Qualification Introduction & Qualification of UV-Visible Spectrophotometry

B.Pharm.VI Sem (BP 606)

By

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INTRODUCTION

VALIDATION: It is a act of demonstrating and documenting that the process operates effectively and reproducibly to produce a product meeting its predetermined specifications and quality attributes.

The aim of validation is to show that the critical steps are under control and lead continuously to the desirable quality.

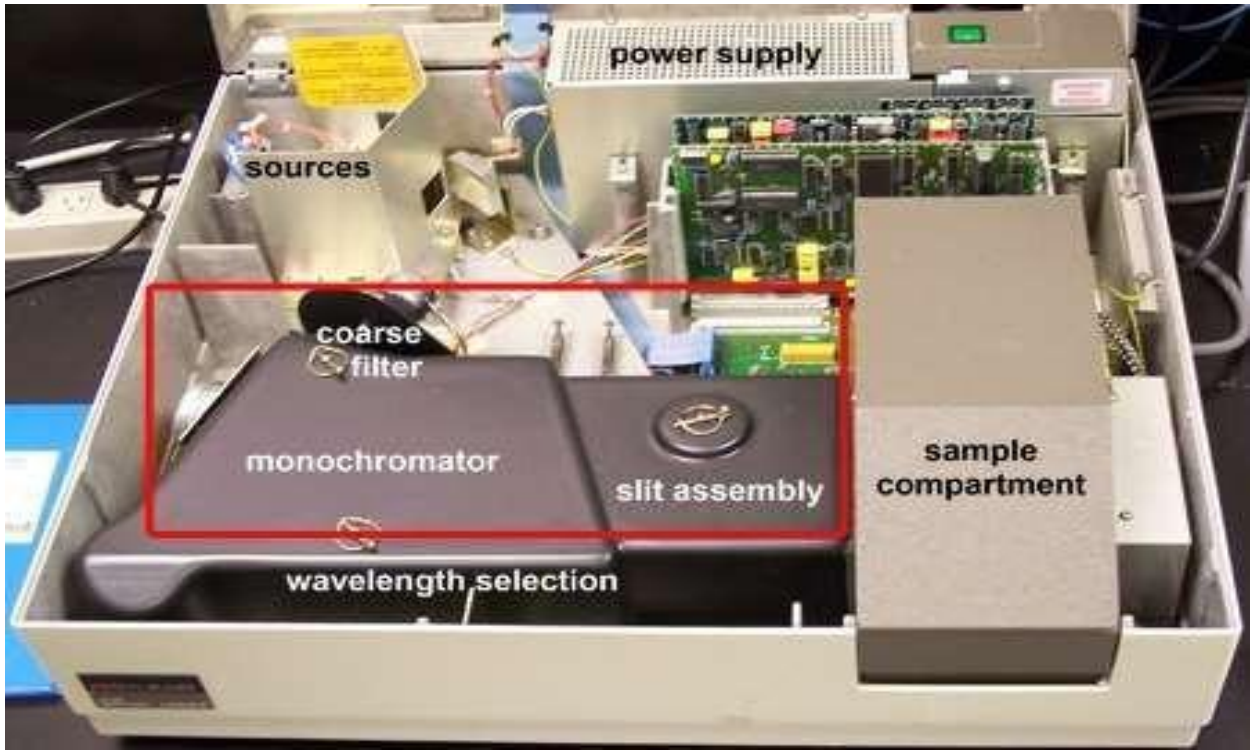
CALIBRATION: Calibration is a comparison between measurements – one of known magnitude or correctness made or set with one device and another measurement made in as similar a way as possible with a second device.

QUALIFICATION: Qualification is an act or process to assure something complies with some conditions, standard or specific requirements.

- **Design Qualification:** Documented evidence which shows that the plant design agrees with the design specifications of the customer.
- **Installation Qualification**: Written evidence is given that all parts of equipment are installed according to the equipment supplier's and purchase specifications.
- **Operational qualification**: Documented evidence which shows that all parts of the plant and equipment work within their specifications and process parameters.
- **Performance Qualification**: Provides documented evidence that all parts of a plant and other processes produce products of specified quality under conditions of normal production for a longer period of time.

UV-VISIBLE SPECTROPHOTOMETER

- UV-Visible spectroscopy is concerned with ultra violet and visible regions which ranges from 200-780 nm.



INSTALLATION PROCEDURE:

- 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.

INSTALLATION SITE:

- Room temperature during use of 15 to 35 °C.
- 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.

ACCEPTANCE PROCEDURES:

Item to be checked	Specification
Appearance	No defect
Number of parts	No missing parts
ROM check	Latest version
Linearity of Absorbance	Bent: ±0.002Abs (Shock noise: ±0.004 Abs)
Noise level	Noise width: ±0.002Abs (Shock noise: ±0.004 Abs)
Accuracy of wavelength	±0.5nm
Repeatability of wavelength	±0.1nm

PERFORMANCE QUALIFICATION

- **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.

Acceptance: ± nm in UV range (200-380 nm) and

± nm in visible range (380- 800 nm) Three repeated scan 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 out side the band width of the wavelength selected.

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.

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 out put 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 lineatr 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 $\geq$ 0.999

CONCLUSION

Qualification of equipment is pre-requisite for validation of the process in which the equipment is being used. Many types of equipment have measuring devices on them.

Calibration of measuring devices is a part of qualification. Calibration of measuring devices is important, as the data is often collected through them.

If the data collected is not from a measuring devices that have been calibrated, the data can not be relied upon. Thus the whole validation exercise can be questioned.

THANK YOU