



PHARMADEVILS

IT DEPARTMENT

[Appendix 2n-Template of Retirement Protocol]

Title: Retirement Protocolfor <System Name>

Document No.:

<Document No.>

Page:1 of 9

**Retirement Protocol
For
<System Name>**



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IT DEPARTMENT

[Appendix 2n-Template of Retirement Protocol]

PRE-APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date



Table of Contents

1.0	OBJECTIVE.....	4
2.0	SCOPE	4
3.0	RESPONSIBILITIES	4
4.0	QUALIFICATION PARTICIPANTS DATA/ SIGNATURES RECORD	4
5.0	PROTOCOL EXECUTION INSTRUCTIONS	4
6.0	FLOW DIAGRAM OF RETIREMENT PROCESS	4
7.0	PROTOCOL EXECUTION.....	4
7.1.	Test 01	5
7.2.	Test 02	5
7.3.	Test 03	5
8.0	DISCREPANCY AND CORRECTIVE ACTION REPORT FORM	6
9.0	DEVIATION & INCIDENT LOG.....	7
10.0	SUPPORTING DOCUMENTATION	8
11.0	SUMMARY OF TEST RESULTS	8
12.0	ABBREVIATIONS	8
13.0	CHANGE CONTROL	8



[Appendix 2n-Template of Retirement Protocol]

1.0 OBJECTIVE:

This section describes the reason for performing the tests contained in the protocol document.

2.0 SCOPE:

This section describes the aspects or areas of the system that will be challenged by the tests in the protocol.

3.0 RESPONSIBILITIES:

This section describes the responsibilities of the individual validation team members in preparing and executing the protocol.

4.0 QUALIFICATION PARTICIPANTS DATA/SIGNATURES RECORD:

Name	Designation	Signature/ Initials	Date

5.0 PROTOCOL EXECUTION INSTRUCTIONS:

- All recorded data must be completed using blue ballpoint pen only and must be legible
- Any individual involved in the execution or review of this document must complete the signature page.

The individual should also be trained on the protocol and all related SOP's. If the individual is not the employee of SQUARE he /she should also be trained on all related SOP's such as documentation, qualification and general GMPs (all training records must be filed with the training department)

- Any blank spaces must be crossed out with a single line
- When completing information on the various checkout sheets, write N/A if not applicable or N/AV if not available then sign and date next to it
- If a mistake (which is self- evident) is made, place a single line through the item, write in the correct information and initial and date the entry. Include an explanation of the change in the comment section as needed
- All documentation must comply with SQUARE for good documentation practices
- All printouts and other supporting data included must be cross-referenced to the specific test in this protocol, signed and dated, then attached to this protocol as an appendix.

6.0 FLOW DIAGRAM OF RETIREMENT PROCESS:

7.0 PROTOCOL EXECUTION:

This section contains all the tests that will be executed for the computerised system. Each test is to have an objective, Mention to execute the test, and an expected result.

Each test shall contain following sections



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[Appendix 2n-Template of Retirement Protocol]

- Objective
- Tools required
- Procedure
- Acceptance Criteria

7.1. Test 01

7.2. Test 02

7.3. Test 03

.....
.....
.....
.....



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[Appendix 2n-Template of Retirement Protocol]

8.0 DISCREPANCY AND CORRECTIVE ACTION REPORT FORM:

Protocolnumber	
Discrepancynumber	

DISCREPANCY

Descriptionofdiscrepancy:	
Category:	
Reportedby:	Date:

CORRECTIVEACTION

Describecorrective actiontaken (Attachadditional sheetsifnecessary)	
Reportedby:	Date:

DISPOSITION ACTION

Acceptable?	Yes	No
Discussion		
Approvedby:	Date:	

COMPLETION

Completed by:	Date:
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[Appendix 2n-Template of Retirement Protocol]

9.0 DEVIATION & INCIDENT LOG:

This section summarizes the approach to take while handling discrepancy found during execution. Discrepancies will be reported as per the table provided below and classified in Critical, Major or Minor depending upon its impact.

Minor deficiency:	
Sr.	Discrepancy Information
Major deficiency:	
Sr.	Discrepancy Information
Developmental work required/Not required: (Attach details)	
Critical deficiency:	
Sr.	Discrepancy Information
Developmental work required/Not required: (Attach details)	

- Category A (Minor):** Discrepancy is accepted with deficiency
- Category B (Major):** Provisional or conditional acceptance, discrepancy to be corrected either by Supplier or user
- Category C(Critical):** Discrepancy to be rectified before proceeding further



[Appendix 2n-Template of Retirement Protocol]

10.0 SUPPORTING DOCUMENTATION:

This section provides summary of Annexures attached with protocol as test evidences.

11.0 SUMMARY OF TEST RESULTS:

This section summarizes the results of the testing and references any discrepancies that have been documented during protocol test execution. The following text should be used in this section:

S.No.	Test Name	Pass/ Fail	Discrepancy Found? Yes/ No	Verified By/ Date	Reviewed By/ Date

12.0 ABBREVIATIONS:

This section will describe various abbreviations used in the document.

13.0 CHANGE CONTROL:

REVISION DATE	REVISION NUMBER	DESCRIPTION OF CHANGE
<date>	<Number>	Original Document



PHARMADEVILS

IT DEPARTMENT

[Appendix 2n-Template of Retirement Protocol]

POST-APPROVAL PAGE

Prepared By:

Name	Designation	Department	Signature	Date

Reviewed By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date