PHARMA TEST

PHARMA CUSTOMER SUPPORT

BSI®

Instrument Log

Qualification and Control of
Pharma Test instruments.

Instrument type: _____

Serial number: _____

Test Instrument number: _____

Log Book number: _____

Version number: _____

Date / Signature: _____

Replacement Version Nr.: _____

Date / Signature: _____

Service contract Nr.: _____

_____

For service or repair call PHARMA-TEST on Tel nr.: _____

_____

General Introduction:

Test results must be comparable; this is the basis for reproducible and controlled production processes which in turn will lead to continued product quality.
The PHARMA TEST Log Book will provide a focal point for documentation of activities that are required to be formally recorded concerning the written qualification needed for instruments used in routine operation. This information is intended to provide a support for the operator's activities and represent a guide for the daily operation of Pharma Test instrumentation.
The correct management of this Log Book is the responsibility of the end user or operator.

Instrument Qualification:

1. Design Qualification

The end-user defines his requirements, in that the test instrument should be able to perform the tasks for which it is intended (e.g. work within allowable tolerance limits). There is also a requirement for the manufacturer to take into account certain technical criteria: for example the measurement range, instrument accuracy, number of data (measurement) points and the degree of automation. Also to be taken into consideration are the possible service requirements and a means to certify the qualification process. Key operational issues can be found either in the instruction manual or by consulting our Customer Service Department. The Design Qualification is not an integral part of this log book.

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2. Installations Qualification (IQ)

This documentation which is delivered as part of the standard paperwork supplied with the instrument contains full instructions for the implementation of the Installation Qualification or IQ. Here one will find a step by step guide as to the correct installation of the test instrument, as well as the scope of delivery and possible optional extras. Once the written activities described within the IQ protocol have been successfully carried out, it is certain that the instrument is in operational condition. The IQ is not an intended part of this Log Book.

3. Operational Qualification (OQ)

This documentation contains detailed instructions concerning the commissioning of the instrument, and a review of the installed operational parameters which will guarantee the operational function of the instrument. At some point in this process, there will be a need to refer to the use of standards which have to be certified against a traceable source. During this section of the qualification process, the operator can be trained in the general manipulation of the instrument. The OQ documentation is not an intended part of this Log Book.

4. Performance Qualification (PQ)

As a rule, this section of the qualification process is run using samples so that the reproducibility of the instrument can be confirmed. In addition, it is a necessary requirement to run further tests using identical samples (test materials or customer samples). After the PQ section of the qualification process, a final examination report is written and the instrument signed off and released for routine use. The PQ documentation is not an intended part of this Log Book.

Routine Qualification : Calibration

We recommend that the end user performs regular calibration routines using dedicated standard methods. In this way one can be sure that the operation of the instrument and its accuracy are both within the originally defined tolerance ranges.

This routine verification should contain regular tests by the user / operator using certified materials and should include instrument specific calibration procedures carried out preferably by PHARMA TEST Customer Service personnel or by one of our trained, PHARMA TEST approved, representatives. The results of these trials are fully documented in a Calibration Certificate. In this Log Book the operator / user can document all events pertinent to the instrument's history including repairs, routine and preventative maintenance, modification schedules and any other occurrences which are relevant during the instrument's operational lifetime.

Installation Qualification (IQ)

The Installation Qualification corresponding to the instrument or system described below has been successfully accomplished according to the valid IQ hand book. The system described meets the user defined performance as described in the Design Qualification.

User / Operator: _____ **Date:** _____
Signature DD/MM/YYYY

Approved by: _____ **Date:** _____
Signature DD/MM/YYYY

Operation Qualification (OQ)

The Operation Qualification corresponding to the instrument or system described has been successfully accomplished according to the valid OQ hand book . The OQ certificate supplied contains all of the instrument's technical data which has been checked by PHARMA TEST. The operator is familiar with the operation of the instrument and has received appropriate training for routine use.

User / Operator: _____ **Date:** _____
Signature DD/MM/YYYY

Approved by: _____ **Date:** _____
Signature DD/MM/YYYY

Training Record:

Name:	DD/MM/YY	Participant's Signature	Trained by: (Name)	Trainer's Signature

User / Operator: _____ **Date:** _____
Signature DD/MM/YYYY

Approved by: _____ **Date:** _____
Signature DD/MM/YYYY

Performance Qualification (PQ)

The validation of the instrument's function as per the service manual has been successfully accomplished.

User / Operator: _____ **Date:** _____
Signature DD/MM/YYYY

Approved by: _____ **Date:** _____
Signature DD/MM/YYYY

Final Report

The test instrument meets all of the requirements as laid down in the Design Qualification and can be released for routine operational use.

User / Operator: _____ **Date:** _____
Signature DD/MM/YYYY

Approved by: _____ **Date:** _____
Signature DD/MM/YYYY

Remarks / Comments:

_____

_____

_____

Routine Validation

The necessary routine validation procedures are dependant on instrument type. Here below the user has an opportunity to develop (in conjunction with the instruction manual) a routine validation procedure along with the time periods when this validation should be carried out.

Validation Interval : _____ Months

Necessary Validation Materials : _____

_____

_____

_____

Recalibration Interval : _____ Years
(Normally 1-2 Years)

General Information for the Performing of Validation Procedures

1. The test devices must be kept at the same temperature as the instrument environment.

2. The instrument must be ready for operation, and correctly positioned.

3. The instrument must be switched on and attention must be paid to the length of time required for the heater element to be on, or for warming up time.

4. The test instruments and validation materials must be maintained in good order.

5. Validation test instruments should be installed in the instrument (depending on type).

6. The tolerance limits of the results are to be defined _____ (by the user / operator).

7. The displayed and printed values which includes measured parameters along with acceptable tolerances should be reviewed. In the case of deviation from acceptable values (refer to instruction manual), the tests must be repeated, and if the deviation persists then the instrument must be placed out of service and our Service Department informed.

8. The validations should be documented in the log book.

Results of the performed validation procedures

Test performed on:	Description of Test	Within acceptable limits?	
		Yes	No

Results of the performed validation procedures

Test performed on :	Description of tests	Within acceptable limits?	
		Yes	No

Calibrations carried out by authorised PHARMA TEST representatives

Calibration Interval: Annually ☐ Half yearly ☐ Monthly ☐

Defined by: Operator ☐ Supplier ☐

Allowable overdue period: Days: _____ Months: _____

PHARMA TEST Calibration Certificate: Yes ☐ No ☐

PHARMA TEST Certificate Listing:

Technician's Name	on	Certificate Nr.	Within Tolerances? Yes	No

PHARMA TEST Certificate Listing:

Technician's Name	on	Certificate Nr.	Within Tolerances? Yes	No

Additional Notes