QUALIFICATION

It is the action of proving and documenting that equipment or ancillary systems are properly installed, work correctly and actually lead to the expected results.

Activities have been grouped into four phases:

- Design Qualification (DQ)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

DESIGN QUALIFICATION (DQ):

It is documented review of the design, at an appropriate stage in the project, for conformance to operational and regulatory expectations.

The Design Qualification activity is most suitably performed by the instrument developer/manufacturer. Since the instrument design is already in place for the commercial off-the-shelf (COTS) systems, the user does not need to repeat all aspects of DQ.

DQ Check Items:

• GMPs and regulatory requirements

• Performance criteria

• Facility air flow, movement flow & pressure regimes

• Reliability & efficiency

• Commissioning requirements

• Construct ability & installation of equipment

• Maintenance & access to critical equipment &instrumentation

• Safety & environment impact

INSTALLATION QUALIFICATION (IQ):

It is documented verification that all aspects of a facility, utility or equipment that can affect product quality adhere to approved specifications and are correctly installed.

Installation Qualification is a documented collection of activities needed to install an instrument in the user's environment. IQ applies to a new, pre-owned or an existing on-site but not previously qualified instrument.

The activities and documentation associated with IQ are as follows:

System Description: Provide a description of the instrument, including its manufacturer, model, serial number, software version, etc. Use drawings and flowcharts where appropriate.

Instrument Delivery: Ensure that the instrument, software, manuals, supplies, and any other accessories arrive with the instrument as the purchase order specifies and that they are undamaged.

Utilities/Facility/Environment: Verify that the installation site satisfactorily meets vendor-specified environmental requirements.

Network and Data Storage: Some analytical systems require users to provide network connections and data storage capabilities at the installation site.

Assembly and Installation: Assemble and install the instrument and perform any initial diagnostics and testing. Assembly and installation of a complex instrument are best done by the vendor or specialized engineers, whereas users can assemble and install simple ones.

Installation Verification: Perform the initial diagnostics and testing of the instrument after installation. On obtaining acceptable results, the user and (when present) the installing engineer should confirm that the installation was successful before proceeding with the next qualification phase.

OPERATIONAL QUALIFICATION (OQ)

After a successful IQ the instrument is ready for OQ testing.

It is documented verification that all aspects of a facility, utility or equipment that can affect product quality, operate to intend throughout all anticipated ranges.

The OQ phase may consist of these test parameters:

Fixed Parameters: These tests measure the instrument's nonchanging, fixed parameters such as length, height, weight, etc. If the vendor-supplied specifications for these parameters satisfy the user, he or she may waive the test requirement. However, if the user wants to confirm the parameters, testing can

be performed at the user's site. Fixed parameters do not change over the life of the instrument and therefore never need redetermining.

Secure Data Storage, Backup, and Archive: When required, secure data handling, such as storage, backup, and archiving should be tested at the user site according to written procedures.

Instrument Functions Tests: Test important instrument functions to verify that the instrument operates as intended by the manufacturer and required by the user. The user should select important instrument parameters for testing according to the instrument's intended use. Vendor-supplied information is useful in identifying specifications for these parameters.

PERFORMANCE QUALIFICATION (PQ)

It is documented verification that all aspects of a facility, utility or equipment perform as intended in meeting predetermined acceptance criteria.

After the IQ and OQ have been performed, the instrument's continued suitability for its intended use is proved through performance qualification.

The PQ phase includes these parameters:

Performance Checks: Set up a test or series of tests to verify an acceptable performance of the instrument for its intended use. PQ tests are usually based on the instrument's typical on-site applications.

Preventive Maintenance and Repairs: When PQ test(s) fail to meet specifications, the instrument requires maintenance or repair. For many instruments a periodic preventive maintenance may also be recommended.

Standard Operating Procedure for Operation, Calibration, and Maintenance: Establish standard operating procedures to maintain and calibrate the instrument. Use a logbook, binder, or electronic record to document each maintenance and calibration activity.

QUALIFICATION OF UV - VISIBLE SPECTROPHOTOMETRY

The qualification of a UV-Visible spectrophotometer is a critical process to ensure the instrument's accuracy, reliability, and compliance with regulatory requirements. Qualification confirms that the spectrophotometer performs within specified parameters and provides reliable measurements

UV-Visible spectroscopy is concerned with ultra violet and visible regions which ranges from 200-800 nm.

INSTALLATION QUALIFICATION (IQ):

While the UV instrument was shipped after the precise adjustment and inspection at the factory, it is recommended to install according to the following procedures so as to provide its optimum performance and to meet the user's demands.

- Verify that the spectrophotometer is installed correctly according to manufacturer's recommendations and specifications.
- Check the power supply, connections, and proper grounding of the instrument.
- Ensure that all required accessories and peripherals are installed and functioning properly.
- Document the installation process, including photographs, equipment specifications, and the environment in which the instrument is placed.
- Room temperature during use should be of 15 to 35℃
- Out of direct sunlight.
- No strong vibration or continuous weak vibration.
- No strong magnetic fields or electromagnetic fields.
- Humidity of 45 to 80%.
- No corrosive gases or organic or inorganic gases with absorptivity in the ultraviolet range.
- Small amount of dust.

OPERATIONAL QUALIFICATION (OQ):

- Verify the functionality and performance of the spectrophotometer under normal operating conditions.
- Perform a range of predefined tests using standard reference materials and known samples to ensure the instrument meets its operational specifications.

- Test critical parameters such as wavelength accuracy, resolution, photometric accuracy, stray light, linearity, and wavelength repeatability.
- Verify the instrument's software functionalities, including data acquisition, data processing, and instrument control.
- Document the test procedures, results, and any deviations or discrepancies encountered during the operational qualification process.

PERFORMANCE QUALIFICATION (PQ):

Wavelength accuracy

It is defined as the deviation of the wavelength reading at an absorption band and emission band from the wavelength of the band.

Procedure:
Weight accurately 1.0 gm of Holmium Oxide and dissolve it in 1.4 M Perchloric acid solution. Makeup to 25 ml with the same solvent. Select the method file of CONTROL OF WAVELENGTH in the instrument. After selecting the file press Reference button for baseline correction. Then fill the Cuvette with 1.4M Perchloric acid and put in the sample cubicle and press reference to zero. After auto zero put the Holmium perchlorate solution in sample cubicle then press start key. Scan it and verify the wavelength using absorption maxima of Holmium Perchlorate solution.

Acceptance: ± nm in UV range (200-380 nm) and ± nm in visible range (380-800 nm), three repeated scans of the same peak should be with in ±0.5 nm.

Stray light

Stray light is defined as the detected light of any wavelength that is outside the band width of the wavelength selected.

Procedure:
Weight accurately 1.20 g of dried potassium chloride and dissolve it in 50 ml distilled water. Make up to 100 ml with the same solvent. Select the method file of LIMIT OF STRAY LIGHT in the instrument. After selecting the file press Reference button for baseline correction. Check the absorbance of above solution using water as a blank at 200 nm.

Acceptance: the transmittance of the solution in a 1cm cell should be less than 0.01 or the absorbance value should be greater than 2.

Resolution power

The resolution of the UV-VIS spectrometer is related to its spectral band width. The smaller the band width the finer the resolution. The SBW depends on the slit width and the dispersive power of the monochromator.

Procedure:
Prepare 0.02%v/v solution of Toluene in Hexane. Select the method file of RESOLUTION POWER in the instrument. After selecting the file press Reference button for baseline correction. Measure the absorbance of above solution at 266 nm and 269 nm using Hexane as blank solution.

Acceptance: The ratio of the absorbance at 269 nm and absorbance at 266 nm should be greater than 1.5

Noise

Noise is the measurement affects the accuracy at the both end of the absorbance scale. Photon noise from the light source affects the accuracy of the measurement leads to low absorbance.

Acceptance: The RMS noise should be less than 0.001 AU

Baseline flatness

The flat baseline test demonstrates that the ability of the instrument to normalise the light intensity measurement and the spectral output at different wavelength throughout the spectral range.

Acceptance: The measurement is typically less than 0.01 AU

Stability

The lamp intensity is a function of the lamp age, temperature fluctuation and wavelength of the measurement. These changes can lead to errors in the value of the measurements, over an extended period of time.

Acceptance: The deflection is less than 0.002 AU/ hr

Photometric accuracy

Photometric accuracy is determined by comparing the difference between the measured absorbance of the reference material and the established value.

Acceptance: Six replicate measurements of the 0.006% w/v of the potassium dichromate solution at 235, 257, 313 and 350 nm should be less than 0.5% RSD.

Linearity

The linearity dynamic range of measurement is limited by stray light at high absorbance and by noise at low absorbance. The accuracy of the quantification of the sample depends on the precision and linearity of the measurements.

Acceptance: Correlation coefficient $r > 0.999$