PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Instrument Qualification	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for Qualifications of Instruments.

2.0 SCOPE:

This SOP is applicable to Chemical lab Quality Control laboratory.

3.0 RESPONSIBILITY – Execution – Executive QC.
Checked by – Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 General procedure:

5.1.1 Check the physical condition of instrument at the time of receiving.

5.1.2 Check the description of instrument against purchase order/packing list.

5.1.3 Designated personal shall carry out instrument qualifications with the help of manufacturer's instrument engineer.

5.1.4 Ensure that the location, space requirement, environmental conditions and electrical power supply is suitable.

5.1.5 Perform the IQ, OQand PQ before regular use.

5.1.6 IQ/OQ/PQ shall be done of critical instruments only like HPLC,GC, UV etc…

5.1.7 Installation qualification shall be done by vendor /qualified personal, using vendor qualified or in-house approved protocol.

5.1.8 The qualification protocol should contain details steps to performed for installation, operation and performance qualification. Also should contain required supporting equipment details for the qualification.

5.1.9 Read the supplier instruction for installation and safety instructions before starting the installation qualification.

5.1.10 Give the identification number (instrument code no.) to the instrument.

5.2 Installation Qualification

5.2.1 Check the received equipment, software, accessories and spare parts as applicable with purchase order/packing list.

5.2.2 Check the receipt of operating manuals, maintenance manuals, operating procedure for testing and safety.

5.2.3 Check the receipt of tools if received and document the details of received items along the instrument

5.2.4 Check the equipment for any damage, if so mentions in the qualification report and intimate to vendor.

5.2.5 Final install hard ware by following the manufacturers instructions.

5.2.6 Switch on the instrument and check instrument for what is described in the instruction manual (Operation manual) and record the observations.

5.2.7 Install software (if required) on computer by following the manufacturer instructions.

5.2.8 Connect all peripherals like printers and equipment modules.

5.2.9 Record the date received, date placed and current location.

5.2.10 Record the condition when received e.g., new, used, reconditioned in history record.

5.2.11 Check the hardware and software that is connected properly or not, by switching the instrument and check for any error message.

5.2.12 Record all required details in the qualification protocol. Also mention any deviation from the protocol.

5.2.13 Prepare the summary report of IQ as per Annexure -I

5.3 Operation qualification

5.3.1 Operational qualification shall be done after completion of installation qualification.

5.3.2 Operational qualification shall carry out as per protocol with predefined specifications.

5.3.3 Check the required operational parameters of the instrument and verify against the specification.

5.3.4 Record all required details in the qualification protocol. Also mention any deviation from the protocol.

5.3.5 Prepare the summary report of OQ as per Annexure -I

5.4 Performance Qualification.

5.4.1 Performance Qualification shall be done after completion of operation qualification.

5.4.2 Performance Qualification shall carry out as per protocol with pre defined specifications.

5.4.3 Check the mentioned performance parameters of the instrument and verify against the specifications.

5.4.4 Record all required details in the qualification protocol. Also mention any deviation from the protocol.

5.4.5 After completion of instrument qualification and data recording, get it approved by the concerned authority.

5.4.6 Prepare SOP based on the qualification study for the regular usage and performance check.

5.4.7 Allot the usage book for the instrument and also prepare the instrument history card.

5.4.8 Update the calibration schedule for the performance check of the instrument.

5.4.9 Prepare the summary report of Qualification as per Annexure -II

5.5 Re Qualification

5.5.1 When the instrument is shifted from one laboratory (Change in premise) to another laboratory, re qualification (IQ/OQ/PQ) is required.

5.5.2 When the instrument is shifted within the laboratory premises (one room to another room), re qualification (PQ) is required.

5.5.3 When the instrument is upgraded or after having a major repairing, qualification (OQ/PQ) is required.

6.0 SAFETY & PRECAUTIONS:

Not Applicable.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable.

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

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QC : Quality Control

IQ : Installation Qualification

OQ : Operation Qualification

PQ : Performance Qualification

Annexure I : Summary Report For Performance Qualification

Annexure II : Summary Report.

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ANNEXURE - I

SUMMARY REPORT FOR PERFORMANCE QUALIFICATION

SUMMARY REPORT FOR_____

Name of Instrument : Make:

ID No. : Model :

Date of Report : S.No. :

IQ: Date of IQ : _____

Performed by : _____

Remarks : _____

OQ: Date of OQ : _____

Performed by : _____

Remarks : _____

PQ: 1) The instrument is successfully completed the _____as per laid down requirements.

2) The instrument is released for _____

Prepared By_____ Checked By_____ Approved By_____

Date: Date: Date:

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ANNEXURE-II

SUMMARY REPORT

SUMMARY REPORT FOR_____	
Name of Instrument :	Make:
ID No. :	Model :
Date of Report :	S.No. :
1) The instrument is successfully completed the _____as per laid down requirements. 2) The instrument is released for _____	
Prepared By_____ Date:	Checked By_____ Date: Approved By_____ Date: