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Computer System Validation of UV Spectroscopy Instrument Software (CARRY UV) using V Model

Vignesh. K, Sujatha. K*, and Sonia. K

Department of Pharmaceutical Chemistry, Sri Ramachandra Faculty of Pharmacy, Sri Ramachandra Institute of Higher Educationand Research, SRIHER(DU), Porur, Chennai- 600116

*Correspondence e-mail: sujatha.k@sriramachandra.edu.in

Abstract

Computer System Validation (CSV) is a critical aspect of ensuring that any software or system used in regulated environments, such as pharmaceuticals, healthcare, and biotechnology, meets its intended purpose and operates consistently within specified parameters. The UV spectroscopy instrument, specifically the CARRY UV software, is a pivotal tool in analytical laboratories for measuring the absorbance and transmission of ultraviolet and visible light by a sample. Validating this software using the V-Model ensures its reliability, accuracy, and compliance with regulatory standards. The V-Model, or Validation Model, is a systematic approach widely used in software development and validation. It emphasizes verification and validation activities corresponding to each stage of the software development lifecycle. Key aspects include accuracy in measurement, data integrity, user access controls, and audit trails. This stage involves outlining the software's capabilities, such as wavelength range, data processing algorithms, user interface design, and integration with laboratory information management systems (LIMS). The design specifications phase involves creating a blueprint for the software's architecture. This includes the design of databases, software modules, and user interfaces. For CARRY UV software, it is crucial to ensure that the design supports robust data handling, secure user access, and accurate data processing. For the CARRY UV software, developers must focus on implementing algorithms for accurate spectral data analysis and ensuring the software's compatibility with various hardware configurations. Integration testing involves combining individual modules and testing them as a group. System testing validates the complete and integrated software to ensure it meets the specified requirements. For the CARRY UV software, this involves testing the entire workflow from sample measurement to data analysis and reporting. It ensures the software performs reliably under different conditions and usage scenarios Users test the CARRY UV software in a real-world environment to ensure it performs as expected. This phase includes installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) to ensure the CARRY UV software is installed correctly, operates according to specifications, and performs consistently in the production environment. Throughout the validation process, meticulous documentation is maintained. This includes validation plans, test scripts, test results, and validation reports. Documentation is essential for demonstrating compliance with regulatory requirements, such as those set by the FDA, EMA, or other relevant authorities. Validating the CARRY UV software using the V Model ensures a structured and thorough approach to verifying and validating the software's functionality, performance, and compliance. This methodical process helps identify and mitigate risks early, ensuring the software's reliability and integrity in critical analytical applications. Through rigorous testing and documentation, the V Model supports the delivery of a robust and compliant UV spectroscopy instrument software, ultimately enhancing laboratory efficiency and accuracy.

Keywords: Installation Qualification, Operational Qualification, & Performance Qualification, quality, safety, identity, efficacy

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Introduction

Computer system validation is a meticulous and well-documented process that ensurescomputer-based systems will generate information and data that meet predetermined requirements [1-3]. This validation process is crucial in pharmaceutical companies and medical device industries as it helps to enhance the handling of complexities and system performance. The primary objective of computer system validation is to guarantee accuracy, consistency, reliability, and consistent performance of the system in line with predefined specifications [4-7]. In the pharmaceutical industry, computer system validation plays a pivotal role in improving product quality, streamlining processes, and supporting the production of high-quality products. One of the major advantages of validating computer systems is the support it provides for quality controls, ensuring that processes are followed correctly and reducing the likelihood of manual errors [8-9]. To maintain industry standards, both the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) have issued guidelines for Computer System Validation (CSV) practices.Computer system validation is a unique and essential process that maximizes effectiveness and enhances the overall quality in the pharmaceutical Indus.

Methods and Materials

Instruments required

1. UVSpectroscopy
2. Software(carryUV)
3. Computer

Installation qualification (IQ)

The purpose of the Installation Qualification is to verify and document that all the key aspects of the hardware and software installation, including operating system details adhere to approved Design Specifications manufacturer's recommendations and environmental conditions. An IQ protocol shall be prepared and will define the level of validation required. The IQ protocol may be separate for hardware and software in the (Tables 1 & 2).

Operational qualification (OQ)

The purpose of the OQ is to verify and document that the individual and integrated components of the System perform reliably and consistently within specified operating ranges as stated in the functional specification. OQ testing will be based on the Impact Assessment. OQ testing shall be conducted in a production environment or a validation environment that has been demonstrated to be equivalent tothe production environment. An OQ protocol shall be prepared for each of the Systems and will define the level of verification required (Table 3).

Performance qualification (PQ)

The purpose of the PQ is to challenge the fully configured release of the System in its normal integrated environment. A protocolshall be prepared which will verify the performance of the System in accordance with the approved URS, Standard Operating Procedures and relateddocumentation.

Testing will be developed to challenge the System as it is used and operated under routine conditions and environmental parameters. This includes the review of each procedure that interfaces with the System and provides evidence that the procedures are in existence, current, applicable and being followed. Sections of the PQ can be incorporated into the OQ (Tables 4 & 5).

Functional risk assessment:

Functional risk assessments should be used to identify and manage risks to patient safety, product quality, and data integrity that arise from failure of the function under consideration.

Functions which impact on patient safety, product quality, and data integrity are identified by referring to the URS, functional specification document (FSD), and the output of the initial risk assessment. Risk

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Table 1: Software Categories

Category	Description	Validation Approach	Typical Example
Category-1 Infrastructure Software	Layered Software used to manage the operating environment	Record version number, verify correct installation by following approved installation procedures.	• Operating Systems • Database Engines • Middleware • Programming Languages • Statistical Packages • Spreadsheets • Network Monitoring Tools • Scheduling Tools
Category-2 Non Configured Software	Run Time Parameters may be entered and stored, but the software cannot be configured to suit the business process	Abbreviated life cycle approach: URS, Risk based approach to supplier assessment, Record version number, verify correct installation, Risk-based tests against requirements as directed by use. Procedures in place for maintaining compliance and fitness for intended use.	• Firmware based applications • COTS software • Laboratory Software • PLC
Category-3 Configured Software	Software, often very complex, that can be configured by the user to meet the specific needs of the user's business process. Software code is not altered	Life Cycle Approach: Risk- based approach to supplier assessment, Demonstrate supplier has adequate QMS, Some life cycle documentation retained only by supplier (e.g. Design Specification). Record Version Number Verify	• LIMS • Data Acquisition System • SCADA • ERP • DCS • BMS • HMI
		Correct installation. Risk based testing to demonstrate application works as designed in the test environment. Risk-based testing to demonstrate application works as designed within the business process. Procedures in place for maintaining compliance and fitness for intended use. Procedures in place for managing data.	

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Table 1: Software Categories

Category	Description	Validation Approach	Typical Example
Category-4 Custom software	Software Custom designed and coded to suit the business process	Same as configurable, Plus: More rigorous supplier assessment, with possible supplier audit. Full Life cycle (FS, DS, Structural Testing, etc.) Designand Source Code Review.	• Internally and Externally developed IT Applications. • Internally and externally developed process control Applications. • CustomLadderLogic. • Spreadsheets-Macro.

Table 2: Installation qualification document

Availability of hardware software configuration					
Step No.	Name document	Expected result	Actual result	Results Pass/Fail	Verified By Name (project trainee)
1.	Instrument name	UV visible spectrophotom eter	UV visible spectrophotomet er	Pass	Vignesh
2.	Make	Agilent Technologies	Agilent technologies	Pass	Vignesh
3.	Model	Carry 3500 UV vis	Carry 3500 UV vis	Pass	Vignesh
4.	Serial number	MYD00473	MYD00473	Pass	Vignesh
5.	System ID	APRD/AD/0009	APRD/AD/0009	Pass	Vignesh
Verification of client software					
1.	Log into system	System allow user to log in	System allow user to log in	Pass	Vignesh
2.	Windows activation	Activation available	Activation available	Pass	Vignesh
3.	Date and time synchronization	Date and time Synchronized with calibrated Master clock	Date and time Synchronized with calibrated Master clock	Pass	Vignesh
4.	Click the Windows Startbuttonthen (All) Programs, Agilent and Carry UV	Windows Start button then (All) Programs, Agilent and Carry UV Available	Windows Start button then (All) Programs, Agilent and Carry UV Available	Pass	Vignesh

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Table 2: Installation qualification document

Verification of client software					
Step No.	Name document	Expected result	Actual result	Results Pass/Fail	Verified By Name (project trainee)
5.	The first time the Carry UV software is open a Software Registration dialog willappear.Click Next	Carry UV software Registration dialog will appear. Click Next is appear	Carry UV software Registration dialog will appear. Click Next is appear	Pass	Vignesh
6.	Complete all the fields on the 'Customer Details' page. Click Next.	Its appear 'Customer Details' page. Click Next.	Its appear 'Customer Details' page. Click Next.	Pass	Vignesh
7.	Complete all the fields on the 'Work Environment Details' page. Click Register.	Its appear 'Work Environment Details' page. Click Register	Its appear 'Work Environment Details' page. Click Register	Pass	Vignesh

Table 3: Operational qualification document

Verification of audit trail					
Step No.	Procedure	Expected result	Actual result	Results Pass/Fail	Verified By Name (Project trainee)
1.	Log in the System administrator ID and Password	System should allow to Login the administrator	System should allow to Login the administrator	Pass	Vignesh
2.	Obtain the audit log of all the transactions executed by the user in this protocol along with Login and Logout history capturing the below information (but not limited to) • UserID /Name • Date/time of run • Original value	Audit trail content should match transaction and activity performed on the system.	Audit trail content should match transaction and activity performed on the system.	Pass	Vignesh

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Table 3: Operational qualification document

Verification of audit trail					
Step No.	Procedure	Expected result	Actual result	Results Pass/Fail	Verified By Name (Project trainee)
3.	Verify that audit trail cannot be turned off/ there is no option for the user to turn off the audit trail.	User should not be able to turn off the audit trail.	User should not be able to turn off the audit trail.	Pass	Vignesh
4.	Try to edit the audit trail	Application should not allow to delete audit trail	Application should not allow to delete audit	Pass	Vignesh
5.	Try to delete the audit trail	Application should not allow to delete audit trail	Application should not allow to delete audit	Pass	Vignesh

Table 4: Verification of Backup

Step No.	Procedure	Expected result	Actual result	Results Pass/Fail	VerifiedBy name (Project trainee)
1.	Login the system Administrator ID and Password	System should allow to Login Administrator	System should allow to Login Administrator	Pass	Vignesh
2.	Verify the data backup	Data backup should take place	Data backup should take place	Pass	Vignesh
3.	Verify that user can be able to access & take data backup	Administrator only should have the access and authorization to take data backup	Administrator only should have the access and authorization to take data backup.	Pass	Vignesh

Assessment consists of identification of risks and the analysis and evaluation of risks associated with system.Risk Identification- is a systematic use of information to identify hazards referring to the risk question or problem description. Risk Analysis- Risk analysis is the estimation of the risk associated withthe identified hazards. It is the qualitative or quantitative process of linking the likelihood of occurrence and severity of harms (Tables 6-8).

Results and Discussion

In order to UV spectroscopy instrument software (CARRYUV) using V Model URS, FRA, IQ, OQ & PQ Tests were

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Table 5: Performance qualification document	
Severity–Rating	
Value	Severity(S)
1	Legligible: • Temporary and in significant impact on GxP requirements which can be mitigated without change to Computer system and within existing procedures.
2	Marginal: • Minor failure, not noticeably affecting functional quality of the computerized system, however, are likely to result in a minor deviation from GxP requirements.This can be mitigated with verification.
3	Catastrophic. • Direct and significant impact on data security / integrity / GxP requirements. A failure that could reasonably result in a safety issue (potential harmto worker) shall be considered as Catastrophic.Designand implementation review to be done with corrective and preventive actions. Risk assessment shall be performed. Review of testing protocols and revision (if necessary) to intensify testing in the failed components. Review and possible revision of impacted SOPs.
4	Critical: • Acritical failure that mayrender the system in operable or result in significant reduction in performance of the computerized system and/or quality of the product or having an impact on data security/integrity GxP requirements. • These risks shall be investigated with corrective and preventive actions, review of testing protocols and revision (if necessary) to intensify testing in the failed components. Review and possible revision of impacted SOPs. Risk assessment shall be performed.
5	Moderate: • Moderate failure likely resulting in reduction in performance of computerized system or quality of the product. These failures are likely to result in a major deviation from GxP requirements. • Risk assessment shall be performed and investigation with corrective action plan shall be derived to mitigate the risks (if any).

done according to the protocol. During the execution of protocol, the tests of the UV Spectroscopy Instrument Software (CARRY UV) using V Model URS, FRA, IQ, OQ & PQ were mentioned the process as follows:

The key process parameters like FRA, IQ, OQ & PQ tests passes all steps and final results are with acceptance limit of user requirement specification. Under user requirement specification all steps are done and all are meet their specifications.

Table 6: Probability–Rating	
Value	Probability (p)
1	Rare, Failure is unlikely
2	Unlikely, Relatively few failures
3	Possible, Occasional failures
4	Likely, Repeated Failures
5	Almost certain, Failure is almost in evitable

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Table 7: Detectability– Rating	
Value	Detectability(D)
1	Very high, will almost certainly be detected
2	High, has a good chance of detecting the risk
3	Moderate, a potential risk maybe detected
4	Low, the risk is unlikely to be detected
5	Very low, the risk will not be detected

Functional risk assessment (FRA). The risks is calculated according to this risk assessment calculation and finds risk is in minor level and it iscorrected and recovered. All tests under Installation qualification (IQ) is passed all tests Including Hardware and Software verification tests are matching with URS. All tests under operational qualification (OQ) is passed all tests Including system security and verification backup are matching with URS. All tests under Performance qualification (PQ) is passed all tests including Performance qualification procedures and performance qualification test plan are matching with URS. Handling of discripancies and risk assessment mitigation action tests

Table 8: Qualitative or quantitative process of linking					
Severity (S) Probability (P)	Negligible (1)	Marginal (2)	Moderate (3)	Critical (4)	Catastrophic (5)
Almost certain(5)	5	10	15	20	25
Likely(4)	4	8	12	16	20
Possible(3)	3	6	9	12	15
Unlikely(2)	2	4	6	8	10
Rare(1)	1	2	3	4	5

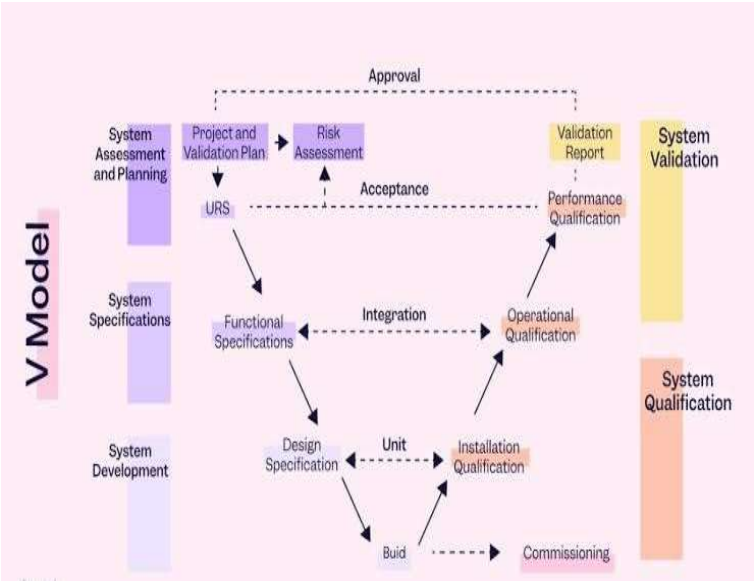

Fig 1: V Model

Computer System Validation

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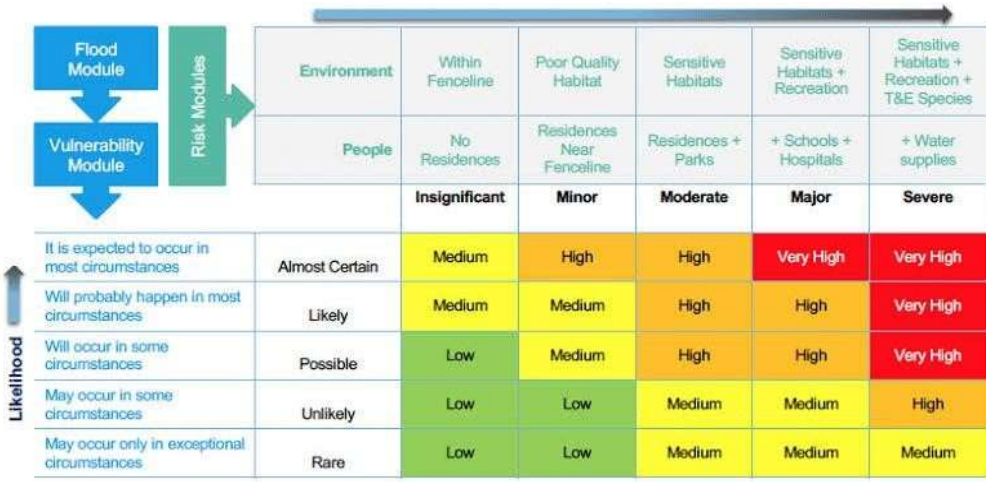

Fig 2: Key Process Parameters

are found with in the acceptance limit. So all, tests are passed and meeting their URS (Figures 1 and 2).

Conclusion

The system must be validated according the Quality System and approved protocols to provide user were data integrity, security and traceability. The computer system validation of UV spectroscopy instrument software will be assessed by using V model. Based on the summary UV spectroscopy instrument software (CARRY UV) using V model were completed successfully. UV spectroscopy instrument software (CARRY UV) using V model were performed and meets their URS and provide quality products as output.

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