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# UV-Spectroscopy analytical method development and Validation of Teneligliptin Hydrobromide Hydrate

Kulshreshth Sharma*[1], Gyanendra Patel, Gurmeet Chhabra, LalitDhakar, Nimitamanocha

[1.] *Indore institute of Pharmacy*
*Corresponding author- Kulshreshth Sharma*

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**ABSTRACT**
A simple, selective, and rapid UV-Vis spectrophotometer (UV-1800AD) method for the analysis of teneligliptin hydrobromide hydrate in bulk and in tablet dosage form has been developed and validated. The diluent of water: MeOH in the ratio of 80:20 ml v/v was delivered. Studies were performed on a UV-Vis Spectroscopy λmax at 245nm. The method is specific to teneligliptin hydrobromide hydrate and is able to quantify it from the tablet. The calibration curve was linear over the concentration range of 10-60µg/ml (r=0.999). The results of the analysis of method precision and intermediate precision were found within the acceptance criteria of ±2. The proposed method is applicable to the routine analysis of Teneligliptin Hydrobromide Hydrate in bulk and in tablet dosage form.

**Keywords:** Teneligliptin Hydrobromide Hydrate, UV-Vis Spectrophotometer (UV-1800AD), validation.

## I. INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic disease, in which there is persistent hyperglycemia due to defects in insulin secretion or insulin action or both. It is one of the biggest global health issues faced by hundreds of millions of people around the world and is also a major cause of morbidity and mortality, and healthcare costs. The International Diabetes Federation (IDF) estimates that in 2021 there were 537 million adults with diabetes, the number is expected to rise to 643 million in 2030 and to 783 million in 2045. Nearly 90-95% of all diabetes cases are related to Type 2 diabetes mellitus (T2DM), which is closely linked to childhood/obesity, sedentary lifestyle and unhealthy eating habits, aging and genetic predisposition. The risk of developing diabetic nephropathy, retinopathy, neuropathy, cardiovascular disease and stroke are significant with persistent hyperglycemia, so there is a need for appropriate glycemic control and quality pharmaceutical products for long-term use. **[1–3]**

Dipeptidyl peptidase-4 (DPP-4) inhibitors are one of the most clinically important oral antidiabetic medications due to their efficacy for improving glycemic control, low risk for hypoglycemia and lack of weight gain, and efficacy as monotherapy and in combination with other medications. DPP-4 inhibitors exert their antihyperglycemic effect by inhibiting the enzymatic degradation of incretin hormones, mainly glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). These hormones, when released in higher amounts, increase the secretion of insulin, dependent on glucose, and decrease glucagon secretion, which ultimately improves blood glucose levels after meals and throughout the night.**[4-6]**

Teneligliptin hydrobromide hydrate belongs to the third generation of DPP-4 inhibitors and has shown to be a highly effective drug in the treatment of T2DM in Asian countries such as India and Japan. Unique J-shaped molecular structure which gives excellent binding affinity to the catalytic site in the DPP-4 enzyme, causing enzyme inhibition to be extended, which leads to glycemic control. After oral administration, Teneligliptin is rapidly absorbed, achieving peak plasma level in about 1 hour and a half-life of almost 24 hours for the maximum once-daily dosing. The drug has good pharmacokinetic and pharmacodynamic characteristics and is commonly used in combination with other oral hypoglycemic agents and/or metformin.**[5-7]**

Throughout the pharmaceutical product lifecycle, reliable analytical methods are needed to verify the identity, purity, potency and stability of the drug substance and finished dosage forms. Analytical procedures are routinely used in raw material testing, formulation development, in-process quality control, dissolution, stability testing and batch release. Analytical methods should be scientifically validated in order to be used routinely by regulatory agencies

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and to provide consistent results that are accurate, precise and reproducible. Typical parameters used for validation are specificity, linearity, accuracy, precision, robustness, limit of detection (LOD) and limit of quantification (LOQ).**[8]**

Several analytical techniques have been reported for the quantitative estimation of Teneligliptin in bulk drug, pharmaceutical formulations and biological matrices. These encompass reverse-phase high-performance liquid chromatography (RP-HPLC), high-performance thin-layer chromatography (HPTLC), liquid chromatography–mass spectrometry (LC-MS/MS), ultra-performance liquid chromatography (UPLC) and UV-visible spectrophotometry. While sensitive and selective, chromatographic methods are less practical for routine QC labs with limited resources due to the need for expensive solvents, complex instruments and long analysis times and the need for highly trained staff.**[9-12]**

UV-Visible spectrophotometry is one of the most accepted methods for routine pharmaceutical analysis, due to its simplicity, speed, accuracy, reliability, low cost and ease of use. It is a technique that is based on the absorption of ultraviolet radiation by chromophoric groups that are present in the drug molecules, and is known as the Beer–Lambert law at a suitable range of concentration. The spectrophotometric method is based on UV and these methods require little sample preparation and comparatively less quantity of solvents and are capable of being used in routine estimation of the pharmaceutical formulation in the industrial and academic laboratory.**[13-14]**

Previously several spectrophotometric methods using ultraviolet spectroscopy have been reported for estimation of Teneligliptin in pharmaceutical dosage forms. But progress is still underway to create analytical procedures that are simpler, more cost-effective, environmentally friendly, and fully conform to the most recent guideline from the International Council for Harmonisation (ICH) Q2(R2) for validation of analytical procedures. It is highly desirable to have a validated UV spectrophotometric method with high accuracy, precision, robustness and reproducibility for routine QC applications.**[8-10,14]**

For this reason, present work was undertaken to develop and validate the simple, rapid, accurate and precise UV spectrophotometric method for the quantitative estimation of Teneligliptin in bulk drug and marketed tablet dosage form with economy. The developed analytical method was validated following ICH Q2(R2) guidelines which included evaluation of specificity, linearity, accuracy, precision, robustness, limit of detection, limit of quantification and assay, which resulted in the development of a reliable analytical method for routine pharmaceutical quality control applications.

**Structure**

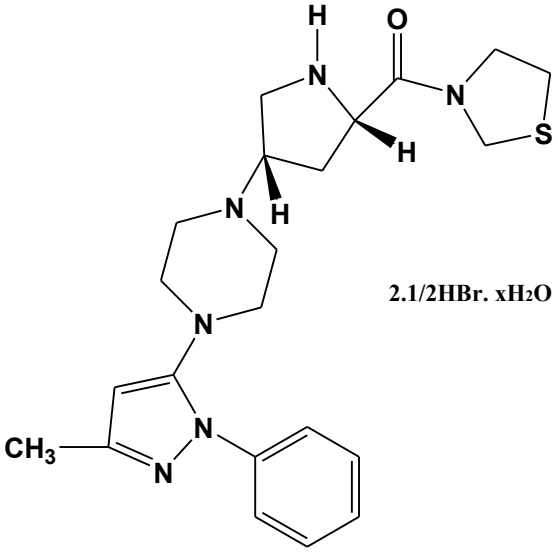


**Figure 1: Structure of Teneligliptin HBr**

## II. MATERIALS AND METHODS:

**Instrumentation:**
Analysis was performed using a double-beam UV-Visible spectrophotometer 1800AD, a model of Shimadzu equipped with matched 1 cm quartz cells and UV analysis software. An analytical balance with a sensitivity of 0.1 mg, an ultrasonic bath, and Whatman No. 41 filter paper were used during the study.

**Chemicals and reagents:**
Teneligliptin Hydrobromide Hydrate working standard (purity ≥99.5%) was obtained as a gift sample from Micro Labs, Bengaluru. Methanol (HPLC grade), distilled water, and analytical reagent (AR) grade chemicals were used throughout the study. All solutions were prepared using freshly prepared distilled water.

**METHOD DEVELOPMENT:**

**Selection of wavelength:**
The λ max of Teneligliptin was determined by using a UV-visible spectrophotometer 1800AD and found to be 245nm.

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**Preparation of standard stock:**

Approximately 10 mg of Teneligliptin was accurately weighed and transferred into a 100 mL volumetric flask. The drug was dissolved in the selected solvent with sonication for 10 minutes and diluted to volume to obtain a stock solution of 100 µg/mL.Linear alternatives are established by diluting the stock solution with the diluent. Concentrations of 10, 20, 30, 40, 50, 60µg/mL of teneligliptin are prepared in 10ml volumetric flasks. pipette 1, 2, 3, 4, 5, 6ml, and dissolved in the diluent to obtain these concentrations dimension of 10-60µg/mL.A suitable aliquot was further diluted to obtain a working solution of 10 µg/mL. The solution was scanned between **200 and 400 nm** against the corresponding blank solvent using a UV-Visible spectrophotometer. The wavelength showing maximum absorbance (λmax) was selected for subsequent quantitative analysis. Previous studies have reported λmax values around **245 nm**, although the exact value should be confirmed experimentally.

**Preparation of Calibration Curve:**

Aliquots of teneligliptin are made from the stock solution (100µg/mL) in a 10ml volumetric flask sequence. The Diluent has been used to dilute the label to achieve a concentration range of 10-50µg/mL. Solutions were observed for the absorbance and reported. The calibration curve has been set. The law on beer applies to 10-50µg/mL range.The absorbance of each working standard solution was measured at the selected λmax using the blank solvent as reference. A calibration curve was constructed by plotting absorbance versus concentration, and linear regression analysis was performed to obtain the regression equation and correlation coefficient ($R^2$).

## III. METHOD VALIDATION

**Lenearity:**

It consisted of a matrix sample processed without analyte and a matrix sample with calibration standards. It is showing good linearity over the range of 10 to 60µg/ml with a coefficient of correlation of 0.999.

**Table 1: Calibration data of TeneligliptinHBr by UV spectroscopy method**

| Sl. No | Conc. (µg/ml) | Absorbance of Teneligliptin Hbr |
|---|---|---|
| 1 | 10 | 0.234 |
| 2 | 20 | 0.420 |
| 3 | 30 | 0.596 |
| 4 | 40 | 0.790 |
| 5 | 50 | 0.971 |
| 6 | 60 | 1.160 |

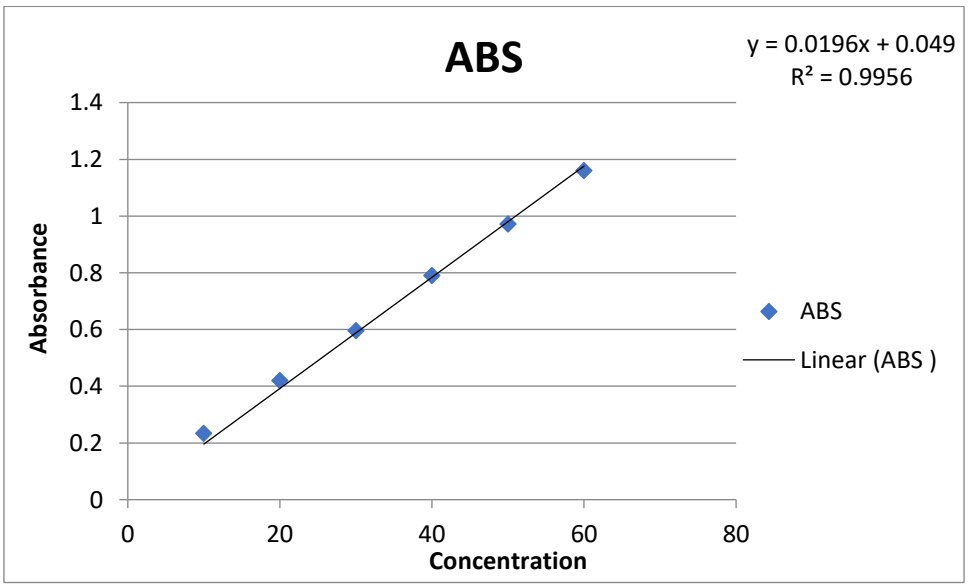


**Figure 2: Linearity graph of Teneligliptin HBr by UV spectroscopy method**

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**Accuracy:**
At 80 percent, 100 percent, and 120 percent generic solution rates, the accuracy of Teneligliptin was calculated. Absorption was estimated at 246nm, and percent recovery results were reported.Each level was analyzed in triplicate, and percentage recovery was calculated.

**Table 2: Results for the Accuracy of Teneligliptin HBrby UV spectroscopy method**

| % Conc. | Test Sample | Spiked Conc. (ug/ml) | Abs | % Recovery | AVG | STDEV | % RSD |
|---|---|---|---|---|---|---|---|
| **80** | Test 1 | 2.4 | 0.436 | 99.2 | 99.93 | 0.66 | 0.66 |
| | Test 2 | 2.4 | 0.429 | 100.1 | | | |
| | Test 3 | 2.4 | 0.430 | 100.5 | | | |
| **100** | Test 1 | 3.0 | 0.541 | 101.0 | 100.46 | 0.75 | 0.75 |
| | Test 2 | 3.0 | 0.543 | 99.6 | | | |
| | Test 3 | 3.0 | 0.547 | 100.8 | | | |
| **120** | Test 1 | 3.6 | 0.634 | 100.1 | 99.76 | 0.35 | 0.35 |
| | Test 2 | 3.6 | 0.671 | 99.4 | | | |
| | Test 3 | 3.6 | 0.636 | 99.8 | | | |

**Precision:** Precision was evaluated as repeatability, intraday precision, and interday precision. Six replicate determinations were performed, and results were expressed as percentage relative standard deviation (%RSD).

**Table 3: Results for the Precision of TeneligliptinHBr by UV spectroscopy method**

| Sl. No | ABS | RESULT | |
|---|---|---|---|
| 1 | 0.541 | 101.0 | **STDV** = 0.657<br>**% RSD** = 0.754 |
| 2 | 0.543 | 99.6 | |
| 3 | 0.547 | 100.8 | |
| 4 | 0.540 | 99.5 | |
| 5 | 0.545 | 100.1 | |
| 6 | 0.548 | 100.8 | |
| | **MEAN** | 100.3 | |

**Ruggedness (Intermediate Precision):** Ruggedness was determined by performing the analysis using different analysts and on differentdays under identical experimental conditions.

**Table 4: Results for the Ruggedness (Intermediate Precision) of TeneligliptinHBr by UV spectroscopy method**

| Concentration | % Assay (Analyst1) | %Assay (Analyst2) |
|---|---|---|
| 30µg/ml | 0.547 | 0.550 |
| | 0.532 | 0.549 |
| | 0.542 | 0.546 |
| | 0.548 | 0.554 |
| | 0.540 | 0.552 |
| | 0.541 | 0,548 |
| **Average** | 0.542 | 0.550 |
| **SD** | 0.006 | 0.003 |
| **%RSD** | 1.061 | 0.551 |
| **Difference between Precision and intermediate precision should not more than 2** | 0.307 | 0.203 |

**LOD & LOQ:**
The limit of detection (LOD) represents the lowest amount of analyte that can be detected but not necessarily quantified accurately. LOD was calculated statistically using the standard deviation of the response (σ) and the slope (S) of the calibration curve according to the following equation: LOD = 3.3 × (σ/S)

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The limit of quantification (LOQ) is defined as the lowest concentration of analyte that can be quantitatively determined with acceptable accuracy and precision. LOQ was calculated using the equation: LOQ = 10 × (σ/S)

**Table 5: Results for LOD & LOQ of Teneligliptin by HBrUV Spectroscopymethod**

| | |
|---|---|
| **LOD (µg/ml)** | 1.42 |
| **LOq (µg/ml)** | 3.77 |

**Robustness:**

**(A) Change in diluent ratio:**

The robustness of a method is a measurement of its ability to remain uninfluenced by limited, but deliberate, system parameter variations and offers a performance indicator during routine use.

**Table 6: Results for Change in diluent ratio of Teneligliptin HBr by UV Spectroscopy method**

| **Diluent Ratio** | 50:50 v/v ml | 80:20 v/v ml |
|---|---|---|
| **Concentration** | 30µg/ml | 30µg/ml |
| | 99.02 | 100.8 |
| | 98.12 | 99.1 |
| **%Assay** | 98.42 | 100.2 |
| **Average** | 98.52 | 100.03 |
| **SD** | 0.458 | 0.463 |
| **Difference between precision and Robustness should not more than 2** | 1.94 | 0.43 |

**(B) Change in Absorbance ratio:**

**Table 7: Results for Change in Absorbamce of Teneligliptin HBr by UV Spectroscopymethod**

| **Concentration** | **243nm** | **247nm** |
|---|---|---|
| 30µg/ml | 101.296 | 100 |
| | 98.518 | 0.998 |
| | 100.370 | 99.272 |
| | 101.481 | 98.181 |
| | 100 | 100.36 |
| | 100.1 | 101.45 |
| **Average** | 100.29 | 99.84 |
| **SD** | 1.06 | 1.09 |
| **%RSD** | 1.06 | 1.09 |
| **Difference between Precision and intermediate precision should not more than 2** | 0.31 | 0.34 |

## IV. RESULT AND DISCUSSION

UV Visible spectrophotometric method for Teneligliptin hydrobromide Hydrate was developed it was found accurate, precise and robust. Developed method shows high $R^2$ valve of 0.995.There is a moderate level of correlation between concentration and absorbance. High accuracy is achieved, withThe recovery rate is 98%-102%, and ensuring reliable quantification. Precision is also noteworthy, with relative standard deviation (RSD) values less than 2% indicating consistent and reproducible results. The robustness of the method and ruggedness further enhance its reliability under varying conditions. Can be applied for commercial purposes.The formulations are broadened to increase the range of its use. The The simplicity of the technique, combined with its cost-effectiveness, is an attractive option for Periodic quality control analyses. Additionally, the The wide linear range gives the possibility to analyzeSamples of different concentrations, Improving versatility of the method in pharmaceutical applications.

## V. CONCLUSION:

API form of Teneligliptin hydrobromide was thoroughly developed and validated by UV spectrophotometric analytical method for quantitative determination. The presented method was found to be simple, precise, accurate, rugged, reproducible and gives an acceptable recovery of the analyte, which can be directly easily applied to the analysis of pharmaceutical tablet formulation of Teneligliptin Hydrobromide Hydrate.

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