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Development and Validation of UV Spectrophotometric Method for Determination of Antidibetic Drug

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Abstract: *Analytical Chemistry is the branch of science that uses advance technologies in determining the composition by analytical technique . The scientific field of analytical chemistry employs cutting-edge technologies to ascertain composition using analytical techniques. It is possible to attain both quantitative and qualitative outcomes. The process of obtaining accurate and dependable analytical data heavily relies on analytical tools.[1,2]*
A quantitative analytical method called ultraviolet-visible (UV-Vis) spectroscopy calculates the amount of light that a chemical material absorbs in the visible and ultraviolet portions of the electromagnetic spectrum. It's a fundamental method for describing molecules and one of the most used approaches for quantitative analysis.[3].

Keywords: Analytical Chemistry

I. INTRODUCTION

Analytical Chemistry is the branch of science that uses advance technologies in determining the composition by analytical technique . The scientific field of analytical chemistry employs cutting-edge technologies to ascertain composition using analytical techniques. It is possible to attain both quantitative and qualitative outcomes. The process of obtaining accurate and dependable analytical data heavily relies on analytical tools.[1,2]
A quantitative analytical method called ultraviolet-visible (UV-Vis) spectroscopy calculates the amount of light that a chemical material absorbs in the visible and ultraviolet portions of the electromagnetic spectrum. It's a fundamental method for describing molecules and one of the most used approaches for quantitative analysis.[3]

Diabetes:
Diabetes is a long-term metabolic illness characterized by high blood sugar levels that eventually cause major harm to the heart, blood vessels, eyes, kidneys, nerves, and other tissues[6,7]

Types of diabetes: Type 1 Diabetes:
The autoimmune destruction of the pancreatic islets of Langerhans is the usual cause of type 1 diabetes. Antibodies against insulin and other islets of Langerhans components are present in the serum of patients with type 1 diabetes. A decrease in insulin secretion may be linked to the antibodies, which are frequently present for several years prior to the onset of diabetes. Genetic variants linked to the human leukocyte antigen (HLA) complex, which is involved in presenting antigens to immune cells and starting the creation of autoantibodies—antibodies that attack the body's own cells—are present in some type 1 diabetic individuals. However, immune cells that have become sensitive in some ways are regarded to be the cause of the real demise of the islets of Langerhans

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Type 2 diabetes:

Obesity and type 2 diabetes are closely linked conditions that arise from insulin resistance and insufficient insulin. Patients with type 2 diabetes who are obese frequently have elevated serum insulin concentrations due to insulin resistance, a common feature of the disease.

Hyperglycemia results from some fat people's insufficient ability to create enough insulin, which prevents them from responding appropriately to elevated blood glucose levels. A person who is healthy will secrete more insulin than an obese person if their blood glucose content is raised to the same level in both.[]

ANTI-DIABETIC DRUGS

The drugs used to treat diabetes called antidiabetic drugs.

Insulin and Insulin Analogues:

1. Rapid-acting insulin (e.g., aspart, glulisine, lispro)
2. Short-acting insulin (e.g., regular)
3. Intermediate-acting insulin (e.g., NPH)
4. Long-acting insulin (e.g., glargine, detemir)
5. Premixed insulin (e.g., biphasic aspart, biphasic insulin)

Oral Hypoglycemic Agents

1. Sulfonylureas
   - First-generation (e.g., tolbutamide, chlorpropamide)
   - Second-generation (e.g., glyburide, glipizide)

2. Biguanides (e.g., metformin)
3. Thiazolidinediones (e.g., pioglitazone)
4. DPP-4 Inhibitors (e.g., sitagliptin, saxagliptin)
5. SGLT2 Inhibitors (e.g., empagliflozin, canagliflozin)
6. Meglitinides (e.g., repaglinide, nateglinide) 7. Alpha-glucosidase inhibitors (e.g., acarbose)

SEMAGLUTIDE:

semaglutide is a glucagon-like peptide-1 (GLP-1) receptor agonist, which mimics the action of the natural hormone GLP-1.

Pharmacokinetics:

1. Half-life: 168 hours (7 days), allowing once-weekly administration.
2. Absorption: Slowly absorbed from subcutaneous tissue.
3. Bioavailability: 89%
4. Duration of action: 63.6hr
5. Distribution: Widely distributed, primarily bound to plasma proteins.
6. Metabolism: Metabolized by proteolytic enzymes.
7. Excreation:Urine and feces
8. Elimination half life:7days

Its mechanism of action involves:

GLP-1 Receptor Activation

- Semaglutide binds to GLP-1 receptors in various tissues, activating live pathways that:
- Enhance Insulin Secretion: Stimulates insulin release from pancreatic beta cells in a glucose-dependent manner.
- Suppress Glucagon Secretion: Reduces glucagon release from pancreatic alpha cells, decreasing hepatic glucose production.

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- Slow Gastric Emptying: Delays gastric emptying, reducing postprandial glucose peaks.
- Increase Satiation: Enhances feelings of fullness and reduces appetite

SIDE EFFECT:

- Nausea.
- Vomiting.
- Diarrhea.
- Abdominal pain.
- Constipation.
- Heartburn.
- Burping.

UV SPECTROSCOPY:

An analytical tool called a UV-vis spectrophotometer calculates how much ultraviolet (UV) and visible light a sample absorbs. It is a commonly used method for identifying and quantifying chemicals in a range of samples in the domains of chemistry, biochemistry, and other sciences. A light beam is passed through the sample using a UV-vis spectrophotometer, which measures the amount of light absorbed at each wavelength. The concentration of the absorbing chemical in the sample determines how much light is absorbed.[5,8,9]

FEATURES:

- High sensitivity
- Rapid Analysis capabilities
- Sensitivity: UV-Visible spectroscopy can detect very low concentrations of samples Broader peaks and simpler spectra: UV- visibles pectroscopy has broader peaks and simpler spectra than other spectroscopic techniques.
- Light source: UV- visible spectroscopy requires a steady light source that can emit light across a wide range of wavelengths of action involves:

Applications:

- UV-VISible Specopy(Electronic spectrophotometer)
- Qualitative and quantitative analysis
- Detection of impurities from organic mixture
- Elucidation of structure molecules
- Forensic toxicology
- Molecular weight determination
- Fat quality determination
- Determination of metal contaminants.
- UV-Visible spectroscopy can also be used to find contaminants in a sample and track the development of a reaction
- A sample's purity can be ascertained and the concentration of molecules in solution measured using UV-Visible spectroscopy.

INSTRUMENTATION:

- A UV-Visible spectrophotometer consists of a light source, a monochromator, a detector, and a data recorder.
- The light source provides illumination at one or more specific wavelengths.
- The monochromator is used to select the wavelength of light that passes through the sample

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- The detector measures the intensity of the light that passes through the sample.
- The data recorder records the absorbance or transmission of light at each wavelength.[7,8]

METHODS:

UV-Visible spectroscopy can be carried out primarily using two techniques: transmission and absorption spectroscopy. A sample is put in the path of light in absorption spectroscopy, and the absorbance of light at each wavelength is measured.

The sample is put in a cuvette for transmission spectroscopy, and the amount of light that is transmitted at each wavelength is measured.

II. LITERATURE SURVEY

Merugu Manasa et al. [2021]: New simple, economic and stable methods were developed and validated to estimate the Semaglutide using UV-Visible spectroscopy, Under the accelerated conditions the drug degradation was less than 10%. Hence the developed methods were stable as pe the guidelines. From assay studies the % of dug present in the sample solution was between 99102%. Hence the developed methods were suitable to separate the analyte present in the formulation [14]

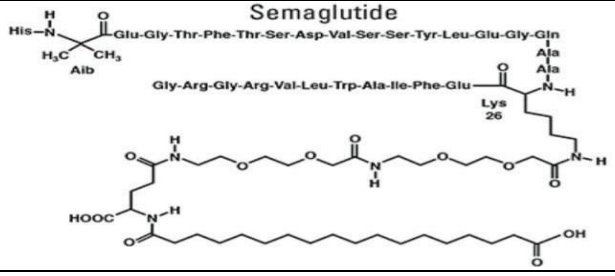
K.L. Rajita et al . [2020]:A rapid and precise UV-VISIBLE spectrophotometric method has been developed for the estimation of semaglutide in its bulk and pharmaceutical dosage form. Spectrophotometry was carried out on a UV-Visible spectrophotometer (UV-T60-India) in quartz cells using ethanol as suitable solvent, the detection is carried out at 288nm.The drug obeyed Beer-Lambert's law over the concentration range 5-30µg/ml. The accuracy was found to be 99.92% for 50% concentration, 99.08% for 100% concentration, 99.95% for 150% concentration. [13]

M. Venanzi et al.2020]: The aggregation properties of Semaglutide, a lipidated peptide drug agonist of the Glucagon-like peptide 1 receptor recently approved for treatment of diabetes type 2, have been investigated by spectroscopic techniques (UV-Vis absorption, steadystate and time-resolved fluorescence, electronic circular dichroism) and Molecular Dynamics simulations**.** Semaglutide is present as monomeric and dimeric species, with a characteristic monomer-to-dimer transition occurring at around 20 µM **[12]**

R. Sundararajan et al. [2019] The method development of semaglutide was carried out using Shimadzu 1800 UV Visible Spectrophotometer with a pair of 10mm path length matched quartz cells. The solutions were scanned in the range of 200-400 nm with medium scanning speed. All the parameters such as linearity, accuracy, precision, limit of detection and limit of quantification were chosen according to ICH guidelines and validated statistically. [4]

SUBHA HARIKA PENMETSA et al. [2019]: The method development of semaglutide was carried out using Shimadzu 1800 UV Visible Spectrophotometer with a pair of 10mm path length matched quartz cells. The solutions were scanned in the range of 200-400 nm with medium scanning speed.). The absorption maximum of semaglutide was found to be at 293nm. The drug obeyed Beer-Lambert's law over the concentration range of 1-15µg/ml. [15]

DRUG PROFILE:

NAME	**Semaglutide**
MOLECULAR STRUCTURE	
IUPAC NAME	**4-Hydroxyquinoline-3-caraboxylic acid**
MOLECULAR FORMULA	**C187H291N45O59**
MOLECULAR WEIGHT	**4113.614g/mol**

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CATEGORY	**Antidibetic**
CAS NUMBER	**910463-68-2**

AIM AND OBJECTIVE:

AIM: Development And Validation Of Uv Specctrophotometric Method For Determination Of Antidibetic Drug.

OBJECTIVE:

- The objective of this dissertation work is as follows
- Aim of the present work is to develop some new analytical methods for the estimation of drug formulations.
- To develop rapid, sensitive and selective method
- Economic and accurate method .
- Method validation according to ICH guidelines

PLAN OF WORK:

- Literature survey
- Procurement of drug sample and other chemicals.
- Determination of λmax by UV- spectrophotometry.
- Analytical Method Validation.

Validation parameters.

- Specificity
- Linearity
- Hange
- Accuracy
- Precision
- Repeatability
- Intermediate Precision
- Detection Limit
- Quantitation Limit
- Robustness

EXPECTED OUTCOME:

Stability and Degradation

- Identification of degradation products
- Degradation rate constants (k).
- Shelf-life prediction.
- Study of semaglutide interactions with excipients

III. FUTURE SCOPE

- Investigation of semaglutide stability and degradation products using UV spectroscopy.
- Analysis of semaglutide in biological matrices (e.g., plasma, urine) using UV spectroscopy.
- Study of semaglutide interactions with other molecules using UV spectroscopy
- Integration of UV spectroscopy with other analytical techniques (e.g., HPLC, MS) for comprehensive semaglutide analysis
- Development of more sensitive and selective UV methods for semaglutide detection

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