below mention procedure steps to establish GxP relevance i.e. having impact Patient Safety, Product Quality and Data Integrity.

GxP relevant questionnaire to be executed for laid down in the respective module. Similar process step which come across multiple processes shall be performed once.

- All answers shall be recorded in GxP Assessment documents with Yes/No marking.
- Identify the potential GxP criticality by counting the 'Yes' marked answer for individual process.
- All processes gaining a 'Yes' in the questionnaire shall be deemed GxP critical and shall be further assessed for risks in a detailed manner under Risk Assessment.

6.2.3 VALIDATION PLAN: The Validation Plan (VP) establishes the approach of the validation / compliance effort, summarizes the activities that will be performed in the entire validation project, identifies the measures of success and clearly defines the criteria of final acceptance for Computer System and Software for HPLC This plan specifies all validation requirements and deliverables for the validation effort inclusive of the different types of reports that will be produced in this project to cover the progress made, issues raised and the acceptance of the different phases of the Validation Plan (VP).

6.3 SPECIFICATION PHASE:

6.3.3 CONFIGURATION SPECIFICATION (CS): The Configuration specification defines the specific system, Configuration and design specification of Computer system hardware and software installed. The CS contain test and validate description of various components and configurations.

6.3.4 RISK ASSESSMENT: Risk assessment will be carried out for Computer system and Software for HPLC in order to assess the GMP risks associated with systems in order to evaluate the need, scope and extent of validation, preventive maintenance, standard operating procedures etc. The risk assessment process allows users to identify and minimize the impact of adverse events, while at the same time providing the necessary justification for the validation approach taken to support the system qualification. A Plan for How the Risk will be assessed shell also be Prepared.

6.4 QUALIFICATION PHASE:

6.4.1 Qualification protocol cum report: Qualification Protocol cum report shall be prepared in order to Qualify Computer System and Software.

The Objective of Each Protocol is Summarized Below:

Installation Qualification (IQ): Installation Qualification Protocol shall be developed & executed to qualify the installation of Computer system Hardware and Software for HPLC system, the tests to be performed during the IQ shall be described in detail in the IQ protocol Cum Report, which will be approved before execution. The results of the IQ will ensure that the Computer System Hardware and Software for HPLC has been installed according to pre-approved specifications.

Operational And Performance Qualification Cum Report (OPQ): Operational and Performance Qualification shall be developed & executed to qualify the operation and performance Computersystem and Software for HPLC the tests to be performed during the OPQ shall be described in the OPQ protocol, which will be approved before execution. The results of the OPQ will ensure that the Computer system and Software for HPLC are operating and performing as intended.

6.4.2 TEST STRATEGY: The Computer System And Software for HPLC used at Site configured based on system requirements specification. Hence the emphasis of testing shall be generation of electronic data, electronic records, storage of data/records, data backup, user independent audit trail generation, system security and overall data integrity. System security testing will include physical security as well as logical security verification and supporting procedures for authorized access and control of data.

The number of levels of testing and test specifications will vary based on GAMP categorization of system and risk assessments.

For critical processes, the tests will include positive case as well as negative case testing to challenge system's ability. For the purpose of this document, manual testing shall be utilized unless otherwise provided by supplier testing documentation.

Supporting documentation such as printouts, screenshots etc. may be considered to support test results. This will depend upon nature of test, GxP impact and complexity of function. This need will be identified in individual protocol.

6.4.3 DISCREPANCY MANAGEMENT: There may arise occasions, during testing, when discrepancies will be found. These may be:

- Results which fail to meet the acceptance criteria.
- Conflicts with specifications.
- Information which is unavailable.
- Discrepancy from protocol methodology.
- Documentation discrepancies (e.g. incorrect reference number, issue number, etc.).

All the discrepancies encountered during a validation activity shall be recorded in the appropriate section of the protocol / Report / data sheet as per discrepancy report format. The observed discrepancy shall be evaluated by Validation and QA and will be closed before completion of validation. Before completion of validation activity all discrepancies shall be corrected tested and closed.

6.4.4 ACCEPTANCE CRITERIA: All required Qualification activities shall be performed and all corresponding data collecting forms are completed. Completion of data collection forms shall indicate that actual installation, operational and integration conditions have been compared to specified conditions. All amendments and discrepancy shall be adequately resolved and approved by all individuals listed by title on the Qualification Completion and Approval.

6.4.5 TRACEABILITY MATRIX: The Traceability Matrix will cross-reference / traceability of requirement defined in the URS documents to the corresponding tests and measures executed in the qualification document. The TM will ensure that all qualification testing has challenged the requirements defined in the URS document for Computer system ad Software, the results

of the Qualification Tests will ensure that the system will satisfactorily perform the required functions and behave correctly, consistently and reliably.

6.5 REPORTING PHASE:

6.5.1 VALIDATION SUMMARY REPORT: A validation summary report will be developed for Computer System and software to summarized all validation activities as specified in this validation plan and will be issued for final approval and acceptance that all validation activities have been completed .The approval of the VSR will serve as the milestone, indicating the completion of the validation activities for the Computer System And Software.

7.0 INITIAL GxP IMPACT ASSESSMENT:

Initial impact assessment of the Computer system shall be performed to identify the GxP impact and GAMP software category. The GxP assessment is carried based on comprehensive understanding of respective Computer system and its intended use. Any of the questions below answered as Yes; the system is GxP and requires control system validation in accordance to validation master plan for Computer systems.

7.1 GxP Assessment of Computerized System (Hardware and Software):

S.No.	Question	Yes	No
1.	Is system used to generate data used in support if regulatory submission?	☑	☐
2.	Is system used to monitor, Control or supervise a GxP Manufacturing or packaging process and have potential to affect Product Quality, Safety Identity or Efficacy?	☐	☑
3.	Is System used to hold and/Or Manipulate clinical study data?	☐	☑
4.	Is system used to monitor, control or supervise packaging labelling operations?	☐	☑

S.No.	Question	Yes	No
5.	Is system used to create critical study control data?	☑	☐
6.	Does the system hold Electronic records that are or could be used in electronic form to make GxP decisions?	☑	☐
7.	Is system used to transmit e – data/records to other systems for execution of GxP activities?	☑	☐
8.	Is the system is used for GxP Analytical Quality Control?	☑	☐
9.	The system manipulates data, or produce reports, to be used by GxP quality related decision authorization / approval processes, where the data supports the decision process or electronic record constitutes the master records.	☑	☐
10.	Is the system used to maintain compliance with a GxP requirement?	☑	☐
11.	Is system used to monitor, control or supervise warehouse or distribution within GxP requirement?	☐	☑
12.	Is System used for GxP Batch sentencing or batch records?	☐	☑
13.	Is system used to store GxP documents for example, SOP, Specifications, BMR, BPR, DMF?	☐	☑
14.	Is system used to store GxP data backup, restore , archival or storage, data security or access / Domain control?	☐	☑
15.	Is system used for physical access to GxP to environment (i.e., area or location)?	☐	☑

S.No.	Question	Yes	No
16.	Dose system support a GxP application i.e. LAN/WAN?	☑	☐

Conclusion:

System belongs to:- GxP ☑ Non GxP ☐

If any of the above questions are answered **"Yes"** then the system has GxP impact and system requires level of validation and control through Computer System Validation.

If all the questions are answered **"No"** then the that system may be deemed not to have a GxP Impact. This Should be documented to support the decision not to perform formal validation. The validation approach and deliverables will be determined by the project team in consultation with QA.

Electronic record and Electronic signature availability				
S.No.	**Question**	**Yes**	**No**	**Remark**
1.	Does the system implement any E-signature	☑	☐	Electronic Signatures are being used in the software used in system.
2.	Are there any electronic records associated with the system?	☑	☐	Yes, there are electronic records associated with the system.

7.2 System Categorization (Hardware and Software):

Refer below checklist shall be used to classify the systems into one of the system categories:

S.No.	Question	Yes	No
1.	Is the system established commercially and is used to run other programs/ applications?	☐	☑
2.	Dose the system consist of software which is not directly useful for business purposes but make the computer hardware useful? An Example is Windows Operating System?	☐	☑
3.	Is system used to perform basic tasks, such as recognizing input from the keyboard, sending output to the display screen, keeping track of files and directories on the disk, and controlling peripheral devices such as disk drive printers?	☐	☑
4.	Is system available as a ready – made product for sale to the general public?	☑	☐
5.	Can the system be implemented without performing any customization or configuration to it (i.e. system will be used "As-Is")?	☐	☑
6.	Can system be configured for use for a specific function without altering the basic Program? In other words, can the system be tailored to meet your business requirements/ Needs?	☑	☐
7.	Dose the system consists of a program or group of programs specially designed for the end users?	☐	☑

Based on above question Application Software falls into one of the categories as-

1. **Category 1:** Operating System [Note: If answer to question 1 and 3 is yes, then this category is applicable]
2. **Category 3:** Standard Software Packages (Commercial of the Shelf (COTS) As –Is) [Note: If the answer to question 4 and 5 is Yes, then this category is applicable]
3. **Category 4:** Configurable software packages (Configurable COTS [If the answer to question 4 and 6 are Yes, then this category is applicable]
4. **Category 5:** Custom (Bespoke) Software. [Note: If the answer to the question 7 is Yes, then this Category is applicable]

GAMP 5 Hardware Category	Question	Yes	No
1	Is this a standard hardware component which is commercially available and no customization is made?	☐	☑
2	Is the hardware component, configured in addition to the standard hardware and customized as per requirement?	☑	☐

Component	Software Category	Hardware Category
PC Hardware	NA	2
Operating System	1	NA
Empower Software for HPLC	4	NA

8.0 VALIDATION REQUIREMENT:

Validation requirement	Yes ☑ No ☐
Validation type	Initial validation ☑ Re-validation ☐ Other ☐

9.0 VALIDATION DELIVERABLES:

Identify the documents which shall be prepared as part of the validation of Computer System to meet the necessary regulatory requirements applicable to respective systems.

Document Title	Requirement of Documents/ Deliverables
User Requirement Specifications (URS)	**Required ☑ Not Required ☐**
Validation Plan(VP)	**Required ☑ Not Required ☐**
GXP Assessment of Software	**Required ☑ Not Required ☐**
Configuration (Software and Hardware)	**Required ☑ Not Required ☐**
Risk Assessment Plan(RAP)	**Required ☑ Not Required ☐**
Risk Assessment (RA)	**Required ☑ Not Required ☐**
Installation Qualification (IQ)	**Required ☑ Not Required ☐**
Operational And Performance Qualification (OPQ)	**Required ☑ Not Required ☐**
Traceability Matrix	**Required ☑ Not Required ☐**
Validation Summary Report (VSR)	**Required ☑ Not Required ☐**
Change Control	**Required ☑ Not Required ☐**
Training	**Required ☑ Not Required ☐**

10.0 CHANGE CONTROL: Changes (If Any) shall be handled as per the applicable SOP for change Controls and shall be documented and attached as Annexure herewith.

11.0 TRAINING ATTENDANCE RECORD:

Training Title: **Venue:**

Faculty Name: **Date :**

S.No	Name of Employee	Designation	Signature	Evaluation of Result

Remarks (If Any):

_____

_____

Name of Faculty:
Signature:

Date:

12.0 ABBREVIATIONS:

ABBREVIATION	FULL FORM
GAMP	Good Automated Manufacturing Practices
QM	Quality Management
QC	Quality Control
CSV	Computer System Validation
GMP	Good Manufacturing Practices
SOP	Standard Operation Procedure
IT	Information Technology
DB	Database
OS	Operating System
VP	Validation Plan
GxP	Generic acronym for pharmaceutical regulations, Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) & Good Clinical Practice (GCP)
URS	User Requirement Specification
CS	Configuration Specification
RA	Risk Assessment
IQ	Installation Qualification
OPQ	Operation and Performance Qualification
TM	Traceability Matrix
VSR	Validation Summary Report
PIC/S	Pharmaceutical Inspection Co-operation/Scheme
N/A or NA	Not Applicable
Sr.	Serial
No.	Number

13.0 CONCLUSION:

The Computer system belongs to GxP category; hence validation of above Computer System is required.

14.0 APPROVAL PAGE

Department	Name	Designation	Signature	Date
Prepared by: M/s.				
ENGINEERING				
Reviewed by: M/s.				
QUALITY ASSURANCE				
Reviewed by: M/s.				
ENGINEERING				
Reviewed by: M/s.				
IT DEPARTMENT				
Reviewed by: M/s.				
QUALITY CONTROL				
Approved by: M/s.				
QUALITY ASSURANCE				