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Method Development And Evaluation Of Pharmaceutical Dosage Form By Uv-Visible Spectroscopy

Inamdar Muskan[1], Gholap Anuja[1], Dongare Vaishnavi[1], Dr. Hole Mangesh[2]

[1]Student, Samarth College of Pharmacy, Belhe, Pune, Maharashtra, India.

[2]Assistant Professor, Samarth College of Pharmacy, Belhe, Pune, Maharashtra, India.

ABSTRACT:

UV-visible spectroscopy is a widely employed analytical technique in pharmaceutical analysis, ensuring the quality and regulatory compliance of dosage forms. This comprehensive review focuses on the principles, advancements, and applications of UV-visible spectroscopy in method development for quantitative analysis of active pharmaceutical ingredients. The review also explores the versatility of UV-visible spectroscopy in analyzing various dosage forms, including tablets, capsules, and solutions. The review emphasizes the importance of analytical method validation in accordance with ICH guidelines and regulatory requirements. Various methods such as the calibration curve method, absorptivity value method, and multicomponent analysis are reviewed.

KEYWORDS:

UV-visible spectroscopy, Analytical method development, Method Validation, Pharmaceutical Analysis.

INTRODUCTION TO UV VISIBLE SPECTROSCOPY:

UV spectroscopy is a method that measures the absorption of ultraviolet and adjacent visible light in the electromagnetic spectrum. Also known as UV-visible spectrophotometry or electronic spectroscopy, it is popular due to its low cost and ease of use across various applications. For a sample to be analyzed, it must absorb light in the UV-Vis range, showing that it is a chromophore. This technique complements fluorescence spectroscopy, focusing on parameters like absorption, transmission, and reflectance, and their changes over time.

Electromagnetic Spectrum-

Electromagnetic radiation interacts with atoms and molecules, creating unique absorption or emission profiles vital for spectroscopy. The wavelength of this radiation determines the visible colour spectrum, which ranges from 400 to 800 nm. A specific visible wavelength corresponds to optical density measured by spectrophotometers, leading to absorption and the light becoming invisible. The relationship between absorbed and transmitted light wavelengths is illustrated, such as how a blue substance strongly absorbs the complementary colour orange.

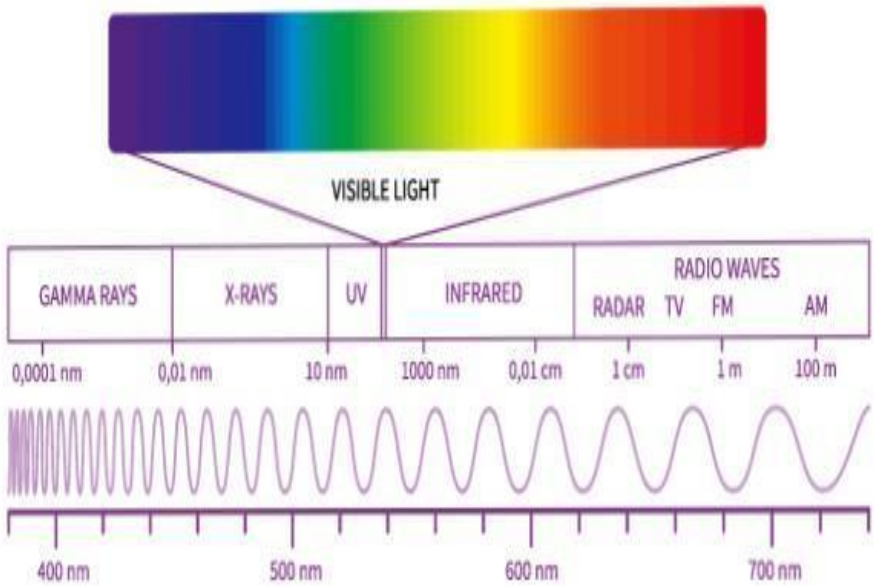


Fig.1.Electromagnetic Spectrum[19]

Beer's Law:

The intensity of incident radiation is greater than the emerging radiation when electromagnetic radiation travels through an absorbing material. Beer's law provides a quantitative description of how radiant energy is absorbed by materials. It states that the amount of radiation absorbed or transmitted is inversely related to the concentration of the absorbing substance and the distance the radiation travels through the sample. A plot of absorbance versus concentration will yield a straight line with a slope equal to the product of molar absorptivity and path length. The relationship can be expressed by the equation

$A = -\log(I/Io) = \epsilon bc$,

where ϵ is a constant not affected by concentration or path length. By knowing the path length and molar absorptivity, the concentration of an organic molecule can be determined by identifying its maximum absorbance in the UV-Vis absorption spectrum.

Principle of UV-Vis Spectroscopy:

When radiation causes an electronic transition in a molecule or ion, the sample shows absorption in the visible or ultraviolet range. This absorption leads to a change in the electronic state of the molecules, where electrons are promoted from a lower energy ground state orbital to a higher energy excited state orbital. Up to three types of ground state orbitals may be involved in this process.

Sigma (Σ) electrons: Saturated bonds have only sigma electrons that are held tightly, leading to high bond strengths and requiring significant energy for excitation. As a result, compounds with only these bonds absorb primarily in the vacuum UV region, unlike other chromophoric groups that absorb in the near UV region. The near UV region does not provide enough energy to excite the sigma electrons. Saturated compounds, such as alkanes like n-hexane, serve as effective solvents in the near UV region.

Pi (π) electrons: Pi electrons are found in unsaturated compounds such as alkenes, alkynes, and aromatic compounds. They are loosely held and oriented perpendicular to the nuclear axis. Near UV radiation can excite these electrons to higher energy levels, applicable to all alkenes, alkynes, and aromatic compounds.

Non-bonding (n) electrons: Non-bonding electrons are unshared outer electrons found on hetero atoms like oxygen, nitrogen, sulphur, or halogens. These electrons are not involved in atomic bonding and need less energy for excitation. Consequently, the energy needed to excite these electrons follows a specific order.

Sigma (Σ) electron > Pi (π) electron > Non-bonding (n) electron.

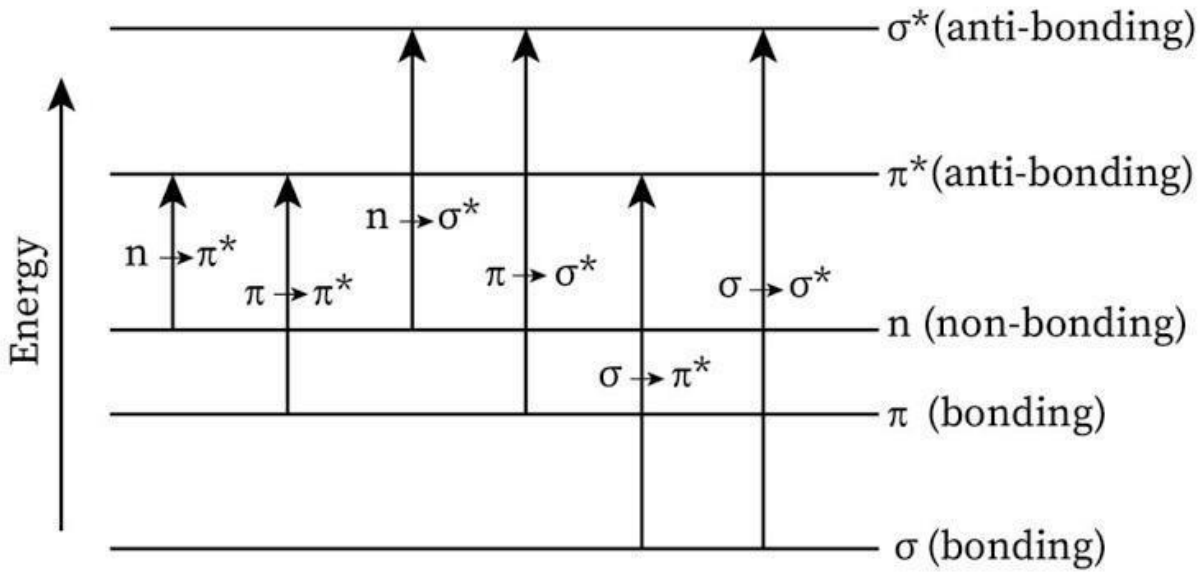


Fig.2.Electron Transition graphically represented.

INSTRUMENTATION OF UV- VISIBLE SPECTROPHOTOMETER :

The Essential components of UV-VIS Spectrophotometer are as follows:

1. Sources (UV and visible)
2. Monochromator
3. Sample containers (Cuvette)
4. Detector
5. Amplifier and recorder

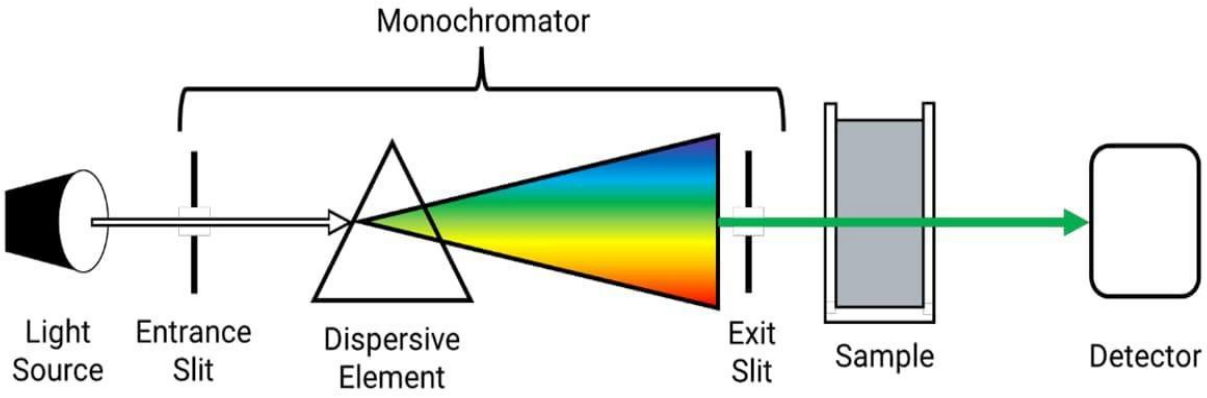


Fig.3. UV Visible Spectrophotometer[20]

SOURCES:-

A continuous source, or one that produces radiation at a variety of wavelengths, is necessary for UV-Vis Spectroscopy. Assorted UV radiation sources include the following:

1. Hydrogen lamp:

Hydrogen lamps are reliable, steady, and continuously emit radiation between 160 and 380 nm. It consists of Hydrogen gas at high pressure, which causes an electrical discharge. The excited hydrogen molecules produce radiation.

2. Deuterium lamp:

A gas discharge lamp called a deuterium lamp is frequently employed as a UV source. It emits radiation in the160–450 nm range. It costs more than a hydrogen lamp.

3. Tungsten lamp:

The most typical light source utilized in spectrophotometers is the tungsten lamp. With a wavelength range of roughly 330 to 900 nm, it comprises of a tungsten filament encased in a glass envelope and is utilized for the Visible spectrum.

4. Xenon discharge lamp:

A xenon lamp is a discharge light source that contains xenon gas inside a bulb. Xenon lamps emit radiation in the 250–600 nm range.

MONOCHROMATOR:-

By filtering out undesirable wavelengths from the radiation source light, a monochromator creates monochromatic Light. Through the entrance slit, multi-wavelength polychromatic light enters the monochromator. Following Collimation, the beam is directed at an angle toward the dispersion component. The grating or prism separates the Beam's wavelengths into their individual components. Only radiation of a specific wavelength exits the Monochromator through the exit slit when the dispersing element or the exit slit are moved.

Types of monochromators:

1. Prism monochromator
2. Grating monochromator

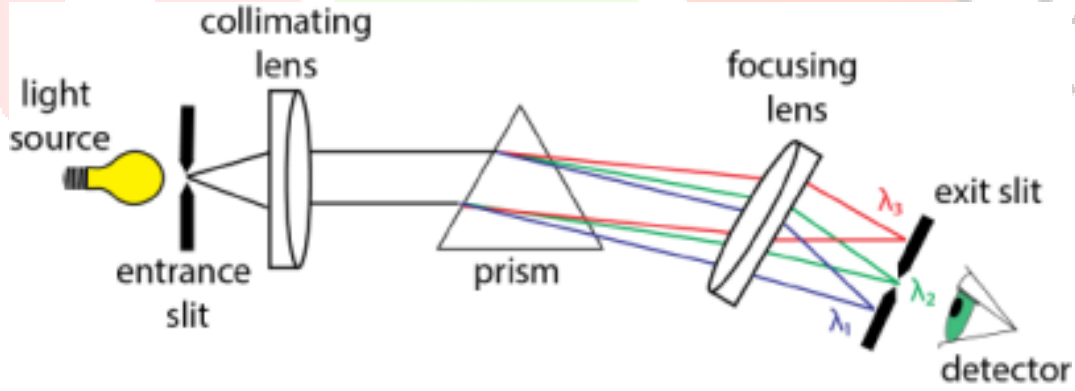


Fig.4.Prism Monochromator[19]

All Monochromator contain the following component parts: An entrance slit, a collimating lens, a dispersing device, a focusing lens, an exit slit.

Radiation with many wavelengths, or polychromatic radiation, enters the monochromator through the entrance Slit. After being collimated, the beam angles toward the dispersing component. The grating or prism separates the Beam's wavelengths into their individual components. Only radiation of a specific wavelength exits the Monochromator through the exit slit by changing the dispersing element or the exit slit.

SAMPLE CONTAINERS (CUVETTE):

Cuvettes are sample containers that are transparent to all wavelengths of light flowing through them and are used to hold samples for spectroscopic measurements. The cuvette is composed of quartz, is square in shape, has a 1 Cm route length, and may be utilized for wavelengths between 190 and 200 nm.

DETECTORS:

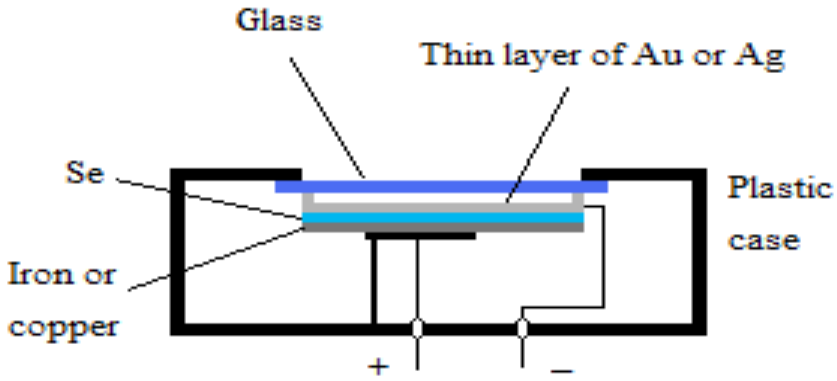
Device which converts light energy into electrical signals, that are displayed on readout devices.

The transmitted radiation falls on the detector which determines the intensity of radiation absorbed by sample

The following types of detectors are employed in instrumentation of absorption spectrophotometer

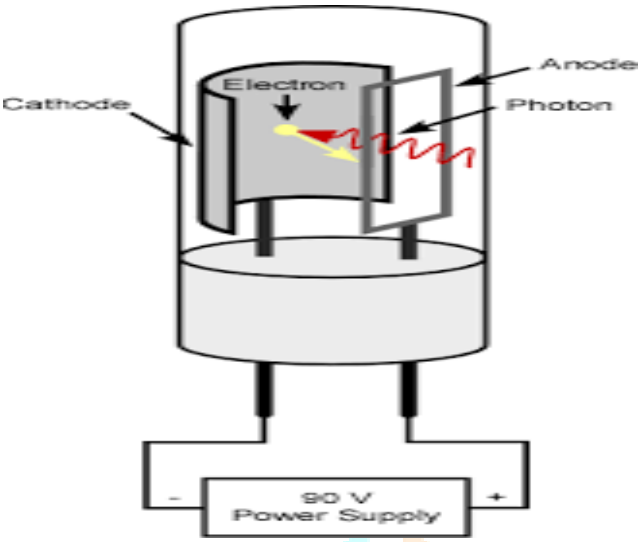
1. Barrier layer cell/Photovoltaic cell
2. Phototubes/Photo emissive tube
3. Photomultiplier tube.

1. <u>Barrier layer cell / Photovoltaic cell:</u>



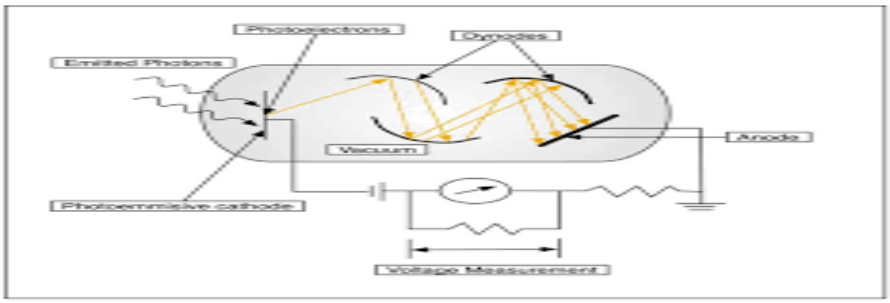
• The detector has a thin film metallic layer coated with silver or gold and acts as an electrode.
• It also has a metal base plate which acts as another electrode.
• These two layers are separated by a semiconductor layer of selenium.
• When light radiation falls on selenium layer, electrons become mobile and are taken up by transparent metal layer.
• This creates a potential difference between two electrodes and causes the flow of current.
• When it is connected to galvanometer, a flow of current observed which is proportional to the intensity and wavelength of light falling on it.

2. Photo Tubes/ Photo emissive Tubes:



• Consists of a evacuated glass tube with a photocathode and a collector anode.
• The surface of photocathode is coated with a layer of elements like caesium, silver oxide or mixture of them.
• When radiant energy falls on photosensitive cathode, electrons are emitted which are attracted to anode causing current to flow.
• More sensitive compared to barrier layer cell and therefore widely used.

3. Photo Multiplier Tubes:



The principle employed in this detector is that, multiplication of photoelectrons by secondary emission of electrons.
• In a vacuum tube, a primary photo-cathode is fixed which receives radiation from the sample.Some eight to ten dynodes are fixed each with increasing potential of75-100V higher than preceding one.
• Near the last dynode is fixed an anode or electron collector electrode.
• Photo-multiplier is extremely sensitive to light and is best suited where weaker or lower aviation is received.

ANALYTICAL METHOD DEVELOPMENT:

Method validation is the process of confirming that the analytical testing strategy for a specific test is appropriate for its intended use. The outcomes of method validation are used to evaluate the consistency of analysis results, ensuring the quality and reliability of products.

A well-developed method is essential for reliable testing, as it characterizes the testing requirements and supports the identification, purification, and potential action of medicines, including their physical characteristics.

Long-term stability studies are facilitated by well-developed Methods.Safety evaluation is crucial during pre-clinical trials, followed by pre-formulation and stability studies.Analytical method validation supports these processes. The nature and characteristics of active pharmaceutical Ingredients (API) are studied, and the analytical methods are refined throughout drug development.

The methods should be simple yet robust, adhering to regulatory guidelines.The purpose of analytical methods throughout product development and manufacturing includes assessing product degradation for stability, analyzing API properties for factors like uniformity and bioavailability, studying impurities for drug safety, and evaluating the potential activities of the finished product to determine correct dosing.

Different UV spectrophotometric methods for

- **Single component analysis:**

Single component analysis focuses on the determination of a single drug or active pharmaceutical ingredient (API). The methods employed for this analysis include,

1.Use of absorptivity value:

The absorptivity value A (1%, 1cm) at a specific wavelength in a selected solvent is determined for a standard, which is then used to determine the concentration of a sample by comparing it with the standard value.

2.Calibration curve method:

In this procedure, the absorbance of several standard solutions at different concentrations is measured, and a calibration graph is created. The concentration of the analyte in the sample solution is determined from this graph, which plots concentration against absorbance. Calibration data is crucial when there is a linear relationship between concentration and absorbance.

3.Single point standardization:

It involves the measurement of absorbance of sample solution Identify the conc of standard solution should be equal to or close to sample solution. The conc of sample solution can be calculated by formula:
Ctest = Atest / Astd x Cstd
Here,
Ctest = conc of sample of sample solution
Atest = Absorbance of sample solution
Cstd = conc of standard solution
Astd = Absorbance of standard solution

4.Double point standardization:

A linear but non-proportional relationship between concentration and absorbance may occur, necessitating a two-Point bracketing standardization to find the concentration of a sample solution. One standard solution has a higher Concentration than the sample, while the other has a lower concentration. The concentration of the sample can be
Calculated using a specific equation.
Ctest= (Atest-Astd1)(Cstd1-CStd2)+Cstd1(Astd1-Astd2)/Astd1-Astd2
Where-
Ctest=concentration of sample solution
Atest=Absorbance of sample solution
Cstd1=concentration of standard contain higher conc. Than sample
Cstd2=concentration of standard contain low conc than sample
Astd1= Absorbance of standard solution contain higher conc than sample
Astd2 = Absorbance of standard solution contain lower conc than sample.

- **Multicomponent Analysis:**

Includes determination of two or more API in sample

1. Simultaneous equation method
2. Absorbance Ratio method/ Q method
3. Assay as a single component sample
4. Assay using absorbance corrected for inference
5. Assay after solvent extraction of samples
6. Geometric correction method
7. Orthogonal polynomial method
8. Difference spectrophotometry
9. Derivative spectrophotometry (DS)
10. Isosbestic "isoabsorptive" point method

1. Simultaneous equation method:

If a sample contains two absorbing drugs (x and y) each of which absorbs at the λ max of the other, it may be Possible to determine both drugs by the technique of simultaneous equation (Vierordt's method) provided that Certain criteria apply.

The information required is

- The absorptivities of x at λ1 and λ2, ax1 and ax2 respectively
- The absorptivities of y at λ1 andλ2, ay1 and ay2 respectively
- The absorbance of the diluted samples at λ1 and λ2, A1 and A2 respectively.

Let Cx and Cy be the concentration of x and y respectively in the diluted samples. Two equations are constructed

At λ1 $A1 = ax1\ bcx + ay1\ bcy$ …… *(1)*

At λ2 $A2 = ax2\ bcx + ay2\ bcy$ …… *(2)*

Based upon the fact that at λ1, the absorbance of the mixture is the sum of the individual absorbance of x and y.

For measurements in 1 cm cells, b =1cm. Rearrange Eq. (2)

$Cy = A2 – ax2cx / ay2$

Substituting for Cy in eq. (1) and rearranging gives

$Cx = A2ay1 – A1ay2 / ax2ay1 – ax1ay2$

And

$Cy = A1ax2 – A2ax1 / ax2ay1 – ax1ay2$

Criteria for obtaining maximum precision, based upon absorbance ratios, have been suggested that place limits on the relative concentrations of the components of the mixture. The criteria are that the ratio and should lie Outside the range 0.1-2.0 for the precise determination of y and x respectively. These criteria are satisfied only when the λmax of the two Components reasonably dissimilar and if the two components do not interact chemically, thereby negating the Initial assumption that the total absorbance is the sum of the individual absorbances. Simultaneous equation Method was developed for simultaneous determination of several mixtures, e.g., atenolol and indapamide, and Dexibuprofen and paracetamol.

2.Q-absorbance ratio method:

This method also termed "absorption ratio method" is a modification of the simultaneous equation's method. According to this method, the ratio of absorbance at any two wavelengths for a substance, which obeys Beer's Law, is a constant value independent of the concentration and path length. This constant is termed as "Hufner's Quotient" or Q-value. The method involves the measurement of absorbance at two wavelengths, one being the λmax of one of the components (λ 2) and the other being a wavelength of equal absorptivity of the two

components (λ 1), called the iso-absorptive point. The concentration of each component can be calculated by mathematical Equations

$$Cx = (Qm-Qy/Qx-Qy) * A/a1 \quad \ldots\ldots\ldots\ldots\ldots\ldots (1)$$
$$Cy = (Qm-Qx/Qy-Qx) * A/a2 \quad \ldots\ldots\ldots\ldots\ldots\ldots (2)$$

Where; Cx and Cy are the concentrations of x and y respectively, A is absorbance of sample at isoabsorpitive Wavelength and a1 and a2 are the absorptivity of x and y respectively at isoabsorpitive wavelength.

3.Difference spectrometry:

The selectivity and accuracy of spectrophotometric analysis of samples containing absorbing interference may be markedly improved by the technique of difference spectrophotometry. The essential feature of this method is that the measured value is the absorbance difference (ΔA) between two equimolar solutions of the analyte in different chemical forms which exhibit different spectral characteristics.

4. Derivative spectrophotometry (DS):

DS involves the conversion of a normal spectrum to its first, second or higher derivative spectra by differentiating absorbance of the sample with respect to wavelength. The differentiation of zero order spectrum can lead to separation of overlapped signals, elimination of background caused by presence of other compounds in a sample, improvement of resolution of mixtures as it enhances the detectability of minor spectral features, and enhancement of sensitivity

ADVANTAGES:

The UV-VIS spectrophotometer offers several advantages, including high accuracy, ease of handling, reliable operation, and cost-effectiveness. It covers the full range of ultraviolet and visible light, making it suitable for both qualitative and quantitative analysis. Additionally, it can generate derivative graphs and is useful in studying drug degradation, but it is limited to analyte that possess a chromophore.

DISADVANTAGES:

Only molecules with chromophores are analyzed. Factors such as pH, temperature, Contaminants, and impurities can influence absorption results. Only liquid samples can be analyzed, and preparation takes time. Additionally, the handling of cuvettes can impact the sample readings.

VALIDATION:

Validation is defined as a demonstration of giving that any procedure, strategy, process, instrument, materials, action, frame work or analyser proceed as planned criteria.

Types of Validation:

1) Process Validation
2) Analytical method Validation
3) Cleaning Validation
4) Computerized System Validation

- **Process Validation:**

Process validation is the documented process of proving that a manufacturing process consistently produces a product that meets predetermined quality standards and specifications. It is an essential aspect of good manufacturing practices (GMP) in industries such as pharmaceuticals, biotechnology, and medical devices. The goal of process validation is to ensure that a process operates reliably and consistently to produce high-quality, safe products.

Types of Process Validation:

1. Prospective Validation: Conducted before the manufacturing process is put into commercial use. It is based on data gathered during the process design and testing phases.

2. Concurrent Validation: Conducted during the actual production of a product batch, often used when a limited amount of data is available before commercial production.

3. Retrospective Validation: Based on historical data collected from past production batches. It is used for existing products and processes where extensive data is already available.

4. Revalidation: Performed when there are significant changes to the manufacturing process, equipment, or product formulation, or if there are indications of process failure.

Analytical Method Validation

According to ICH Q2 (R1), method validation can be defined as, ‘‘Establishing a documented proof, which provides a high degree of assurance that a specific process will consistently produce a desired result at its prearranged specifications and quality characteristics”

According to *USP*

The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit,
linearity, range, ruggedness and robustness.

According to *ICH*

The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit,
linearity, range, system suitability and robustness.

According to *FDA*

The analytical parameters can be validated are accuracy, precision, specificity/selectivity, detection of limit, quantitation limit, linearity, range, system suitability, reproducibility, sample solution stability and robustness.

According to *European guidelines*

The analytical parameters can be validated are accuracy, precision, specificity, detection of limit, quantitation limit, linearity and range.

Key parameters of the analytical method validation:

It is important for to understand the parameters or characteristics involved in the validation process. The various performance parameters, which are grouped as follows,

- Accuracy
- Precision
- Repeatability
- Intermediate precision
- Reproducibility
- Specificity/Selectivity
- Limit of Detection (LOD)
- Limit of Quantitation (LOQ)
- Linearity Range
- Robustness
- Ruggedness System suitability testing.

1. Accuracy :

Accuracy of an analytical method may be defined as, "Closeness of test results obtained by the method to true value". i.e. measure the exactness of analytical method. It is expressed as percent recovery by the assay of known amount of analyte in the linearity range.

1. Determination methods-

Application of analytical method to an analyte of known concentration .The accuracy may be determined by application of the analytical method to an analyte of known purity (example: reference standard) and also by comparing the results of the method with those obtained using an alternate procedure that has been already validated

2. Spiked – placebo recovery method

In this method, a known amount of pure active constituents is added to formulation blank (sample that contains all other ingredients except the active) and then perform the assay of resulting mixture and compare the obtained results with predictable results.

3. Standard addition method –

In this method, perform the assay of given sample, then add a known amount of active constituent to that assayed sample. After that this sample is again assayed. The difference between the results of the two assays is compared with the expected results.

4. Recommended Data

ICH document recommend that accuracy should be measured using a minimum of nine determinations per 3 concentration level.

5. Acceptance criteria

The mean value should be within 15% of the supposed value except at LLOQ, where it should not deviate by more than 20%. The deviation of the mean from the nominal value serves as the measure of accuracy.

2. Precision :

The precision of an analytical method may be defined as, "Closeness of agreement between a series of measurements obtained from multiple sampling of the same standardized sample under the prescribed conditions." Should be investigated using homogeneous, authentic samples. Expressed as SD/ RSD

% RSD = Standard Deviation/ Mean x 10

3. Repeatability :

It expresses the precision under the same operating conditions over a short interval of time. i. e analysis of replicates by the analyst using the same equipment and method

4. Intermediate precision :

It expresses the precision within laboratories variations. i. e different days, different analyst, and different equipment's etc. It is not necessary to study effects individually.

1. Reproducibility: Precision it expresses the precision between laboratories (two-way studies, usually applied to standardization of method) for addition of procedures in pharmacopoeias. i.e. Validation of tests for assay and for quantitative determination of impurities includes an investigation of precision

2. Recommended Data: The standard deviation, relative standard deviation and confidence interval should be reported for each type of precision investigates.

3. Acceptance criteria: The precision determined at each concentration level should not exceed 15% of the coefficient of variation (CV) except for the LLOQ, where it should not exceed 20% of the CV.

5. Specificity:

ICH defines specificity of an assay is the ability to measure accurately and specifically the analyte in the presence of other components that may be expected to present in the sample medium. The term specific generally refers to a method that produces a response for a single analyte only.
ICH document divides specifically into three categories.

1. Identification tests
To ensure the identity of an analyte.

2. Purity tests
To ensure that all analytical procedures performed allow an accurate statement of the content of impurities of an analyte, i.e. related substances test, heavy metals etc.

3. Assay
To provide an exact result which allows an accurate statement on the content or potency of an analyte in a sample.

6. Selectivity

Selectivity of method to detect the analyte in the presence of components that may be expected to be present in the sample matrix. Simply it is the ability of a separative method to resolve different compounds. It is the measure of the relative method location of two peaks. It is the method that provides responses for a number of chemical entities that may or may not be separated from each other. It is determined by comparing the test results obtained on the analyte with and without addition of potentially interfering material.

7. Limit of detection :

The limit of detection of an analytical procedure is the lowest amount of an analyte in a sample that can be detected, but not necessarily quantify under stated experimental conditions. Simply it indicates that the sample is below or above certain level. The LOD will not only depend on the procedure of analysis but also on type of instrument. Measurement is based on Visual evaluation & Signal to noise ratio.

The standard deviation of the response and the slope.
1. Visual evaluation:
LOD is determined by the analysis of samples with known concentration of analyte and by establish the minimum level at which the analyte can be detected. It can be used for instrumental and non-instrumental procedure.
2. Signal to noise ratio:
This approach can only be applied to analytical procedure which shows baseline noise. It is performed by comparing measured signals from samples with known low concentration of analyte with those of blank samples and establishes the minimum concentration at which the analyte can be detected.
Signal to noise ratio 2:1 or 3:1 is generally accepted
The standard deviation of the response and the slope

$$\mathbf{LOD = 3.3\sigma / S}$$

Σ = Standard deviation of the response
S = Slope of the calibration curve of the analyte from regression line.

8. Limit of quantitation :

The LOQ is the lowest amount of analyte in a sample which can quantitatively determine that may be measured with an acceptable level of accuracy and precision under the stated operational conditions of the method. LOQ can vary with the type of method employed and the nature of the sample. It is generally used for the determination of impurities or degradation products.
Measurement is based on Visual evaluation. Signal to noise ratio.
The standard deviation of the response and the slope Visual evaluation LOQ is determined by the analysis of samples with known concentration of analyte and by establish the minimum level at which the analyte can be detected. It can be used for instrumental and non-instrumental procedure.
1. Signal to noise ratio:

This approach can only be applied to analytical procedure which shows baseline noise. It is performed by comparing measured signals from samples with known low concentration of analyte with those of blank samples and establishes the minimum concentration at which the analyte can be detected. Signal to noise ratio 10:1 is generally accepted.

The standard deviation of the response and the slope

LOD = 10 σ /S

Σ = Standard deviation of the response.

S = Slope

9. Linearity:

Linearity is the ability of the method to obtained test results that are directly proportional to the analyte concentration within a given range. A linear relationship should be evaluated across the range of the analytical procedure. It may be established directly on the drug substance by dilution of a standard stock solution. Linearity should be evaluated by visual inspection of a plot a graph of concentration (on x – axis) Vs mean response (on Y – axis). Calculate the regression equation, Y- intercept and correlation coefficient. Data from the regression line itself may be helpful to provide mathematical estimates of the degree of linearity. For the determination of linearity, a minimum of 5 concentrations is recommended.

10. Range:

Range of analytical procedure is the interval between the upper and lower concentration of analyte in the sample for which it has been demonstrated that the analytical procedure has a suitable level of precision, accuracy, and linearity. Normally derived from linearity studies and specific range is dependent upon proposed application of the procedure.

The following minimum specified ranges should be considered:

- Assay of a drug substance or a finished (drug) product: 80 to 120 % of the test concentration.
- Content uniformity: 70 to 130 % of the test concentration
- Dissolution testing: +/-20 % over the specified range

11. Robustness:

It is the measure of the capacity of the analytical method to remain unaffected by small but deliberate changes in procedure to provide an indication about variability of the method during normal laboratory conditions.

12. Ruggedness:

Degree of reproducibility of test results obtained by analyzing the same sample under variety of normal test conditions such as different.

CONCLUSION:

If used with the right standard curve and applied to pure substances, UV-visible spectroscopy is a reliable, Straightforward, and affordable approach for estimating the concentration of absorbing species.

UV-Vis Spectroscopy (or Spectrophotometry) is a quantitative technique used to measure how much a chemical Substance absorbs light. This is done by measuring the intensity of light that passes through a sample with respect To the intensity of light through a reference sample or blank.

Analytical method validation playing a main role in pharmaceutical industry. The main objective of this review article is to guide the young researchers to improve the quality of analytical method development and validation process. The results from method validation can be used to Moderator the quality, reliability and consistency of analytical results, which is an integral part of any good analytical practice.

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