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Determination and Validation of UV Spectrophotometer for the Antihypertensive Drug

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Abstract

Rapid and sensitive UV Spectrophotometric approach for regular assessment of hypertensive medication. For the assessment of drugs in their formulation, a brand-new, secure, and sensitive method of spectrophotometric estimate in the UV-region has been created. The analysis's complete set of parameters were selected in accordance with ICH guidelines and statistically confirmed. System suitability, specificity, precision linearity, accuracy, intraday and interday assays, robustness, ruggedness, LOD, and log experiments were done. There was no excipient or other additive interference while calculating the Commercial Formulation.

Keywords: Hypertension; UV spectroscopy, Valadation, Beer's law; Lambert's law; Antihypertension

Introduction

A lot of people suffer with hypertension, especially after reaching middle age. It is not a disease in and of itself, but it is a significant contributor to morbidity and death in the cardio-vascular system. The distinction between normotensives and hypertensives in manometric readings is arbitrary. Practically speaking, "hypertension" may refer to a blood pressure level at or above which long-term antihypertensive therapy will lower cardiovascular mortality. It is specified as 140 mm Hg systolic and 90 mm Hg diastolic in the JNC 7* and WHO-ISH@ recommendations from 2003, while the risk seems to rise even above 120/80 mm Hg. According to epidemiological research, the risk of cardiovascular disease increases with increasing blood pressure (systolic, diastolic, or both) [1].

Antihypertensive drug

The drug which used in treatment of hypertension are called antihypertensive drug.

Classification

1) Diuretics Thiazides: Hydrochloride, Chlorthalidone, Indapamide Highceiling: Furosemide, etc. K+ Sparing: Spironolactone, Amiloride

2) ACE inhibitors: Captopril, Enalapril, Lisinopril, Perindopril, Ramipril, Fosinopril.

3) Angiotensin (AT, receptor) blockers: Candesartan, Irbesartan, Telmisartan, Losartan, Valsartan.

4) Direct renin inhibitor: Aliskiren.

5) Calcium channel blockers: Verapamil, Diltiazem, Nifedipine, Felodipine, Amlodipine, Nitrendipine, Amlodipine etc.

6) B Adrenergic blocker: Propranolol, Metoprolol, Atenolol, etc. [2].

Mechanism of Action

ACE inhibitors

It decreases the blood pressure by inhibiting the angiotensin-converting enzyme; this causes a decline in the product of angiotensin II and increases the bradykinin position by inhibiting its deterioration, which leads to vasodilation [3].

Calcium channel blockers

The cardiac muscle-specific L-type voltage-gated calcium channels in which CCBs bind restrict Ca2+ entrance into cells as part of their mode of action. When non-dihydropyridines are used, this action can have a negative inotropic impact on the heart muscle by blocking the SA & AV nodes, which results in sluggish cardiac contractility and conduction. This effect can also produce peripheral vasodilation, which is mostly seen in dihydropyridines [4].

Beta-blockers

Work by preventing the beta 1, 2, and 3 receptors from interacting with catecholamines. The majority of beta receptors are present in the heart muscle, while beta-2 and beta-3 receptors are found in the bronchial and peripheral vascular smooth muscles and the adipose tissue of the heart, respectively. Cardio-selective beta-blockers, such as metoprolol tartrate metoprolol succinate, betaxolol, atenolol, and acebutolol, solely inhibit beta-1 receptors and thereby lessen bronchospasms. The beta-blockers' negative inotropic action, which causes coronary and peripheral artery dilatation and a drop in heart rate, lowers oxygen consumption by preventing catecholamines from binding to the beta receptors [5].

Thiazide and Thiazide like diuretics

Thiazides help the distal tubule from transporting sodium by gumming the Na/Cl channels [6]. Thiazides substantially affect the distal tubule, while they might have a little impact on the proximal tube by gumming swab transport. Thiazide diuretics can acutely spark the renin-angiotensin system and beget systemic vascular resistance, which prevents a good response to the diuretic treatment. This increase in renin-angiotensin exertion may resolve with habitual thiazide remedy.

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Thiazides beget original volume reduction associated with dropped cardiac affair, which recovers within 6 to 8 weeks of starting the treatment in a rear autoregulation medium while the blood pressure remains under control.

Loop diuretics

By raising the sodium exertion at the level of the medullary and cortical features of the thick ascending limb, loop diuretics increase sodium excretion. The volume is condensed as a result of this activity, which lowers blood pressure [7].

Potassium sparing diuretics

These diuretics work by inhibiting sodium reabsorption at this position while also reducing potassium and hydrogen ion excretion from the body. They act on the main cells in the late distal tubule and the collecting conduit. Mineralocorticoid receptor antagonists, similar as spirolactone and eplerenone, help the action of the receptor. By lowering Ca2's cytoplasmic content, the arteriolar vasodilator hydralazine prevents Ca2 from being released by the smooth muscles of the highways [8].

ARBs: It Function by preventing angiotensin II from attaching to the angiotensin 1 AT1 receptors, which therefore prevent the angiotensin II action. ARBs do not influence the kinin levels, in contrast to ACE inhibitors.

Clonidine: Clonidine activates the rostral ventrolateral medulla's alpha-2 receptors, which inhibits the sympathetic outflow from the CNS and lowers plasma norepinephrine levels, resulting in a reduction in cardiac output. Adenosine triphosphate-sensitive potassium channels in the soft tissue of the highways are touched off by minoxidil, an arteriolar vasodilator. Nascence-blockers function by precluding nascence-1 receptors from constricting, which results in vasodilation and lower vascular smooth muscle compression.

Alpha-blockers: They work by preventing alpha-1 receptors from contracting vascular smooth muscle, which causes vasodilation [9].

Hydralazine: An arteriolar vasodilator, hydralazine prevents Ca2+ release in vascular muscles by lowering its cytoplasmic concentration, the smooth muscle [10].

Adverse effects

Thiazides Side Effects: Hyperuricemia, Hypomagnesemia, Hyperlipidemia increased glucose levels

CCB Side Effects: Lightheadedness Flushing, Headaches

ACE Is and ARBs Side Effects: Cough, Hypotension, Fatigue, and Azotemia

Loop diuretics: Hypokalemia, Hyponatremia, Hypomagnesemia, Hypochloremia [11].

Spectroscopy methods: It is the scientific field that examines how electromagnetic waves and matter interact. It is one of the most potent tools for atomic and molecular structure research and is used to analyze a variety of materials. The portion of the electromagnetic spectrum between 100 and 400 m is used in optical spectroscopy [12,13].

Ultraviolet-visible spectrophotometry: One of the most widely used methods in pharmaceutical analysis is UV-Visible spectrophotometry (Figure 1). It entails determining how much UV or visible light a material in solution has absorbed. Ultraviolet-Visible spectrophotometers are instruments that measure the ratio, or function of ratio, of the intensity of two beams of light in the U.V. area. If any recorded data is available, a spectrophotometer can be used in qualitative analysis to identify organic substances, and quantitative spectrophotometric analysis is used to determine the number of molecular species absorbing the light. The spectrophotometric method is straightforward, quick, fairly selective, and suitable for tiny amounts of chemicals. The Beer-Lambert rule is the fundamental principle that controls quantitative spectrophotometric analysis [14].

Beer's law: It states that the intensity of a ray of resemblant monochromic radiation decreases exponentially with the number of absorbing motes. In other words, absorbance is commensurable to the attention.

Lambert's law: It states that the intensity of a ray of resemblant monochromic radiation decreases exponentially as it passes through a medium of homogeneous consistence. A combination of these two laws yields the Beer-Lambert law (Figure 2).

Beer Lambert law: When ray of light is passed through a transparent cell containing a result of anabsorbing substance, reduction of the intensity of light may do. Mathematically, Beer-Lambert law is expressed as:

A = a bc.

Where, A = absorbance or optic viscosity a = absorptivity or extermination measure b = path length of radiation through sample (cm) C = attention of solute in result. Both b and a are constant so a is directly commensurable to the attention c When c is in gm/100 ml, also the constant is called A (1, 1 cm) A = A *(1)/(1 cm) * bc [14].

Methods of UV spectrophotometry

i) Simultaneous equation method

ii) Derivative spectrophotometric method

iii) Absorbance ratio method (Q-Absorbance method)

iv) Difference spectrophotometry

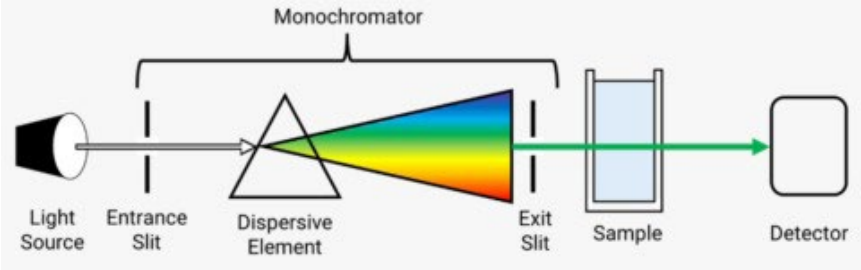

Figure 1: Ultraviolet-Visible spectrophotometry.

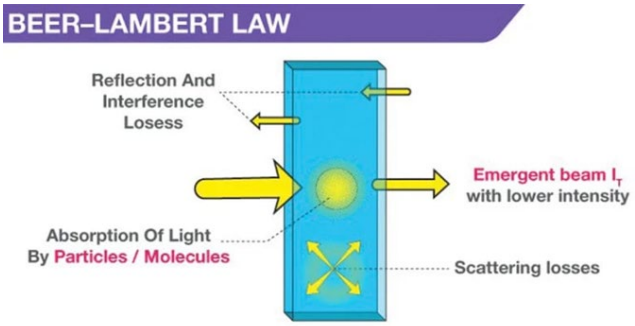

Figure 2: Beer- Lambert law.

v) Solvent extraction method [15].

Validation

According to the International Conference on Harmonization (ICH), validation is the process of producing documentary proof that a technique, process, or activity used in production or testing maintains the intended degree of conformance at all times. According to the FDA, validation entails creating concrete proof that a given method will consistently result in a product that meets its set standards and quality criteria [16].

Objective

1) To serve as a foundation for written production and process control procedures.

2) That are intended to ensure that the pharmaceutical items are what they claim to be in terms of identity, potency, quality, and purity [16].

Principle

The fundamental idea of validation is as follows:

1) Installation Qualification (IQ): Providing objective proof that the installation of all significant pieces of process equipment and associated systems complies with manufacturer-approved specifications and takes into account the supplier's advice.

2) Operational Qualification (OQ): Determining, via the use of objective evidence, the process control limits and action levels that produce a product that satisfies all established requirements.

3] Performance Qualification (PQ): Demonstrating via impartial evidence that the process consistently yields a product that satisfies all present standards under predicted conditions [16].

Validation Parameters as per ICH Guideline

1) Specificity: Identification, Assay and Impurity Test(s).

2) Linearity

3) Range.

4) Accuracy: Assay, Impurities (Quantitation), Recommended Data.

5) Precision: Repeatability, Intermediate Precision, Reproducibility, Recommended Data.

6) Detection Limit: Based on Visual Evaluation, Based on Signal-to-Noise, Based on the Standard Deviance of the Reaction and the Slant.

7) Quantitation Limit: Based on Visual Evaluation, Based on Signal-to-Noise Approach, Based on the Standard Deviance of the Reaction and the Slant, Recommended Data.

8) Robustness.

9) System Suitability Testing [16].

Specificity: Being specific is a capability to accurately assess the analyte with the help of elements that could be considered to be present. Degradants, pollutants, and matrix are often among these. Other supporting analytical procedure(s) may make up for an individual analytical procedure's lack of specificity.

The following conclusions flow from this definition

1) Identification: To confirm analytes identification.

2) Purity Tests: To make sure that all analytical techniques, such as those for related compounds, heavy metals, residual solvents, etc., can accurately report the presence of contaminants in an analytes.

3) Assay (Content or Potency): To give a precise answer that enables a precise assessment of the content or potency of the analytes in a sample [16].

Linearity: The capacity of an analytical process to produce test findings that are directly proportional to the concentration (quantity) of analytes in the sample is known as linearity.

Aspects

1) Test the whole range (at a minimum of 5 concentrations)

2) Assess linearity using statistical methods and visual graphic inspection

3) Determine R2, the y-intercept, the slope, and the residual sum of squares [16].

Conclusion

It was investigated how to develop and validate the UV spectrophotometry technique. As a result, this technique is highly helpful, straightforward, and accurate for identifying antihypertensive medications.

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