



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM

### INSTALLATION QUALIFICATION PROTOCOL

#### ERP SYSTEM

<b>Name of the system</b>	:	ERP System
<b>Location</b>	:	.....
<b>Document No.</b>	:	.....
<b>Validation No.</b>	:	.....
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**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

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**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

**1.0 APPROVAL – INSTALLATION QUALIFICATION PROTOCOL:**

The Installation Qualification Protocol for installed ERP System has been approved for release by the management of .....

		Activity	Name & Designation		Sign.	Date
		Prepared by				
		Department	Name	Designation	Sign.	Date
Reviewed by		Information Technology				
		Purchase				
		Warehouse				
		Quality Control				
		Production				
		Quality Assurance				
		Engineering				
Approved by		Quality Assurance				

**2.0 REVISION HISTORY:**

Version/Revision Number	Revised Date	Reason for Revision
00		New Document



## INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM

### 3.0 OBJECTIVE:

The objective of the installation qualification is to establish documented evidence that the ERP is installed as intended according to the Design Qualification (DQ) at .....

### 4.0 SCOPE:

In this document the installation procedure as prescribed by ERP system and their recommendation in respect of minimum hardware/software requirements for ERP installation shall be specified. Further the document also examines the procedure adopted for the installation of ERP as recommended by M/s. ERP systems.

### 5.0 REASON FOR QUALIFICATION:

Please tick the appropriate option given below

- |  |                          |
|--|--------------------------|
| New Installation                           | <input type="checkbox"/> |
| Existing Installation                      | <input type="checkbox"/> |
| Modification in Hardware & Software Change | <input type="checkbox"/> |
| Others... refer Change Control No.         | <input type="checkbox"/> |

### 6.0 DOCUMENTATION PROCEDURE:

- Complete the pre-requisite for execution before proceeding for qualification execution.
- Perform each test for Installation Qualification as described in the respective test section.
- Record the observation in the relative test sections.
- If the result are not matching with the acceptance criteria go with the discrepancy report and close accordingly.
- Write the overall summary and conclusion for the test performed.
- Close the protocol after QA approval with recommendation to proceed for next stage.
- Fill out complete information in the format /data /test sheet 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 & date.
- Correct the mistakes by drawing a single line through the incorrect data, recording the correct information and then initialising and dating the change.



**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

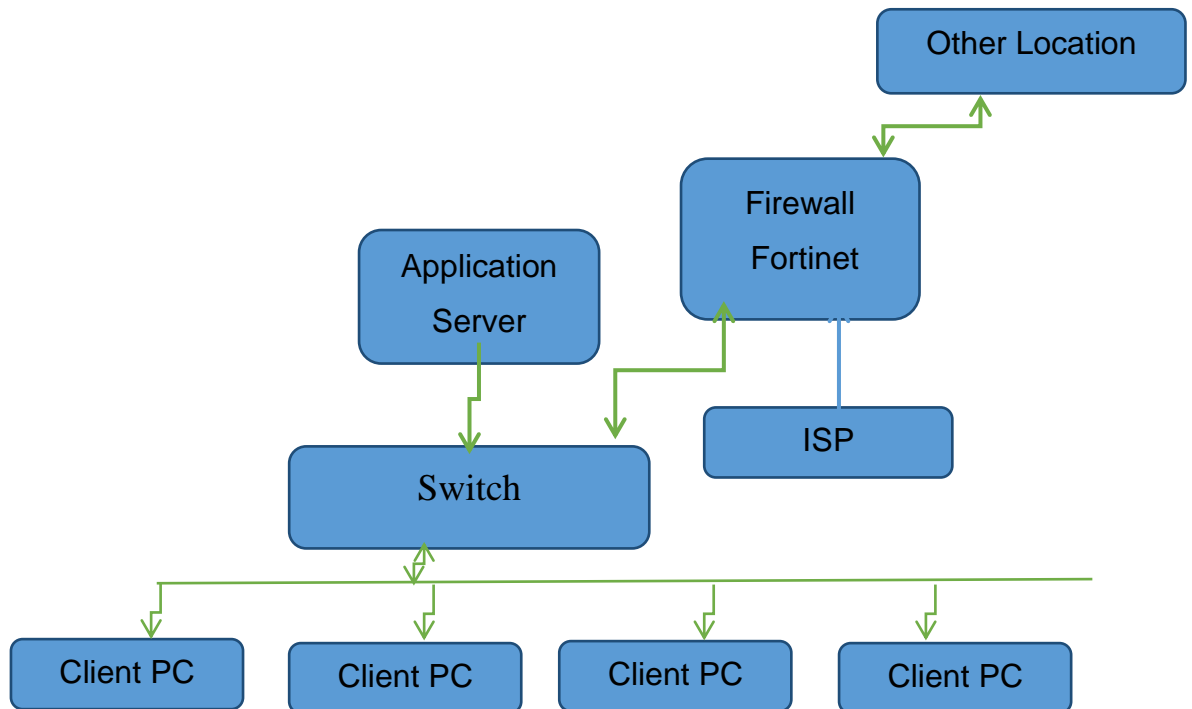
**7.0 RESPONSIBILITY:**

The following departments shall be involved in the execution of the installation qualification.

S.No.	Department	Responsibility
1.	Validation Department	<ul style="list-style-type: none"><li>• Execution of tests.</li><li>• Protocol preparation.</li><li>• Discrepancy reporting.</li></ul>
2.	IT Department	<ul style="list-style-type: none"><li>• Assist in execution and review of tests.</li><li>• Discrepancy closures</li><li>• Verification of tests.</li></ul>
3.	QA Department	<ul style="list-style-type: none"><li>• Review of documents &amp; discrepancy closures.</li><li>• Final protocol verification and approvals.</li></ul>

**8.0 SYSTEM SCHEMATIC DIAGRAM:**

The following figure display typical configurations of ERP System.



**Note:**

1. ERP users should not have the direct access to the database server. ERP users should be allowed to connect through the application server only. ERP is configured through a single server i.e. application server.
2. Application server is located in..... Access of ERP from other location should be through the firewall/static IP.
3. The local ERP users can connect the application server through the LAN connection (Local IP).



## INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM

### 9.0 SYSTEM DESCRIPTION:

ERP system is the enterprise resource planning system supplied and supported by .....

ERP is mainly developed for pharmaceutical industries and it meets all the requirements of the pharmaceutical industry. However it has been customized to meet the SRS of M/s. .... A system for taking backup of data is available in ERP system, which will enable the user to avoid data loss. The system enables the user to restore the data in case the current data is lost or redundant data in the system.

..... has amended / added functions to ERP System to enhance its use in supporting the business. These additional functions are being done to upgrade as part of this remediation project.

ERP is an enterprise resource planning system covering all functional areas in an organization such as system administration, accounts, purchase, warehouse, QC, production, QA and distribution. ERP consists of different modules, each addressing the requirements of a functional area. All the master data and parameters that are common to all other modules can be defined and managed in the setup module. Operations in all the other modules of ERP depend upon the information that is entered in the setup module.

The installation of ERP system at ..... covered by the scope of this project, comprises of the following software and hardware elements:

#### **Minimum Hardware Requirements:**

##### **Server Configuration:**

- Intel Xeon 2.0 Ghz
- Intel Server Board, 8GB RAM, 500GB HDD,
- DVD Writer, RAID Controller, 2QD Server Chassis with 500W + 500W, Zippy RPS, Keyboard & Optical Mouse

##### **Client Configuration:**

- PIV or above
- 512 MB RAM or above
- 160 GB of Hard Drive or above

#### **Minimum Software Requirements:**

##### **Server Configuration:**

- Application Server Operating System – Windows 2008 Server

##### **Client Configuration:**

- Windows 7 or above Operating system

### 10.0 TEST STRATEGY:

Following are the instructions for executing this installation qualification protocol. Each tester or verifier executing any portion of this protocol must read these instructions prior to execution. You must resolve any questions or uncertainties you have prior to executing this protocol.

### 10.1 PERFORMING TESTS:

For each test, perform the instructions indicated in the procedure section for each test. Provide attachments as objective evidence to support recordings made while executing the test.



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### 10.2 RECORDING RESULTS:

Record handwritten entries with blue/black ballpoint pen

- If actual result meets the expected result
  - Tick Yes
- If actual result does not meet the expected result
  - Tick No

Capture the evidences of the tests by taking screenshots wherever applicable. The attachment(s) for a test must be inserted after installation qualification report in sequential order (e.g. Annexure 1, Annexure 2, etc.) immediately behind the test to which it is referenced.

### 10.3 VERIFYING AND REVIEWING TEST RESULTS:

The test results recorded by the tester shall be verified by the reviewer. The reviewer shall verify the following:

- An actual result has been recorded
- Any referenced attachments are present
- The test signature block was correctly completed by the tester
- If the actual result does not match the expected result, a discrepancy report form has been initiated.

### 10.4 RESOLVING DISCREPANCIES:

Discrepancies include the following scenarios:

- Actual results for a test do not match expected results
- Non-availability of appropriate documentation
- Non-availability of required standard operating procedures

Each discrepancy must be identified, the cause must be determined, the impact must be assessed, and a resolution must be made. Each discrepancy must be enlisted in discrepancies handling during qualification documented in a discrepancy report form attached in section 14.0 of installation qualification protocol.

**Note:** A typographical error only requires a “line-through” correction accompanied by the person’s initials and date

### 10.5 TEST ENVIRONMENT:

The server functionality and other challenge test shall be carried out in the application server and database server as applicable. This will have capability to simulate all the features and functionality of the system along with required configuration for necessary controls.



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**10.6 TEST PRE-REQUISITES:**

S.No.	Description	Pre-Requisites
1.	Tools/Tackles and Equipments	Server
		User ID
		Computer system to compile test evidences
		Internet connection wherever required
		Digital/Mobile Camera
		Calibrated Thermo-Hygrometer
2.	Personnel	Availability of ..... Executives and team
3.	Time	Adequate time for carrying out the necessary testing for system.
4.	Documentation	Approved design qualification
		Test tables with test data sets

**11.0 PROTOCOL EXECUTION:**

The operation of the server shall be verified by executing the qualification tests described in this protocol. The successfully executed protocol documents that the server is installed as required and is operating as intended

**Test / Standard equipment / instruments used for qualification**

To execute this report, the following will be needed by the executor:

Standard devices (used for reference readings) along with calibration certificate, traceable to NIST/NPL or equivalent standards

• **Digital Thermo-Hygrometer**

The above test instruments should have valid calibration on the date of report execution and validity certificate to that effect should be available and traceable to NIST/NPL or equivalent standard.

**11.1 EXECUTION TEAM:**

Mention below the list of personnel with their designation, full and short signatures responsible for execution and review of installation qualification.

Full Name	Designation	Full Signature	Short Signature





## INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM

### 11.2 QUALIFICATION COMPLETION AND APPROVAL:

- Verify that all tests required by this protocol are completed, reconciled and attached to this protocol.
- Verify that all amendments and discrepancies are documented, approved and attached to this protocol.
- If all items in the Installation Qualification Protocol for the process system have been reviewed and found to be acceptable, sign the corresponding block in the qualification completion and approval form.

### 11.3 ACCEPTANCE CRITERIA:

The acceptance criteria includes,

- Installation of the system with utility connections as mentioned in Design Specification document.
- Availability of necessary technical documentation.
- Installation of ERP application software at server as per Design Specification document.

### 12.0 VERIFICATION PLAN:

S.No.	Verification Activity
12.1	Verification of environmental conditions
12.2	Verification of installed server
12.3	Verification of antivirus software for server
12.4	Verification of master documents
12.5	Verification of installation procedure for server and ERP
12.6	Verification of ERP access
12.7	Verification of access control and security policies of servers
12.8	Verification of data backup and restoration
12.9	Verification of module wise ERP users
12.10	Verification of ERP date & time synchronization with server



## INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM

### 12.1 VERIFICATION OF ENVIRONMENTAL CONDITIONS:

- Objective** : The objective of this test is to measure and record temperature of the room where the server is installed.
- Tools required** : Digital Thermo-Hygrometer
- Procedure** : Measure temperature and humidity of the Server room with help of calibrated digital thermos-hygrometer and record the same. Verify that observed result is within the specified conditions.
- Acceptance criteria** : The server system room environment conditions measured using digital thermos-hygrometer shall be within the specified limit mentioned in the test data table.
- Reference** : Annexure-1

### 12.2 VERIFICATION OF INSTALLED SERVER:

- Objective** : This test sheet is intended to identify servers and verify its hardware and software configuration.  
To verify server's hardware configuration with design qualification and record installed hardware component's basic specification.  
To verify server's software configuration with design qualification and record installed software's basic specification.
- Tools required** : Not required
- Procedure** :
  1. For each server verify hardware and software information.
  2. Compare the information with server system design specification requirements documents and verify that server database software is satisfying the acceptance criteria as per design qualification.
  3. Attach screen shots / photograph as evidence
- Acceptance criteria** : Server hardware & software configuration should comply with server system design qualification.
- Reference** : Annexure-2



**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

**12.3 VERIFICATION OF ANTIVIRUS SOFTWARE FOR SERVER:**

**Objective** : To verify antivirus software configuration for server system.

**Tools required** : Not Required

**Procedure** : Verify the availability of Antivirus Software and its update for Servers system.  
Verify Antivirus Software Version details in test table.  
Attach Screenshots as evidence.  
Verify the availability of Antivirus Software and its update for Servers system.

**Acceptance criteria** : Licensed Antivirus software should be installed and updated virus definitions shall be available

**Reference** : Annexure - 3



## INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM

### 12.4 VERIFICATION OF MASTER DOCUMENTS:

- Objective** : To ensure that system is adequately documented and this documentation is under appropriate document control.
- Tools required** : Not required
- Procedure** : Verify availability of the following documents related to installation and operation of ERP and verify their revision no., date, etc. details.
- Technical design qualification document
  - Server Technical Agreement
  - Process ERP software configuration document for server
  - Antivirus Software License Copy/Media
  - Licenses of all installed software Copy / Media
  - List of ERP Business Process System users
  - Process ERP software installation manual at client
  - Server Installation Procedure
  - Access Control SOP
  - System Administrator SOP
  - Data Backup and Restore Management
  - Disaster Management and Recovery
  - User creation and deletion SOP
- A. Identification of the documents
1. The executor shall check whether all the documents are available or not. For all the documents the documents number, proper description with name should be available.
  2. The effective date of the documents should be verify if available.
  3. Note down the details in test table.
- B. Check the correctness of the documents
1. The executor shall identify the documents and compare that the documents represent the actual installed system.
  2. Authorized person should have signed all the documents.
  3. The documents should be upgraded as per the latest system.
  4. Note down the details in test table.
- Acceptance criteria** : 1. The documents should display proper information for installation and operation of ERP system.  
2. The documents should have proper document name, number and signed.
- Reference** : Annexure-4



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**12.5 VERIFICATION OF INSTALLATION PROCEDURE FOR SERVER AND ERP:**

- Objective** : The objective of this verification is to describe the standard software installation procedure and to verify the same at .....
- Tools required** : Not Required
- Procedure** : Refer procedure for server installation procedure provided by supplier
- Acceptance Criteria** : As per installation procedure recommended by supplier
- Reference** :  
1. Annexure-5  
2. Server Installation Manual for ERP



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**12.6 VERIFICATION OF PERP ERP ACCESS:**

**Objective:** The objective of this verification is to define the access to different ERP modules and verification of same at .....

**Tools required** : Not Required

**Procedure** :

- 1. Through the shortcuts**
  - Go to the shortcut prepared on the desktop
  - Double click on the desired module, say it is CSA module.
  - Double click on the selected module. Enter the user Id into the given column (user code. location code). For example the user Id is ADMIN and the location of that user is GOA the user code will be ADMIN.GOA
  - After entering the user Id and password, the pin must be entered.
  - The pin entered fetch the information of the user login to the system
  - Detail of every login can be checked from the CSA module.
  - The login Information contains the information of the system used for login, location, time, date etc.
- 2. Login From the Nodes (From run command)**
  - Press (Window+R) key on the keyboard
  - Now path of the specific module can be defined in the column
  - Enter the path of the desired module say CSA module. Press enter, the CSA module gets open.
  - Other modules can be opened in the same way or shortcuts can be created for the different modules as mentioned above.

**Acceptance Criteria** :

1. System should not allow to login into ERP for incorrect user name and pin combination
2. System should restrict an unauthorised user to login into another module where user is not accessible for that module.

**Reference** : Annexure-6



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**12.7 VERIFICATION OF ACCESS CONTROL AND SECURITY POLICIES OF SERVERS:**

**Objective** : This test verifies physical and logical security of installed servers.

**Tools required** : Not required

**Procedure** :

- Verify access control & security policy SOP.
- Verification of access control of servers.
  - a. Server room should be physically locked.
  - b. Click on system application software icon.
  - c. Enter correct user id and password. Note down the observation into test table.
  - d. Enter correct user id and incorrect password. Note down the observation into test table.
  - e. Enter incorrect user id and correct password. Note down the observation into test table.
  - f. Login with Administrative password
- Verification of security policy of servers
  - a. Verify server is physically locked

**Acceptance criteria** : Actual observations noted in respective tables should match with expected results for all required parameters for server's operating system and database server's system.

**Reference** : Annexure-7



**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

**12.8 VERIFICATION OF DATA BACKUP AND RESTORATION:**

**Objective** : To test data backup, restoration and retention requirement functionality.

**Tools required** : Not applicable

**Procedure** :

1. Refer the data back up and restoration policy.
2. Verify compliance with policy.
3. Verify label information on back up media.
4. Verify authenticity of backup data.
5. Verify retention policy.
6. Verify and perform Backup process.
7. Verify and perform Restoration process.
8. Record observation in to test table.

**Acceptance criteria** :

- Data backup shall be available.
- Data shall be backup on defined path and location.
- Data shall be restored to original values.
- Data retention shall be defined.

**Reference** : Annexure-8





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**12.9 VERIFICATION OF MODULE WISE PERP ERP USERS:**

- Objective** : To verify the defined process wise users
- Tools required** : Not applicable
- Procedure** :  
1. Login to CSA module  
2. Go to location and user management → User accounts → location → Application wise user accounts  
3. Verify the module wise defined users
- Acceptance criteria** :  
1. User code should be unique  
2. User name should be specific to particular user only
- Reference** : Annexure-9



**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

**12.10 VERIFICATION OF ERP DATE & TIME SYNCHRONIZATION WITH SERVER:**

**Objective** : The objective of this test is to verify that server clock time and date are synchronized through windows time.

**Tools required** : Not required

**Procedure** :  
1. Login into application server  
2. Open Date and time setting  
3. Adjust the date and time with current time  
4. Restart the server  
5. Verify the ERP time with the server time

**Acceptance criteria** : Server clock time and date should be synchronized with ERP time.

**Reference** : Annexure-10



**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

**13.0 QUALIFICATION STATUS:**

Test Reference No.	Verification Activity	Test Result		Checked By / Date
		Pass	Fail	
12.1	Verification of environmental conditions	<input type="checkbox"/>	<input type="checkbox"/>	
12.2	Verification of installed server	<input type="checkbox"/>	<input type="checkbox"/>	
12.3	Verification of antivirus software for server	<input type="checkbox"/>	<input type="checkbox"/>	
12.4	Verification of master documents	<input type="checkbox"/>	<input type="checkbox"/>	
12.5	Verification of installation procedure for server and ERP	<input type="checkbox"/>	<input type="checkbox"/>	
12.6	Verification of ERP access	<input type="checkbox"/>	<input type="checkbox"/>	
12.7	Verification of access control and security policies of servers	<input type="checkbox"/>	<input type="checkbox"/>	
12.8	Verification of data backup and restoration	<input type="checkbox"/>	<input type="checkbox"/>	
12.9	Verification of module wise ERP users	<input type="checkbox"/>	<input type="checkbox"/>	
12.10	Verification of ERP date & time synchronization with server	<input type="checkbox"/>	<input type="checkbox"/>	

**14.0 DISCREPANCY MANAGEMENT:**

Any discrepancy encountered during a qualification activity shall be recorded. Recorded discrepancy shall be classified as Minor, Major and Critical based on the level of impact on the performance / outcome expected from the process/ system.

Observed deviation shall be evaluated by validation along with QA for applicable action as per deficiency category. Tests being re-executed as necessary before closure and completion of validation shall be performed with the additional sheet issued. Before completion of validation activity all deficiencies shall be corrected, tested and closed.

**Minor Discrepancy:** Those discrepancies which has minor/ no impact on the desired performance / outcome. Such discrepancies can be accepted and closed with justification.

**Major Discrepancy:** Those discrepancies which has major impact on the desired performance / outcome. Such discrepancies can be conditionally accepted but must be corrected and closed within stipulated period. Interim approval shall be done in this discrepancy.



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**Critical Discrepancy:** Those discrepancies which result in non conformance with predefined specifications or acceptance criteria. These discrepancies require mandatory rectification before release of the system. The system shall kept on hold till the rectification of the critical discrepancy.

Record each discrepancy in the table below and attach the completed discrepancy Form (s).

**DISCREPANCY AND CORRECTIVE ACTION REPORT FORM**

Name of the system	
IQ Protocol Number	
Discrepancy Number	
Discrepancy	
Description of Discrepancy	
Reported By:	Sign/Date:
Corrective Action	
Describe corrective action taken (Attach additional sheets if necessary)	
Category: Minor / Major / Critical	
Reported By:	Sign/Date:
Disposition Action	
Acceptable?	Yes                      No
Approved By:	Sign/Date:
Completion	
Completed By:	Sign/Date:





**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

**16.0 LIST OF ANNEXURES:**

<b>Annexure No.</b>	<b>Title / Details</b>
Annexure 1	Verification of Environmental Condition
Annexure 2	Verification of Installed Server
Annexure 3	Verification of Antivirus Software for Server
Annexure 4	Verification of Master documents
Annexure 5	Verification of Installation Procedure for Server and ERP
Annexure 6	Verification of ERP Access
Annexure 7	Verification of Access Control and Security Policies of Server
Annexure 8	Verification of Data Backup and Restoration
Annexure 9	Verification of Module wise ERP Users
Annexure 10	Verification of ERP Date and Time Synchronization with Server

**17.0 ABBREVIATIONS:**

<b>Abbreviation</b>	<b>Full form</b>
CFR	Code for Federal Regulations
EU	European Union
GAMP	Good Automated Manufacturing Practices
LAN	Local Area Network
NA	Not Applicable
No.	Number
IQP	Installation Qualification Protocol
IP	Internet Protocol
IQ	Installation Qualification
PCS	Professional Consultancy Services
QA	Quality Assurance
DQ	Design Qualification
SOP	Standard Operating Procedure



**INSTALLATION QUALIFICATION PROTOCOL FOR ERP SYSTEM**

<b>Abbreviation</b>	<b>Full form</b>
Sr.	Serial
UPS	Uninterrupted Power Supply
USFDA	United States Food and Drug Administration
WAN	Wide Area Network
ERP	Enterprise Resource Planning
Csa	Centralized System Administration
Dms	Document Management System
Exp	Export
Inv	Mfg. Inventory
Mnt	Maintenance
Prd	Production
Pur	Purchase
Qcs	Quality Control
Rqs	Requisitions
Slm	Sales Inventory
Stm	Set up
ID	Identification
NPL	National Physical Laboratories
NIST	National Institute of Standard and Technology
AC	Alternating current
IIS	Internet Information Services
OS	Operating System
ISP	Internet Service Provider