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Development and Validation of UV-FTIR Spectoscopics Methods for Analysis of Teneligliptin IP

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Abstract: *A simple, sensitive, and accurate UV-IR spectroscopic method was developed and validated for the analysis of teneligliptin in pharmaceutical formulations. The method involves the use of UV-Vis spectroscopy and FTIR spectroscopy to analyze teneligliptin standard solutions and pharmaceutical formulations. The method parameters were optimized to achieve maximum sensitivity and accuracy. The developed method was validated using parameters such as linearity, accuracy, precision, and specificity. The results showed that the method is linear over the concentration range of 10-100 µg/mL., with a correlation coefficient of 0.999. The accuracy and precision of the method were found to be within the acceptable limits. The developed UV-IR method was successfully applied to analyze teneligliptin in pharmaceutical formulations. The results were found to be in good agreement with the labelled claims.*

Keywords: Teneligliptin, UV-IR spectroscopy, analysis, pharmaceutical formulations, validation.

I. INTRODUCTION

Analytical chemistry is a branch of chemistry that deals with the study of the introduction of components (qualitative) and the determination of the number of components (quantitative) of substances or samples, or mixtures. There are two different forms of analysis: qualitative analysis and quantitative analysis. Identification of the mixture or sample's constituents or analytes is made by qualitative analysis. Quantitative analysis involves quantifying a mixture of sample components or analytes. Not only chemistry but also biology, zoology, the arts (such as painting and sculpture), archaeology, space exploration, and medical diagnosis require analytical data. The procedures needed to create and validate a drug molecule analytical technique are covered in this review article. The method approaches play important roles in the research development, and production of pharmaceuticals. Obtaining accurate, realistic, and consistent data is the major goal of an analytical measure. Validated analytical techniques are crucial to reaching this objective. Results from methodology validation can be used to determine the quality, dependability, and consistency of analytical findings, which are essential components of any sane analytical procedure. Most laws and quality standards that affect laboratories require the validation of analytical techniques.

1.1 ANALYTICAL METHOD

A sample can be analyzed qualitatively, quantitatively, or structurally for one or more analytes using an analytical method that uses specific technology and specific, step-by-step instructions. Analytical techniques are typically divided into two categories: Instrumental and classical techniques. The classical approach is one in which the signal is inversely correlated with the analyte's absolute concentration. The term "instrumental method" refers to a technique where the signal is inversely proportional to the concentration of the analyte. The three primary categories of classical procedures are:

- Analyte separation
- Qualitative analysis
- Quantitative analysis

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Extraction, distillation, precipitation, and filtering are processes used to Separate analytes. The boiling point, freezing point, colour, odour, density, reactivity, and refractive index are all examples of qualitative analysis. Gravimetric analysis and volumetric analysis are both types of quantitative analysis. Spectroscopic methods, electrochemical methods, chromatographic methods, and other techniques are the four primary categories into which instrumental methods can be broken down. Ultraviolet- visible spectroscopy, infrared spectroscopy, Raman spectroscopy, atomic absorption and emission spectroscopy, x-ray spectroscopy, and nuclear magnetic spectroscopy are examples of spectroscopic techniques. Potentiometry, coulometry, and voltammetry are examples of electrochemical approaches. Chromatographic techniques include column chromatography, paper chromatography, thin layer chromatography, high-performance liquid chromatography, gas chromatography, and contemporary techniques (LC-MS, GC-MS, LC-MS-MS, GC-MS-MS, LC-NMR, and GC-NMR). X-ray methods, radioactivity, mass spectrometry, optical methods (refractometer, optical rotation), thermal methods (thermogravimetry, differential thermal analysis, and differential scanning calorimetry), and radioactivity are further techniques.

1.2 INTRODUCTION TO SPECTROSCOPY:

The study of electromagnetic radiation's interactions with matter is known as spectroscopy. These interactions involve the matter absorbing and emitting radiation (energy). There are two forms of spectroscopy: emission spectroscopy and absorption spectroscopy. Absorption spectroscopy (UV, visible, infrared, nuclear magnetic resonance, microwave, and radio wave spectroscopy) is the study of electromagnetic energy absorbed by the sample and represented as spectra. Emission spectroscopy is the study of electromagnetic radiation emitted by the sample in the form of spectra (flame photometry and fluorimetry). The study of atomic and molecular structure can benefit from the use of spectroscopy, which is also used to analyze a variety of samples. The study of electromagnetic radiation's interactions with atoms and the changes in energy that result at the atomic level is known as atomic spectroscopy (e.g. atomic absorption spectroscopy and flame photometry). The study of electromagnetic radiation's interactions with molecules and energy changes that occur at the molecular level is known as molecular spectroscopy (e.g., ultraviolet and infrared spectroscopy)

UV-VIS spectroscopy: It is based on the Beer-Lambert law, which states that the absorbance of a solution is directly proportional to the concentration of the absorbing species in the solution and path length. Ultraviolet (UV) spectroscopy is a physical method of optical spectroscopy that uses light in the visible, ultraviolet, and near- infrared ranges. Consequently, it can be used to calculate the concentration of the absorber in a solution for a specific path length. Since UV-VIS spectroscopy has been in widespread use for the past 37 years, it has evolved into the most crucial analytical tool in the modern laboratory. It is crucial to understand how quickly the absorbance varies with concentration.

1.3 PRINCIPLE OF UV:

When radiation induces an electronic transition in a molecule or ion's structure, the object will exhibit absorption in the visible or ultraviolet range. As a result, when a sample absorbs light in the ultraviolet or visible range, the molecules inside the sample experience a change in their electronic state. Electrons will be promoted from their ground state orbitals to higher energy orbitals, such as excited state orbitals or anti-bonding orbitals, by the energy provided by the light. Potentially, three types of ground state orbital may be involved.

- E (Bonding) molecular
- Π (Bonding) molecular orbital
- N (non-Bonding) atomic orbital

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Figure 1. UV- Visible Spectroscopy

Instrumentation of UV-Visible spectroscopy:

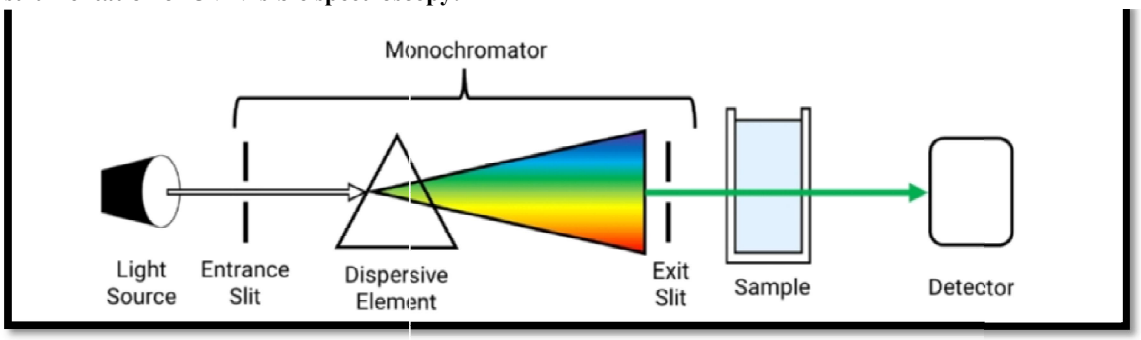

Figure 2. Instrumentation of UV Spectroscopy.

- **Radiation sources:** Most commonly used radiation sources are tungsten lamps, hydrogen discharge lamps, deuterium lamp, xenon discharge lamps and mercury arcs.
- **Wavelength selector:** To distribute the light in accordance with the wavelength, a monochromator is utilized. An entrance slit, a dispersing component, and an exit slit make up the fundamental components of a monochromator.
- **Sample cell:** Cells or cuvettes are sample containers used in UV-Visible spectroscopy to hold liquid samples. Quartz is used to make cuvettes.
- **Photodetector:** The photocell, barrier layer cell, and photomultiplier tube are the detectors that are most frequently employed in UV spectrophotometers.
- **Readout device:** After being amplified appropriately, the detector's output is shown on a readout device.

The **Beer-Lambert law states that** for a given material sample path length and concentration of the sample are directly proportional to the absorbance of the light. Where, A is the amount of light absorbed for a particular wavelength by the sample.

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$$A = \epsilon L c$$

A = Absorbance

ϵ = Molar extinction coefficient

L = Path length

C = Concentration of sample

PRINCIPLE OF FTIR:

It is a technique of collecting infrared spectra. Instead of recording the amount of energy absorbed when the frequency of the infra-red light is varied (monochromator),the IR light is guided through an interferometer.

After passing the sample the measured single is called as the interferogram. Performing a mathematical Fourier transform on this single results in a spectrum identical to that form conventional (Dispersive) infrared spectroscopy.

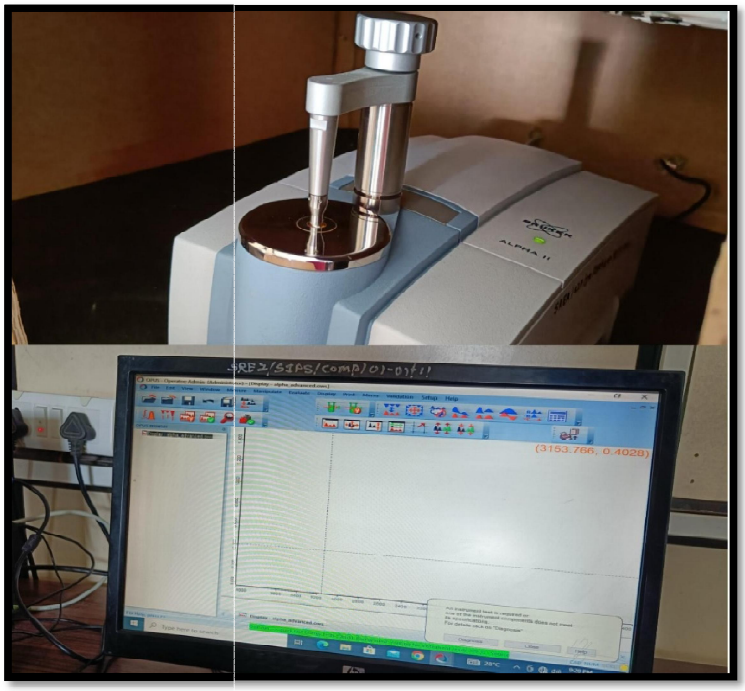

Figure 3. Fourier transform Infrared spectroscopy

Instrumentation of FTIR spectroscopy

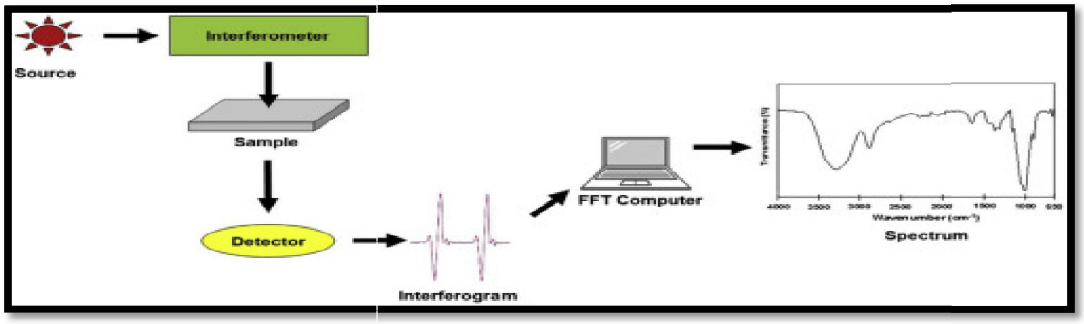

Figure 4. Instrumentation of FTIR spectroscopy

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Source: A source emits infrared radiation, often a heated wire or globar, providing a broad spectrum of radiation.
Michelson Interferometer: This is the heart of the FTIR spectrometer. It consists of a beam splitter, two mirrors (one fixed, one moving), and a path difference generator. The beam splitter splits the IR beam into two paths. The moving mirror's precise movement creates a path difference, which is detected as an interference pattern (interferogram).
Sample Compartment: The sample is placed in the path of the IR beam, where it interacts with the radiation, absorbing specific frequencies depending on its molecular structure.
Detector: The detector measures the intensity of the IR radiation that has passed through the sample, providing data about the interference pattern (interferogram).
Computer: The computer performs a Fourier transform on the interferogram data, converting it into a spectrum that shows the absorbance of different IR frequencies. The spectrum can then be analyzed to identify functional groups and determine the sample's chemical composition.

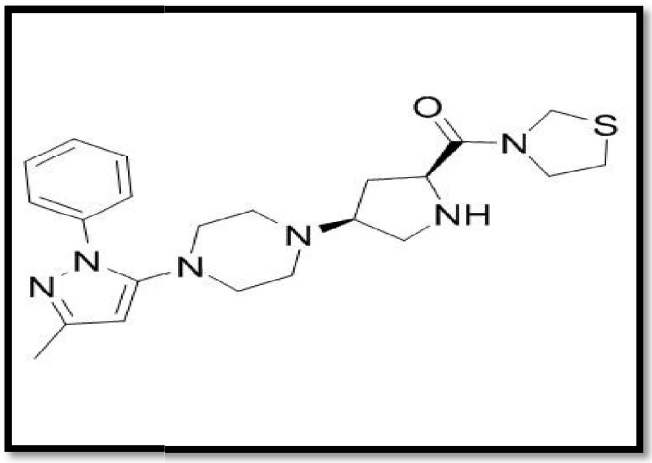

Figure 5. Chemical Structure of Teneligliptin HBr

II. LITERATURE REVIEW

S. A. Kshirsagar et al.(2018): Simple, rapid, sensitive, precise and specific UV Spectrophotometric for the determination of Teneligliptin Hydrobromide Hydrate (THH) in API and pharmaceutical dosage form were developed and validated. In this method solutions of Teneligliptin Hydrobromide Hydrate (THH) were prepared in Dimethyl Sulphoxide (DMSO). Teneligliptin Hydrobromide Hydrate (THH) standard solution was scanned in the UV range (400-200nm) in a 1cm quartz cell in a double beam UV spectrophotometer. The standard solution of THH showed maximum absorption at wavelength 267.2 nm.
T. N. V. Ganesh Kumar et al.(2016): Background Teneligliptin is a new FDA approved drug for treating Diabetes Mellitus. There are no reported evidences for their identified degradation products and their effects on humans. Methods A simple and new stability indicating RP-HPLC method was developed and validated for identification of Teneligliptin and its degradants on Kromasil 100- 5C18 (250×4.6mm, 5µm) column using pH 6.0 phosphate buffer and acetonitrile (60:40 v/v) as a mobile phase in isocratic mode of elution at a flow rate of 1.0 mL/min. The column effluents were monitored by a variable wavelength UV detector at 246 nm.
J. S. Gaffney et al.(2012): Infrared (IR) spectroscopy has always been a powerful tool for the identification of organic materials. However, with the development of Fourier transform infrared (FTIR) spectroscopy, it has become a more popular method for the quantitative analysis of complex mixtures, as well as the investigation of surface and interfacial phenomena. This chapter reviews the basic theory behind FTIR spectroscopy and describes the currently used instrumentation and its application to gas, liquid, bulk and powdered solid samples, and thin films using both transmission and reflectance methods, including specular, diffuse, and attenuated total reflectance (ATR) techniques.

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Ravi Shankar Gupta et al.(2024): This study presents the development and validation of a UV spectrophotometric method for the simultaneous estimation of teneligliptin hydrobromide hydrate (TEN) and pioglitazone hydrochloride (PIO) in pharmaceutical dosage forms. The method measures absorbance at 243 nm for TEN and 265 nm for PIO. Validation was conducted according to ICH guidelines, covering specificity, linearity, range, precision, accuracy, limit of detection, limit of quantification, and robustness.

III. AIM AND OBJECTIVE

Aim: To development and validation of a UV-FTIR spectroscopic methods for analysis of Teneligliptin.

Objectives:

- Develop a UV-IR method for the analysis of teneligliptin.
- Optimize the method parameters for maximum sensitivity and accuracy.
- Validate the developed method using standard teneligliptin solutions.
- Apply the developed method to analyze teneligliptin in pharmaceutical formulations.

IV. PLAN OF WORK

Literature Review:

- Review existing analytical methods for the estimation of Teneligliptin.
- Identify the advantages and limitations of spectroscopic techniques (UV and FTIR) for pharmaceutical analysis.

Selection of Materials and Reagents

- Procurement of pure Teneligliptin standard and pharmaceutical formulations.
- Selection of suitable solvents and reagents for UV and FTIR spectroscopic analysis.

Development of UV Spectroscopic Method

- Determination of the maximum absorption wavelength (max) of Teneligliptin.
- Preparation of standard stock solutions and working dilutions.
- Establishment of a calibration curve by measuring absorbance at selected wavelengths.

Development of FTIR Spectroscopic Method

- Identification of characteristic functional groups in Teneligliptin using FTIR spectroscopy.
- Recording the FTIR spectrum and analyzing peak assignments for molecular confirmation.

Method Validation (As per ICH Guidelines)

- Accuracy: Recovery studies at different concentration levels.
- Precision: Repeatability and intermediate precision studies.
- Specificity: Ensuring no interference from excipients.
- Linearity and range: Constructing a calibration curve and determing correlation coefficient.
- Robustness & Ruggedness: Evaluating method stability under small variations in experimental conditions.

Application of the Method

- Analysis of Teneligliptin in bulk drug and marketed formulations.
- Comparison of results with existing analytical techniques to establish reliability.

Data Analysis and Interpretation

- Statistical analysis of validation parameters.
- Discussion of findings in comparison with previously reported methods.

Documentation and Report Preparation

- Compilation of all experimental data, graphs, and spectra.
- Preparation of a research paper or thesis summarizing the findings.

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V. DRUG PROFILE

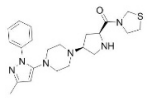
Parameters	Information
Drug Name	Teneligliptin HBr
Brand Name	Teneliglip
Structure	
Weight	426.58 g/mol
Chemical formula	$C_{22}H_{30}N_{60}S$
IUPAC name	(2S,4S)-4-[4-(5-methyl-2-phenylpyrazol-3-yl)piperazin-1-yl]pyrrolidin-2-yl]-(1,3-thiazolidin-3-yl)methanone.
BCS class	Class II
Half life	Approx. 24.2hours
Pka1	0.10
Log P	Approx. 2.24
Particle size	Small 2.5 µm or large 5 um
Hygroscopicity	Non hygroscopic
Polymorphic form	Form A,B,C
Solid state stability	Stable in acidic
Melting point	208°C
Tmax	1 hour
Solubility	Soluble in water

Table1.Drug Profile

VI. MATERIALS AND METHODS

UV Method :

Material :

- Chemical and reagents
- Instrumentation and chromatographic conditions.
- Preparation of standard stock solution.
- Analysis of Teneligliptin HBr

Validation parameter:

- Optimization Of Procedure
- Specificity and Selectivity
- Precision
- Accuracy
- Linearity
- Range

Chemicals & Reagents

- Ethanol, Distilled water

Instrumentation: UV Spectroscopy

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Preparation of Standard :

Weigh and transfer accurately about 20 mg of Teneligliptin working standard to a 100 mL volumetric Flask. Add 70 mL of water and sonicate to dissolve and make up the volume with water.

Preparation of Sample:

Accurately weighed and transferred 20mg of HBr working standard into 100ml clean dry volumetric flask added volume of diluent sonicated for 5 min and made up to the final volume with diluent from the above stock solution 0.2ml,0.4ml,0.6ml,0.8ml and 1ml of Teneligliptin HBr were pipetted into 10ml volumetric flask and made up to 10 ml diluent to get mixed standard solution containing concentration of 20,40,60,80,100 ppm respectively.

Determination of λ max

An appropriate aliquot portion of Teneligliptin HBr (0.2mL) were transferred to two separate 10 mL volumetric flasks, the volume was made up to the mark using ethanol to obtain Tene HBr(2µg/mL). Drug solutions were scanned separately between 200 nm to 400 nm.

Figure 6. Preparation of solutions

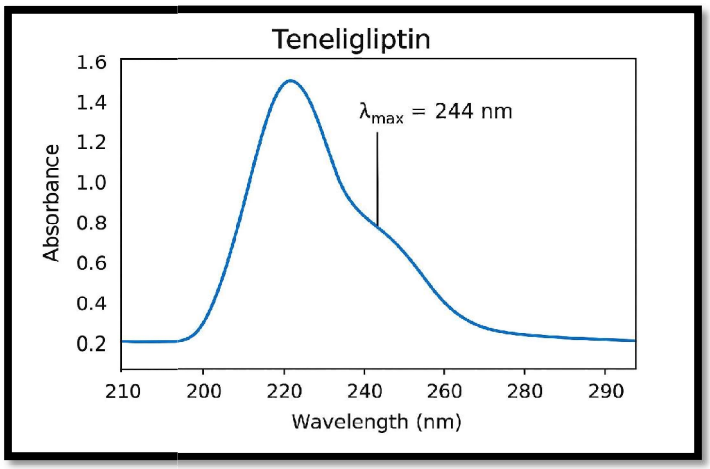

Figure 7. λ max of Teneligliptin

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Validation

Analytical method validation is an essential requirement to perform the chemical evaluation .Method validation is a procedure of performing numerous assessment designed to verify that an analytical test system is suitable for its intended reason and is capable of providing beneficial &legitimate analytical data.

The Proposed method was validated as per the ICH guidelines

Validation parameters:

Specificity and Selectivity

An analytical method's ability to accurately measure the analyte of interest in the presence of other components in the sample matrix, such as impurities, degradation products, or excipients.

Precision

The precision of an analytical method is the degree of agreement among individual test results when the method is applied repeatedly to multiple sampling of a homogeneous sample

Accuracy

The accuracy of an analytical method is the closeness of test results obtained by that method to the true value. The accuracy of an analytical method should be established across its range.

Linearity

The linearity of an analytical method is its ability to elicit test results that are directly, or by a well- defined mathematical transformation, proportional to the concentration of analyte in samples within a given range.

Range

The range of an analytical method is the interval between the upper & lower levels of analyte (including these levels) that have been demonstrated to be determined with a suitable level of precision, accuracy, & linearity using the method as written.

Steps in method validation:

- Develop a validation protocol or operating procedure for the validation
- Define the application, purpose and scope of the method
- Define the performance parameters and acceptance criteria
- Define validation experiments
- Verify relevant performance characteristics of equipment
- Qualify materials, e.g. standards and reagents
- Perform pre-validation experiments
- Adjust method parameters or/and acceptance criteria if necessary
- Perform full internal (and external) validation experiments
- Develop SOPs (standard operating procedures) for executing the method in the routine

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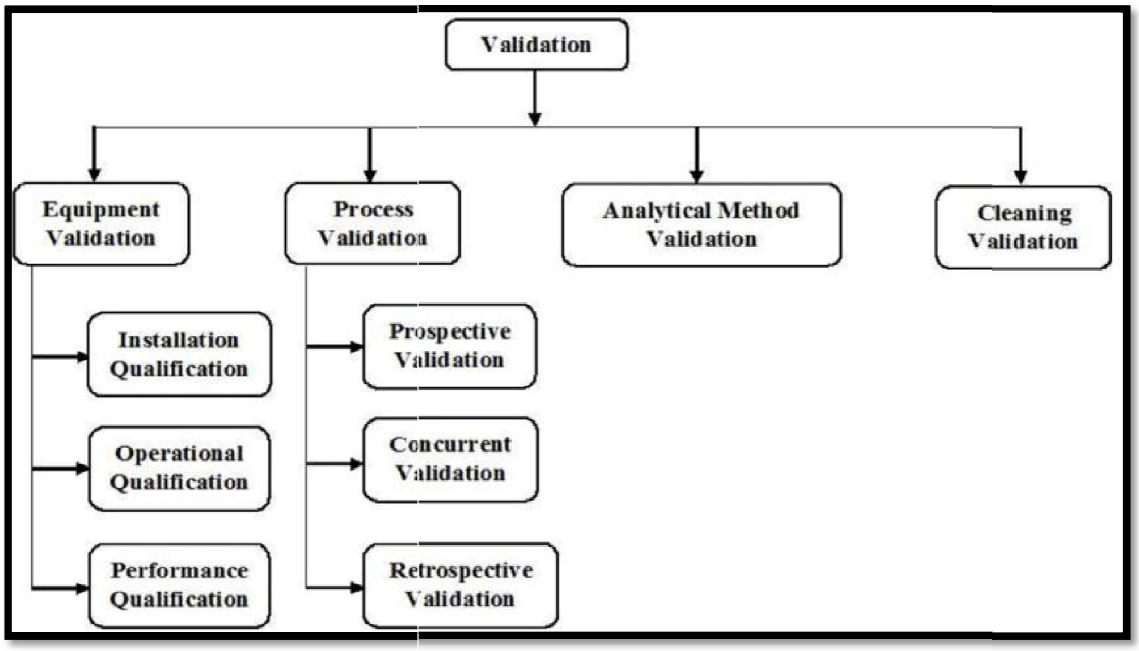

Figure 8. Types of validation

1. Specificity and Selectivity:

The specificity of the method was ascertained by analyzing standard drugs and sample. The retention time (RT) Of Teneligliptin was confirmed by comparing the RT with that of the standard. The use of the standard Teneligliptin and interference was observed in the chromatogram of blank.

Sample	Teneligliptin	Remarks
Blank	0.00	----------
Standard	0.319	No Interference
Sample	0.321	No Interference

Table 2. Specificity study of UV

Acceptance Criteria:

Placebo should not interfere in the absorbance of the Teneligliptin .

Conclusion:

There is no interference in the absorbance of Blank preparation of the Teneligliptin .

2. Precision :

Precision is a measurement of degree of Reproducibility of analytical method and it will be expressed in terms of % relative standard for the area and retention time of Solution prepared. The precision of an analytical procedure Expresses the closeness of agreement (degree of scatter) between a series of measurements obtained from Multiple sampling of the same homogeneous sample under the prescribed conditions.

No. of Sample	UV reading	%Assay
Standard	0.3215	100.06%
Sample	0.3217	

Table 3. Precision study of UV

Acceptance Criteria:

Teneligliptin content should be within limits NLT 90.0% & NMT 110.0% of the labeled amount.

Conclusion:

% Assay is 100.06% for Teneligliptin which is well acceptable limit, hence the method is Precise.

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3.Accuracy:

The accuracy of an analytical method is defined as the closeness between the observed values with actual or true Value for a specific concentration. Accuracy – closeness to the true value, measured by % recovery of sample Spikes or % error in the analysis of a reference sample

Level	Added conc.(mg)	Teneligliptin absorbance	Qty.Recoverd (mg)	%Recovery (Assay)
80%	0.1600	0.2541	0.1603	100.17
100%	0.2000	0.3173	0.2001	100.06
120%	0.2400	0.3825	0.2412	100.52
Average				100.25

Table 4. Accuracy study of UV

Acceptance Criteria:

%RSD for %Recovery should not be more than 2.0 %.

%Recovery should be between 98.0% to 102.0% for individual and for all level

Conclusion:

%Recovery for Teneligliptin is 100.17% for 80%, 100.06% for 100%, 100.52% for 120%, and 100.25% for All level, which is well acceptable limit, hence the method is accurate

4. Linearity and Range:

No.of injection	Conc.(ppm)	Titrant (ml) consume
1.	160.0	0.2618
2.	180.0	0.2948
3.	200.0	0.3257
4.	220.0	0.3543
5.	240.0	0.3876
Coefficient Correlation=		0.9998
Y- Intercept=		0.0012
Slope=		0.0016

Table 5. Linearity study of UV

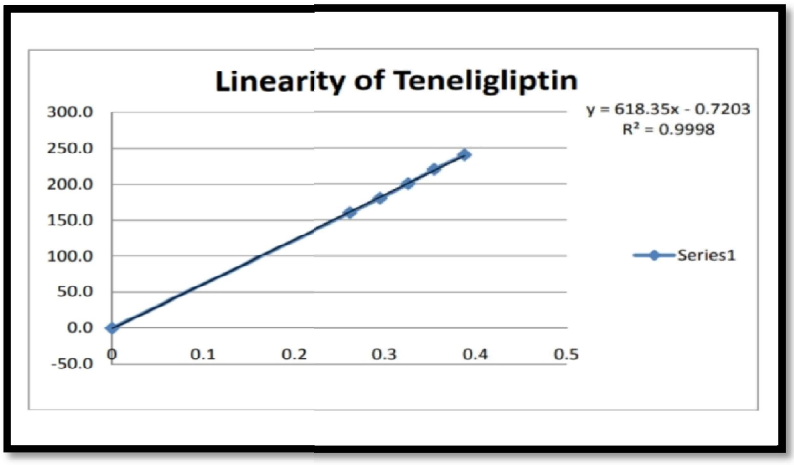

Figure 9. Linearity of Teneligliptin

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Acceptance criteria:

Correlation coefficient should not be less than 0.99

Conclusion:

Correlation coefficient is 0.9998 and method is linear. Which is well acceptable limit hence the method is linear for Teneligliptin .

FTIR Method:

Material :

- Chemical and reagents
- Instrumentation and chromatographic conditions.
- Preparation of standard stock solution.
- Analysis of Teneligliptin HBr

Validation parameter:

- Optimization Of Procedure
- Specificity and Selectivity
- Precision
- Intermediate Precision
- Accuracy
- Robustness

Chemicals & Reagents

- Teneligliptin, potassium bromide

Instrumentation : FTIR Spectroscopy

Preparation of Standard:

Accurately weigh 1-2 mg of Teneligliptin HBr.Mix it with about 100 mg of dry KBr powder. Grind the mixture uniformly using a mortar and pestle.Compress the mixture using a hydraulic press to form a transparent pellet.Run the FTIR spectrum and record characteristic absorption peaks (usually between 4000–400 cm^{-1}).

Determination of Spectrum:

- **Instrument Preparation:** Switch on the FTIR instrument and allow it to stabilize. Check that the instrument is properly calibrated and validated.
- **Background Scan:** Ensure the sample holder is empty or has a clean KBr pellet in place. Run a background scan across the full IR range (typically 4000–400 cm^{-1}).
- **Sample Analysis:** Place the prepared Teneligliptin HBr-KBr pellet into the sample holder. Run the FTIR scan using the same parameters as the background. Collect the sample spectrum by subtracting the background spectrum.
- **Spectrum Evaluation:** Observe and record the absorption peaks in the IR spectrum. Compare the obtained peaks with the reference standard spectrum of Teneligliptin HBr. Confirm the presence of characteristic functional group peaks (e.g., N-H, C=O, C-N, aromatic C=C).

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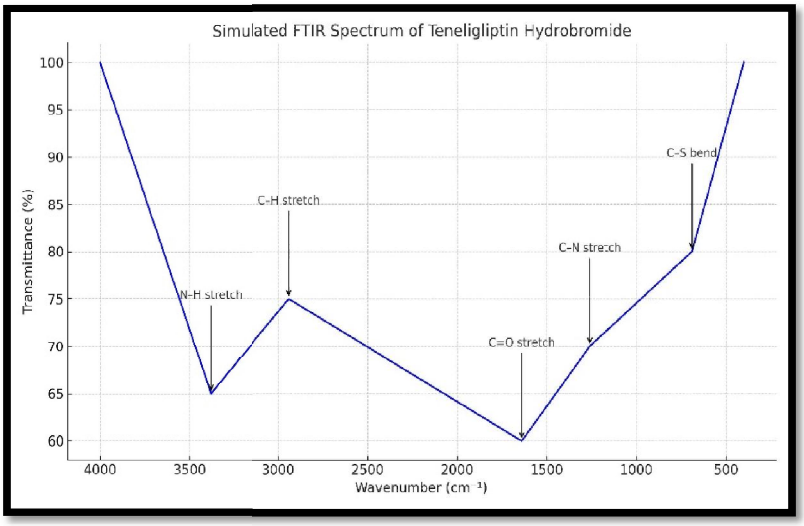

Figure 10. Standard Spectrum of Teneligliptin HBr

Validation:

1. Specificity: Ability to assess the analyte distinctly without interference.

Sample	Outcomes	Result
Standard	Characteristics peak	Pass
Test sample	Same peak as standard	Pass
Blank	No peak at API region	Pass

Table 6. Specificity study of IR

Acceptance Criteria : Sample spectrum should match the standard.

Conclusion: If all characteristic peaks (e.g., N-H at ~3300 cm^{-1}, C=O at ~1700 cm^{-1}, C-N at ~1300 cm^{-1}) appear in the sample and not in the blank, specificity is confirmed.

2. Precision: A series of measurements obtained from multiple samplings of the same homogeneous sample under the same conditions.

Parameter	Value
Mean	0.858
Standard Deviation	0.0024
% RSD	0.28%

Table 7. Precision study of IR

Acceptance Criteria: %RSD of peak intensities or areas for major bands should be ≤2%.

Conclusion: If %RSD is within the acceptance limit, the FTIR method is precise and validated for Teneligliptin API.

3. intermediate precision: To evaluate the intermediate precision (ruggedness) of the FTIR method by assessing variability between different analysts or days.

Parameter	Analyst 1	Analyst 2
Mean	0.858	0.8565
Standard Deviation	0.0024	0.0017
%RSD	0.28%	0.20%

Table 8. Intermediate precision study of IR

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Acceptance Criteria: %RSD ≤ 2.0%

Conclusion: If %RSD of absorbance (or area) for key peaks is ≤ 2%, the precision of the FTIR method for Teneligliptin is validated.

4. Accuracy: To evaluate the accuracy of the FTIR method by calculating the percent recovery of known amounts of Teneligliptin.

Level	Amount Spiked	Amount recovered	%Recovery
80	7.98	99.75	99.75
100	10.02	100.20	100.20
120	12.0	12.03	100.25

Table 9. Accuracy study of IR

Acceptance Criteria: Recovery should be within 98–102% at each level

Conclusion: FTIR method for Teneligliptin API is accurate.

5. Robustness: Slightly vary experimental parameters (e.g., sample amount, pressure in ATR).

Parameter	Variation
KBr: Sample Ratio	90:10 vs 100:1
Pellet Pressure	5 tons vs 6 tons
Scan Number	16 scans vs 20 scan
Resolution	2 cm^{-1} vs 4 cm^{-1}

Table 10. Robustness study of IR

Acceptance Criteria: No significant changes in peak position or intensity.

Conclusion: If all modified conditions produce absorbance values within 2% of the standard and no peak shift occurs, the method is robust.

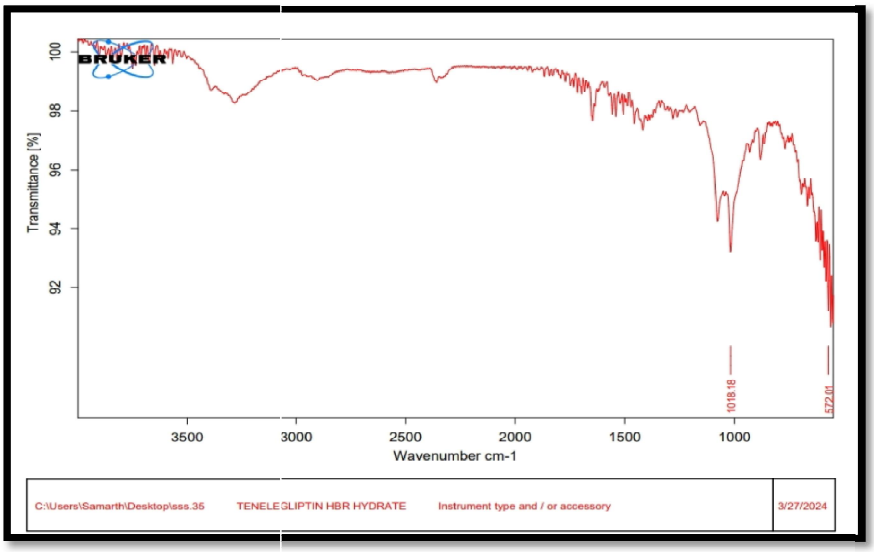

Figure 11. Spectrum of Teneligliptin API

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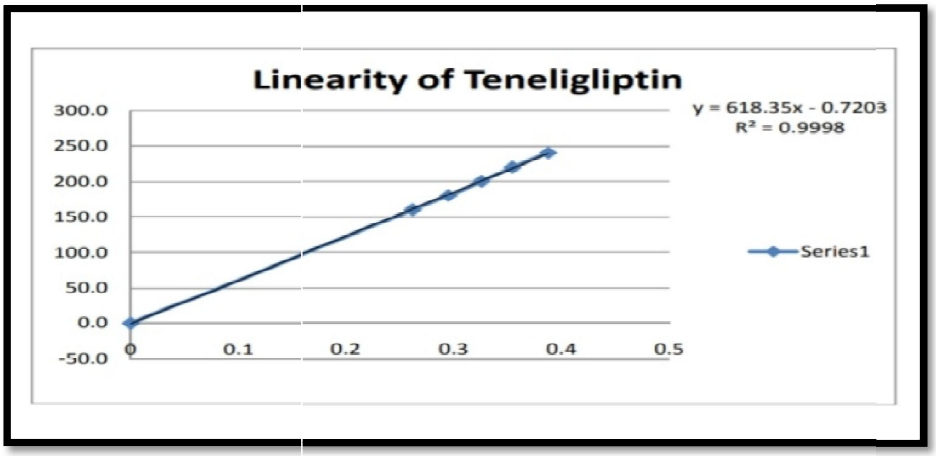
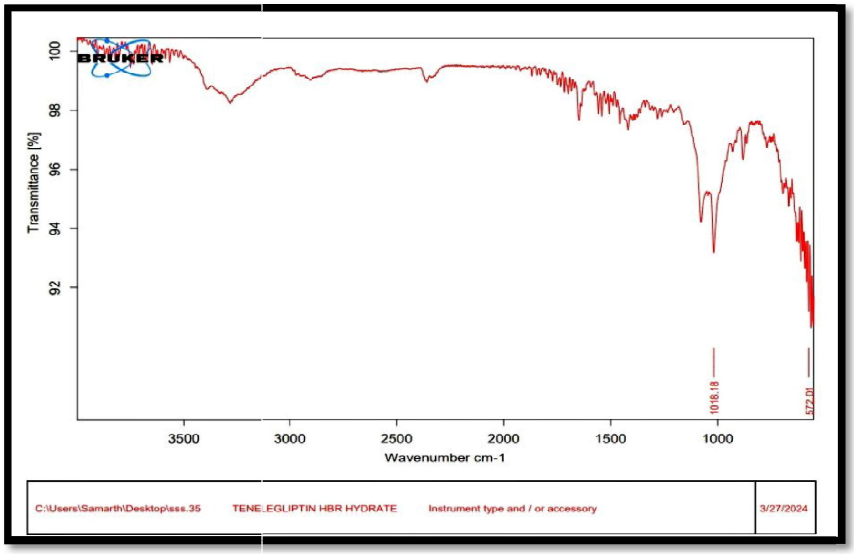
VII. RESUIT AND DISCUSSION:



The present study was carried out to develop a simple, sensitive, precise and accurate UV spectrophotometric method for the simultaneous estimation of Teneligliptin HBr in pharmaceutical dosage forms. The wavelength spectrum of Teneligliptin HBr exhibit at 244 nm respectively. Beer Lambert's law was obeyed.

Precision was found having wavelength 244nm and %RSD was found to be 0.3876 and %RSD NMT 2%.The limit of detection and limit of quantification was found to be 220µg/ml and 240 µg/ml respectively. The linear graph was found. Accuracy was found.



The FTIR spectrum confirms the presence of characteristic functional groups in Teneligliptin HBr Hydrate, including hydroxyl (O-H), amine (N-H), alkyl (C-H), aromatic (C=C), and halogen (C-Br) related absorptions. These results are consistent with the known structure of the compound, supporting its identity and purity.

VIII. SUMMARY AND CONCLUSION:

The study focuses on developing and validating a novel analytical method using UV-Visible and Fourier Transform Infrared (FTIR) spectroscopy for the qualitative and quantitative analysis of Teneligliptin, a DPP-4 inhibitor used in the treatment of type 2 diabetes mellitus. The UV method was optimized at a specific wavelength, while the FTIR method was used to identify functional groups and confirm drug identity. The developed method was validated in accordance with ICH guidelines, evaluating parameters such as Specificity, linearity, accuracy, precision, Intermediate precision

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and robustness. The method showed good linearity over the selected concentration range with high correlation coefficients. Accuracy and precision results were within acceptable limits, indicating the reliability of the method.

The developed UV-FTIR spectroscopic method was found to be simple, accurate, precise, cost-effective, and suitable for the routine analysis of Teneligliptin API in bulk form. The validation results confirmed that the method meets ICH requirements and can be effectively used for quality control purposes in pharmaceutical industries. The combination of UV and FTIR techniques provided a comprehensive approach for both quantitative and qualitative assessment, enhancing method reliability and specificity.

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