



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**OPERATIONAL QUALIFICATION  
FOR  
BUILDING MANAGEMENT SYSTEM**

Effective date: \_\_\_\_\_



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**TABLE OF CONTENTS**

<b>CONTENTS</b>		
<b>S.No.</b>	<b>DESCRIPTIONS</b>	<b>PAGE No.</b>
---	<b>PRE APPROVAL</b>	3
1	<b>INTRODUCTION</b>	5
1.1	Purpose	5
1.2	Scope	5
2	<b>RESPONSIBILITIES</b>	6
3	<b>REFERENCE DOCUMENTS</b>	7
4	SYSTEM ARCHITECTURE AND DESCRIPTION	8
5	<b>DOCUMENT CONTROL</b>	10
6	<b>INSTRUCTIONS FOR TEST EXECUTION</b>	10
7	<b>INSTRUCTIONS FOR TESTERS</b>	11
8	SUPPORTING DOCUMENTS (ATTACHMENTS)	12
9	DESIGN DOCUMENTS	13
10	<b>DETAILS OF TEST AND MEASUREMENT INSTRUMENTS</b>	13
11	SIGNATURE LOG	14
12	SYSTEM SECURITY VERIFICATION	15
13	FIELD CONTROLLER DIGITAL AND ANALOG INPUT/OUTPUT VERIFICATION	16
14	FUNCTION KEYS PARAMETERS DISPLAY VERIFICATION	19
15	SEQUENCES OF OPERATION VERIFICATION	20
16	BMS SERVER DATABASE BACKUP VERIFICATION	21
17	SYSTEM COMMUNICATION VERIFICATION	22
18	TESTING OF INTERLOCKS AND ALARMS MESSAGES	23
19	SYSTEM AUDIT TRIALS AND EVENTS LOG	24
20	VERIFICATION OF BMS SOFTWARE AS PER 21 CFR PART 11 COMPLIANCE	25
21	REVIEW OF RELEVANT SOP FOR THE SOFTWARE SYSTEM	26
22	DEVIATION REPORT	27
23	CONCLUSION AND RECOMMENDATION	28
24	ATTACHMENTS	29
25	POST APPROVAL	30



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**PRE APPROVAL:**

Description	Name	Designation	Signature	Date
Prepared By				
Reviewed By				
Reviewed By				

Description	Name	Designation	Signature	Date
Checked By				
Reviewed By				
Reviewed By				
Reviewed By				
Approved By				

**DOCUMENT VERSION HISTORY :**

Version	Date	Pages	Prepared by	Description of change



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**1.0 INTRODUCTION:**

**1.1 PURPOSE:**

The Operational Qualification (OQ) verifies the operation of the computer hardware, software, instrumentation and equipment interfacing with the system against specifications. The goal is to ensure that all key aspects relating to the hardware and software operation conform to the approved design intentions as described in the user requirements specification (URS).

This document has been prepared by ..... to be used as the Validation Master plan for the Building Management System (BMS) Operated in the ..... The goal of the project is to provide a validated BMS that is in compliance with in 21 CFR Part 11.

**1.2 Scope:**

The OQ applies to the BMS components of hardware, system software, application software, controllers and field devices.

The scope includes:

- 1.2.1 Procedures for verification of the system
- 1.2.2 Documented evidence of verification
- 1.2.3 Defined Acceptance Criteria



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING MANAGEMENT SYSTEM**

**2.0 RESPONSIBILITIES:**

Department	Responsibilities
..... <b>Engineers</b>	<ul style="list-style-type: none"> <li>❖ To write the Qualification Protocol</li> <li>❖ To collect all manuals, drawing and documentation, or any other data necessary for the generation, execution of this protocol from ..... and prepare final protocol.</li> <li>❖ To initiate qualification study in coordination with Engineering department of .....</li> <li>❖ To execute and prepare qualification report.</li> <li>❖ To submit qualification report for approval.</li> </ul>
<b>Engineering</b>	<ul style="list-style-type: none"> <li>❖ To provide necessary documents required for BMS validation to .....</li> <li>❖ To co-ordinate with ..... during activities BMS validation.</li> <li>❖ To review the BMS protocol.</li> </ul>
<b>Production</b>	<ul style="list-style-type: none"> <li>❖ Providing personnel to assist in the operation of the system during the execution of qualification studies.</li> <li>❖ Verifying that the study test requirements are completed and prepared for Quality assurance approval.</li> </ul>
<b>Quality Assurance</b>	<ul style="list-style-type: none"> <li>❖ Reviewing and approving this protocol, the qualification data package and the final report.</li> </ul>

.....**Engineers:** - Preparation and execution of Operational qualification for Building Management System

.....: -Review, verification and approval of Operational qualification for Building Management System.

**3.0 REFERENCE DOCUMENTS:**

The test and execution procedures within the scope of this qualification protocol are consistent with the following references:

- ❖ Good Automated Manufacturing Practices – GAMP-5 Guideline.



## **OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING MANAGEMENT SYSTEM**

### **4.0 SYSTEM ARCHITECTURE AND DESCRIPTION:**

#### **4.1 SYSTEM ARCHITECTURE:**

**Annexure 01 – Final Architecture to be attached.**

#### **4.2 SYSTEM DESCRIPTION:**

The Building Management System is used to control, monitor and record various parameter of HVAC system. Building Management System consists of software PC, interfacing device, DDC Panels, Fields instruments for monitoring various parameters of AHU's.

The BMS handles all the functions enable system monitoring and controlling of field equipment. The DESIGO CC software of BMS system serves as an interface to allow operator interaction with the system.

The Building Management System (BMS) is to collect data from field instrumentation (Temperature, Relative Humidity, Pressure Differential of Room, Filter status etc.), which are installed in different Air Handling Units though DDC panels. BMS software is checked this data predefined limits. If data not found within limits then BMS will create alarm.

The Building Management System (BMS) is recorded all data in form of Trend and audit trial.

The Building Management System (BMS) controlled all following parameter through DDC panel and interfacing unit.

- AHU on / off command
- AHU Auto Manual status
- AHU Run Status
- AHU Trip status
- Return Air T+RH Feedback
- AHU Chilled Water Valve Modulation
- AHU Chilled Water Valve Feedback
- AHU Hot Water Valve Modulation
- AHU Hot Water Valve Feedback
- VFD Modulation
- DP Sensor
- Fresh Air Damper Open/ Close Command
- Dehumidifier On/Off Command
- Dehumidifier Run Status
- Ventilation Exhaust on / off command
- Ventilation Exhaust Auto manual status
- Ventilation Exhaust Run Status
- etc. as applicable as per IO summary



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**4.3 Acronyms and Terms:**

<b>Acronym</b>	<b>Description</b>
BMS	Building Management System
CD	Compact Disc
FSR	Full Scale Range
GB	Giga Byte
GHz	Giga Hertz
CGMP	Current Good Manufacturing Practice
ID	Identity
I/O	Input/output
MA	Milliamp
MB	Megabyte
NA	Not Applicable
NS	National Standards
OS	Operating System
PC	Personal Computer
RAM	Random Access Memory
SOP	Standard Operating Procedure
TCP/IP	Transmission Control Protocol/Internet Protocol
UPS	Uninterruptible Power Supply
VAC	Volts Alternating Current
21 CFR Part 11	Code of Federal Regulations, title 21, part 11 contains regulations with regards to electronic records and signatures



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**5.0 DOCUMENT CONTROL:**

It is the responsibility of ..... to maintain document as per ..... policy. Any change to this document should be managed according to ..... and all changes shall be logged as subsequent version no. in History logs.

**6.0 INSTRUCTIONS FOR TEST EXECUTION:**

**6.1 TEST DOCUMENTATION:**

Each test consists of a test procedure (SCRIPT) and a form or forms. Each test addresses the following types of information, as applicable to the test:

- 6.1.1 Objective
- 6.1.2 Scope
- 6.1.3 Acceptance Criterion
- 6.1.4 Procedure
- 6.1.5 Description
- 6.1.6 Expected Results
- 6.1.7 Actual Results
- 6.1.8 Test Results
- 6.1.9 Signatures

**7.0 INSTRUCTIONS FOR TESTERS:**

General instructions for completing the test documents are noted below.





**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

- 7.1 All prerequisites must be completed before testing.
- 7.2 All permanent ink pens (blue or black ink) are to be used for filling out all documentation.
- 7.3 Ensure that the forms being filled out relate to the procedure being completed.
- 7.4 Some test procedures include a navigation path in Windows 2010 or BMS application software and customize application of BMS. This is provided as a suggestion only and an alternative path may be taken to arrive at the desired destination.
- 7.5 Filling out the documentation.
- 7.6 Completely fill out all cells in each line.
- 7.7 Actual values are to be recorded in the appropriate location on the form.
- 7.8 If a cell is not applicable, write "NA". Explain why the item is not applicable if the reason is not evident.
- 7.9 Each line is to be filled out in consecutive order.
- 7.10 If check Boxes are presented, mark an "X" in the appropriate box.
- 7.11 A deviation represents an actual result that differs from the expected results, as documented in the test procedure. Note that an error on the test procedures (script) or on their associated forms is not a deviation or no deviation report is required for this type of correction.
- 7.12 If there are blank lines or cells remaining after completing the procedure, draw a line through the unused space to show that no additional information will be entered. Initial and date the line.
- 7.13 Correcting an entry on the test documentation:
- 7.14 If a mistake is made during the entering of information, make a single line through the mistake. Keep the original information legible and make the correction. Writing overran obscuring original test data is not acceptable.
- 7.15 Each correction must be initialed, dated and provided with a reason for the change from the table below. Circle your initials when signing to distinguish them from the error code.



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

<b>Code</b>	<b>Definition</b>
CE	Communication error (between testing personnel)
CL	Clarification
CR	Corrected at Review
EE	Entry Error
NA	Not Applicable

**7.16 Completing the documentation:**

- 7.16.1 For all test documents, the page(s) must be numbered as “Page: of \_”.
- 7.16.2 All test documents must be signed and dated by the representative who perform test, on the days the test is executed, use the date format of mm/dd/yy.
- 7.16.3 If two representatives are required to execute a test, the test form must be signed by the person who entered the data on the form.
- 7.16.4 File the completed test documents in the project binder in the appropriate location.

**8.0 SUPPORTING DOCUMENTS (ATTACHMENTS):**

- 8.1 If the attachment is numbered sequentially (“Page: of \_”format).
- 8.2 Staple all pages together.
- 8.3 Label the attachment with the reference test number (and step number if possible)
- 8.4 The tester must sign and date the first page.
- 8.5 If the attachment is not pre-numbered sequentially:
- 8.6 Staple all pages together.
- 8.7 Number the page in the format “Page: of \_”.
- 8.8 Label the attachment with the reference test number (and step number if possible)
- 8.9 The tester must sign and date the first page.
- 8.10 Copies of original documentation must be clearly marked “Copy”.
- 8.11 File the completed documents in the project binder.



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**9.0 DESIGN DOCUMENTS:**

**Essential Documents**

- BMS Bill of material.
- BMS Input Output list
- Design document of BMS
- Controller installation manual
- System operation manual
- BMS network diagram
- Temperature and RH sensor/Transmitter specification.
- Sequence operation and control logics of system
- AHU wise I/O List and wiring diagram
- BMS PC specification

**REFERENCE DOCUMENTS:**

- BMS Panel dimensions drawing
- BMS Panel components Layout drawing

**10.0 DETAILS OF TEST AND MEASUREMENT INSTRUMENTS:**

Detail of test and measurement instruments to be recorded in the operation qualification reports are as follows:

<b>S.No.</b>	<b>Instrument</b>
1.	Digital Multi-meter
2.	T+RH calibrated sensor



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**11.0 SIGNATURE LOG:**

**Signature Log**

**Objective:** Compile a signature list of all persons participating in the OQ.

**Scope:** This signature log list each representative participating in the OQ.

**Responsibility:** All ..... Engineers and ..... representatives who participate in the OQ testing must complete an entry in the signature log.

**Acceptance Criterion:** All test participants have signed the signature log

**Procedure:**

Complete the signature log as follows:

1. **Printed Name** –
2. **Signature** –
3. **Company** -
4. **Initials** -
5. **Date** –
6. **Reviewed by** –

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**12.0 SYSTEM SECURITY VERIFICATION:**

**System Security Verification**

**Objective:** Verify the operation of system security features.

**Scope:** BMS system application software and Operating system.

**Acceptance Criterion:** System security functions as expected

1. Supervisor and Viewer should not exit and shut down BMS software
2. Add and remove hardware and software right should not be available in viewer and supervisor login.
3. Date and time change access should not be available in operator login
4. The station connection properties menu is not accessible/available in supervisor and viewer login
5. Parameter should not change in operator login
6. Security policy configuration and application software access to only administrator.

**Procedure**

Complete the system security verification as follows in all levels:

1. Try to shut down BMS system.
2. Try to add remove software and Hardware
3. Try to change date and time.
4. Try to access local security policy, password policy, and change parameter in operator login.
5. Try to access Application software configuration in operator and supervisor login.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**13.0 FIELD CONTROLLER DIGITAL AND ANALOG INPUT/OUTPUT VERIFICATION:**

**Field Controller Digital and Analog Input-Output Verification**

**Objective:** Verify the field controller Digital Input, Digital Output, Analog Input and Analog Output.

**Scope:** All field controller Digital Input, Digital Output, Analog Input and Analog Output.

**Acceptance Criterion:** Field controller Digital Input, Digital Output, Analog Input and Analog Output are configured as expected

**Procedure:**

Complete the Field controller **Digital Input** verification as follows:

1. Take copy a drawing of each controller to be tested and use the copy for this test. Obtain the drawing with the appropriate controller and verify that controller being tested is the same as the controller identified on the form.
2. In the BMS station, open the graphic of the AHU system.
3. Disconnect the wiring of the point under test from the digital input terminals at the controller.
4. **Point Name** – Name assigned to the hardware point.
5. **Closed Contact State** – Place a wire jumper across the point terminals to simulate a closed contact. Record the state of the point that is displayed on BMS.
6. **Open Contact State** – Remove the wire jumper to simulate an open contact. Record the state of the point that is displayed on BMS
7. Record test result in annexure.
8. Reconnect the wiring of the tested point to the digital input terminals at the controller.
9. Repeat above procedure for all digital inputs.

Complete the Field controller **Digital Output** verification as follows:

1. Take copy a drawing of each controller to be tested and use the copy for this test. Obtain the drawing with the appropriate controller and verify that controller being tested is the same as the controller identified on the form.
2. In the BMS station, open the graphic of the AHU system.
3. Operate the digital output of AHU system by simulating and manual operation and verify status of digital output and record the result
4. Record test result in annexure.
5. Repeat above procedure for all digital outputs.



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

Complete the Field controller **Analog Input** verification as follows:

1. Take copy a drawing of each controller to be tested and use the copy for this test. Obtain the drawing with the appropriate controller and verify that controller being tested is the same as the controller identified on the form.
2. In BMS station, call up the graphic of the system that the point belongs to alternatively; call up the point detail display.
3. Disconnect the wiring of the point under test from the analog input terminals at the controller/sensor and connect calibrator/simulator and apply input 0%, 50% and 100% and record the result in data table.
4. Record test result in annexure.
5. Reconnect the wiring of the tested point to the analog input terminals at the controller.
6. Check, initial and date each point on the copy of the controlled drawing after the point has passed this test. Attach the drawings to the form
7. Repeat above procedure for all Analog inputs.

Complete the Field controller **Analog Output** verification as follows:

1. Take copy a drawing of each controller to be tested and use the copy for this test. Obtain the drawing with the appropriate controller and verify that controller being tested is the same as the controller identified on the form.
2. In BMS station, call up the graphic of the system that the point belongs to alternatively; call up the point detail display.
3. Simulate the analog output by changing set value and check operation of actuator valve and VFD.
4. Record test result in annexure.
5. Repeat above procedure for all Analog outputs.



**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**Signature section:**

1. Performed by –
2. Date –
3. Reviewed by –
4. Date –

**Comments:**





**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**14.0 FUNCTION KEYS PARAMETERS DISPLAY VERIFICATION:**

**Function Keys, Parameters Display Verification**

**Objective:** Verify the Function Keys, Parameters Display Verification.

**Acceptance Criterion:** Function Keys, Parameters Display of the system should function as per defined.

**Procedure:**

**AHU Graphic section**

1. Open AHU graphic screen.
2. Verify function keys and parameters displays of BMS system in normal working condition.
3. Record result in Data sheet.
4. Repeat Step-2 and 3 for all AHU system.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:-**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**15.0 SEQUENCES OF OPERATION VERIFICATION:**

**Sequences of Operation Verification**

**Objective:** Verify that the HVAC system function according to the approved sequences of operation.

**Scope:** Sequences of operation for AHU units.

**Acceptance Criterion:** The BMS system functions and controls HVAC system according to the approved sequence of operation.

**Procedure**

Complete the sequences of operation verification as follows:

1. Verify operation of BMS system as per operation procedure.
2. Change parameter settings or values as necessary to verify the systems behaviour.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**16.0 BMS SERVER DATABASE BACKUP VERIFICATION:**

**BMS Database Backup Verification**

**Objective:** Verify that the BMS Database and software Backup.

**Scope:** The BMS Database and application software.

**Acceptance Criterion:** BMS Database and software files are backed up. Backup for report, Trend, Audit trial and application software should be available.

**Procedure**

1. Verify the backup path of BMS database and software as follows:

.....  
.....

2. Verify backup procedure for BMS system and backup storage location should be as per defined in URS.

**Signature Section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**17.0 SYSTEM COMMUNICATION VERIFICATION:**

**System Communication Verification**

**Objective:** Verify the System Communication status and communication failure condition.

**Scope:** All controllers and BMS software.

**Acceptance Criterion:** All controllers and peripherals are communicating to BMS software properly and during communication failure HVAC system should be run stand alone.

**Procedure**

Complete the communication verification as follows:

**BMS system communication**

1. Check Tx Rx LED status of all Integrator panel.
2. Record result in data table.
3. Check COM LED status of all DDC panel.
4. Record result in data table.
5. Check LAN LED of both router panel.
6. Record result in data table
7. Verify that during communication failure from DDC to AHU system should be run stand alone.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**18.0 TESTING OF INTERLOCKS AND ALARMS MESSAGES:**

**Testing of Interlock and Alarms Messages**

**Objective:** Verify the System software as per interlock and alarm messages.

**Scope:** BMS system.

**Acceptance Criterion:** Interlock and alarm messages operates as per defined.

**Procedure**

Tale List of interlock and alarms of BMS system:

1. Simulate interlock and alarm.
2. Verify system response and message displayed
3. Records results in data sheet.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**19.0 SYSTEM AUDIT TRIALS AND EVENTS LOG:**

**System Audit Trials and Events Log**

**Objective:** Verify the System Audit Trials and Events Log.

**Scope:** BMS application software and operating system Audit Trials and Events Log.

**Acceptance Criterion:** System shall log data periodically on hard disk. System log events and alarms permanently as per configuration. Computerized system should generate proper audit trial for any event or modification.

**Procedure**

1. Verify that proper data/alarms/audit trial is performed by the system. Also verify the validity of data/alarm/event/audit trial logged in the files.
2. Verify that the status reports are generated by the system. Also verify the validity of data printed on the reports.
3. All these reports are attached in annexure.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**20.0 VERIFICATION OF BMS SOFTWARE AS PER 21 CFR PART 11 COMPLIANCE:**

**Verification of BMS Software As per 21 CFR Part 11 Compliance**

**Objective:** Verify the system Software As per 21 CFR Part 11 clauses.

**Scope:** BMS hardware, application software and operating system.

**Acceptance Criterion:** BMS software should comply access control, Audit trail and data back requirements of 21 CFR Part 11.

**Procedure**

Verify all the points as per the test table as per annexure.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**21.0 REVIEW OF RELEVANT SOP FOR THE SOFTWARE SYSTEM:**

**Review of Relevant SOP for Software System**

**Objective:** Review of Relevant SOP for the BMS Software System.

**Scope:** BMS system operation SOP

**Acceptance Criterion:** Review of Relevant SOP for the BMS Software System must in place and implemented properly.

**Procedure**

Complete the calibration certificate verification as follows:

1. Verify the availability control copy of following SOPs.
  - BMS System operation SOP.

**Signature section**

1. **Performed by –**
2. **Date –**
3. **Reviewed by –**
4. **Date –**

**Comments:**





**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING  
MANAGEMENT SYSTEM**

**22.0 DEVIATION REPORT:**

**Deviation Report:**

**Objective:** Document details of each deviation encountered during the execution of the OQ test.

**Scope:** All deviation encountered during the execution of the OQ test.

**Acceptance Criterion:** Each deviation encountered during the execution if the OQ has a deviation report.

**Procedure:**

Document Deviation in Deviation Report-Form

- 1. Deviation Report No.** – Identification number of the deviation report; this number is assigned sequentially based on deviation log.
- 2.** Record Deviation type.
- 3.** Record description of Deviation and justification.
- 4.** Record comments by department head-
- 5.** Record comments by DRA –
- 6. Prepared by** – Signature of the person who prepared the resolution to the deviation.
- 7. Date** – Date on which the resolution was written.
- 8. Reviewed by** - Signature of the person who reviewed the deviation report.
- 9. Date** – Date that the deviation was reviewed

**Comments:**







**PHARMA DEVILS**  
QUALITY ASSURANCE DEPARTMENT

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR BUILDING MANAGEMENT SYSTEM**

**25.0 POST APPROVAL:**

<b>Customer:</b>	
<b>Project:</b>	Building Management System

.....**Engineers**

<b>Responsibility</b>	<b>Name</b>	<b>Designation/Department</b>	<b>Signature</b>	<b>Date</b>
Done By:				
Reviewed By:				
Approved By:				

.....

<b>Responsibility</b>	<b>Name</b>	<b>Designation/Department</b>	<b>Signature</b>	<b>Date</b>
Checked By:				
Reviewed By:				
Reviewed By:				
Reviewed By:				
Approved By:				