SYSTEM REQUIREMENT SPECIFICATION

FOR

COMPUTER SYSTEM OF

QC (Viscometer)

System Name	**QC (Viscometer)**
System ID	
Location	**Instrument Lab**
Effective Date	

SYSTEM REQUIREMENT SPECIFICATION FOR COMPUTER SYSTEM OF VISCOMETER

System Name: QC (Viscometer) **System ID:**

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System Name: QC (Viscometer) **System ID:**

1. PREPARATION AND APPROVALS:

The signature listed below indicates the preparation and approval of this system requirement specification. This approval is joint responsibility of listed functional areas.

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

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

DOCUMENT APPROVAL (M/S …….)
Sign / Date : _____ **Name** : _____ **Designation** : _____ **Quality Assurance**

2. OBJECTIVE:

The objective of the system requirement specification defines the requirements of hardware software, functions and documentation for the Computer System (QC_VISCO) installed at M/s. ……. This document will be cross-referenced with the relevant system specification to ensure that the system specifications have been met according to M/s. ……. requirements.

3. SCOPE:

This document is applicable to validation of Hardware and Software of computer system installed at M/s. …….. Quality control department. This system requirement specification shall define the documentation, references and acceptance criteria to establish that the validation of Hardware and Software of Computer system after modification is installed in accordance with the guidelines laid down by the manufacturer of the system.

4. SYSTEM DESCRIPTION:

Computer system of QC_VISCO defines the controlling of analytical instrument connected to the system. It controlled the process of instrument connected to it by the software installed in the CS. The operator interface is carried out by CS screen. The CS is used to feed required parameters and set points in the system during operation. The system is connected to data server for printing and data backup. The system is secured by IT through password only within the system.

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 the necessary data for system requirement specification activities. ➢ To prepare the system requirement specification in coordination with engineering, validation and quality assurance team. ➢ Comply with regulatory / Guidelines / Standards / validation plan requirements throughout the validation life cycle. ➢ To submit system requirement specification for approval.
Engineering (M/s. ……)	➢ To provide the necessary data for system requirement specification activities. ➢ To review system requirement specification.
IT (M/s. ……..)	➢ To provide the necessary data for system requirement specification activities. ➢ To review system requirement specification.
Quality Control (M/s. ……..)	➢ To provide the necessary data for system requirement specification activities. ➢ To review system requirement specification.
Quality Assurance (M/s. ……..)	➢ To approve and authorized the system requirement specification.

6. REFERENCES:

The publication listed below form part of this reference documents. Each publication shall have latest revision in effect on the date of this document is approved for execution.

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
21 Code of Federal Regulations (CFR), Part 11	21 Code of Federal Regulations (CFR), Part 11 Electronic Records, Electronic Signatures, Final Rule Electronic Submissions; Establishment of Public Docket, Notice
ICH Q9	International Conference of Harmonization (ICH) quality risk assessment Q9
EU GMP	Laying down the principles and guidelines of GMP in respect of medicinal products for human use.
WHO	Appendix 5, validation of computerized systems.

7. DOCUMENTATION PROCEDURE:

- Qualification activities will be performed as defined in the approved document.
- All documentation will be completed during the execution of the qualification.
- Recording of information will be made in permanent ink.
- Fill out complete information in the verification table provided.
- Do not keep any space blank. Mark blank space with a single line throughout the appropriate space with mentioning NA (Not Applicable) and put initial and date.
- Correct the mistakes by drawing a single line through the incorrect data, recording the correct information and then initialing and dating the change.

8. QUALIFICATION COMPLETION AND APPROVAL:

- Verify that all tests required by qualification are completed and attached.
- Verify that all amendments and discrepancies are documented, approved and attached.
- If all items in the qualification for the Computer System Based system (QC_VISCO) have been reviewed and found to be acceptable, sign the corresponding block in the qualification completion and approval form.

9. ACCEPTANCE CRITERIA:

- Installation completion as per manufacturer's recommendations & cGMP requirements.
- Installation of major components as per the design specifications.
- The supply of all necessary documentation from manufacturer.
- The system is operating as intended and is under state of control.
- Operational features meet system requirements and system specifications.

10. SYSTEM REQUIREMENTS:

10.1 Hardware Components

S.No.	Name	Make/ Assemble By	Model No./Specification	Quantity
1.	Monitor	Acer	-	01
2.	CPU	Acer	-	01
3.	Keyboard	Acer	NA	01
4.	Mouse	Acer	NA	01
5.	UPS	Emerson Network System	20 kVA	01
6.	RAM	Acer	4 GB	01
7.	Processor	Intel	I3 3.60 GHz	01
8.	Printer	Canon	3300	01
9.	Analytical Instrument	Brook Field	RVDV2T	01

Communication Port

S.No.	Port Type	Quantity
1.	USB	4
2.	Ethernet	1

10.2 Software Components:

S.No.	Name	Version no.	Quantity
1.	Metrohm Tiamo	2.5	01
2.	Acrobat reader	18.011.20055	01
3.	Windows	7 64 bit SP1	01

10.3 Capacity Requirement

Local Electronic Storage	No more than 50% of the installed hard disk capacity in PCS components should be consumed by installed software.
Historical and Archive Storage	Historical data storage capacity should allow for online retrieval of at forever of any historical data.

10.4 Power Utility:

S.No.	DESCRIPTION	SPECIFIED
1.	Computer System Power Supply	230 VAC
2.	Analytical instrument	(220-240) VAC

10.5 Environmental Condition

S.No.	DESCRIPTION	TEMPERATURE	RELATIVE HUMIDITY
1.	Computer System Environmental Condition	NMT 25 °C	NA
2.	Analytical instrument	NMT 25 °C	NA

10.6 Communication Link Between Server To Computer System

S.No.	DESCRIPTION	Ping with	Pinged Ip
1.	Computer system	File Server	192.168.2.3
2.	Computer system	Printer	192.168.2.120

10.7 Window Security

S.No.	DESCRIPTION	SPECIFIED
1.	Login to PC with blank User ID & Blank password.	Access Denied &Error message displayed.
2.	Login to PC with Correct User ID & Blank password.	Access Denied & Error message displayed.
3.	Login to PC with Correct User ID & incorrect password.	Access Denied & Error message displayed.
4.	Login to PC with Incorrect user ID and correct password.	Access Denied & Error message displayed.
5.	Login to PC with correct password.	Access granted

10.8 Password Security:

S.No.	DESCRIPTION	SPECIFIED
1.	Minimum password length	Password should be minimum 6 characters.
2.	Password Expiry Days	The password shall expire after 90 days.
3.	Password Complexity	Password should be combinations of upper case letters, lower case letters, numbers and special characters.

S.No.	DESCRIPTION	SPECIFIED
4.	Wrong Password Entry	System shall be Generate the popup.

10.9 Verification of User Level and Rights

S.No.	DESCRIPTION	SPECIFIED
1.	User Level & Rights	System should be password protected and indiviual rights should be assigned for user.

10.10 System Response Failure

S.No.	DESCRIPTION	SPECIFIED
1.	CPU Failure	CPU should be off and monitor cannot be response.
2.	Monitor Failure	Monitor should be off and CPU Should Be On.
3.	UPS Failure	UPS should be off and CPU and Monitor cannot response.
4.	Communication failure between CPU and Monitor	Monitor should not be response.
5.	Communication failure with Local area network	Printing should be stop
6.	Power Failure	UPS supply connected with System to safe shutdown.

10.11 Electronic Data Security

S.No.	DESCRIPTION	SPECIFIED
1.	Electronic Record Storage	All the electronic should be store in a correct manner and specified location.
2.	Electronic Data Storage Path Accessbility	Only authorised user shall be access the elecronic storage data.
3.	Access of any other file beside the primary system software	Only qualified and authorized user shall be access other file beside the primary system software.
4.	Electronic Record Maintain	Electronic record shuold maintain in a redundent hard disk / IT server / DVD with specified location.
5.	Print the entire content of electronic records	User should be print the entire content of electroic records.

10.12 Audit Trail:

S.No.	DESCRIPTION	SPECIFIED
1.	Attempt to login account from authorised user	Login Successful. The same is logged in the audit trail automatically.
2.	Attempt to login account from unauthorised user	Login Fail. The same is logged in the audit trail automatically.
3.	New Account Creation and Deletion	Audit trail should record the creation of new account and deletion.
4.	Password Change	Change in the password shall be logged into the audit trail.
5.	Key Parameter and Setting change during operation from any user	Key Parameter and Setting change during operation from any user should be logged into audit trail.
6.	Editing/Deleting in Audit Trail	No editions/deletion possible in the Audit trail.
7.	Audit Trail Content	Audit trail should have facility to logged the data with time, user identity, reason of change and type of change.

10.13 Report Generation:

S.No.	DESCRIPTION	SPECIFIED
1.	Report Edition/Deletion	Report shall not be edit/ delete by user
2.	Date and Time stamp on Report during generation/Print	Date and Time stamp on Report during generation/Print.
3.	Redable Formate	Report shall be in human readable format

10.14 Data Back Up:

S.No.	DESCRIPTION	SPECIFIED
1.	Access to Data Storage Path	System shall have specific Path and limited access for Data Storage.

10.15 User Prevented From Alternating Date and Time:

S.No.	DESCRIPTION	SPECIFIED
1.	User Prevented From Alternating Date and Time	User cannot change or alter the date and time of system.

10.16 21 CFR part 11 Clauses:

S.No.	DESCRIPTION	SPECIFIED
1.	21 CFR part 11 Clauses	System shall be compliance 21 CFR part 11 Clauses

10.17 Control Loops Test:

S.No.	DESCRIPTION	SPECIFIED
1.	Control Loops Test	System shall be should able to control the set process parameter within the specified limit.

11. DISCREPANCIES HANDLING DURING COMPUTER SYSTEM QUALIFICATION:

- In case of discrepancy observed during qualification, document in the defined column in each table and document the details of the observation in the discrepancy log sheet.
- Inform to engineering, IT, QC and quality assurance about discrepancy.
- Investigate the discrepancy and ensure the possible impact.
- If discrepancy does not have potential to impact on operation as well as performance of the system, close the discrepancy with proper justification.
- The engineering, IT, QC and QA will decide whether discrepancy is acceptable or not.
- If discrepancy is acceptable, provide conclusion and recommendation if any into respective column.

12. DISCREPANCY AND CORRECTIVE ACTION FORM:

Protocol Reference	
Discrepancy Number	

DISCREPANCY:

Describe the Discrepancy	
Reported by	Date

CORRECTIVE ACTION:

Describe corrective action taken (Attach additional sheets if necessary)	
Reported by	Date

DISPOSITION ACTION :

Acceptable?	Yes	No	
Discussion			
Approved by			Date

COMPLETION:

Completed by	Date

13. ABBREVIATION:

Abbreviations	Description
GMP	Good Manufacturing Practices
CPU	Central Processing Unit
RA	Risk Assessment
SRS	System Requirement and Specification
IQ	Installation Qualification
OQ	Operation Qualification
PQ	Performance Qualification
QA	Quality Assurance
TM	Traceability Matrix
VSR	Validation Summary Report
SOP	Standard Operating Procedure
NA	Not Applicable
IO	Input Output
ICH	International Conference of Harmonization
UPS	Uninterruptible Power Supply
CS	Computer System
NMT	Not More Than
WHO	World Health Organization