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## Review Article

# A Review on Analytical Method Development for Drug Sitagliptin

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### ABSTRACT

The Sitagliptin offer significant therapeutic benefits in managing type 2 diabetes mellitus (T2DM) and associated cardiovascular risks. The development of accurate, precise, and validated analytical methods is crucial for ensuring their efficacy, safety, and regulatory compliance. This review explores various analytical techniques, including High-Performance Liquid Chromatography (HPLC), Reverse Phase HPLC (RP- HPLC), High-Performance Thin Layer Chromatography (HPTLC), Liquid Chromatography-Mass Spectrometry (LC-MS/MS), and UV spectrophotometry, highlighting their advantages, challenges, and validation parameters.


## INTRODUCTION

The development of analytical methods for drug sitagliptin is crucial in ensuring accurate quantification, quality control, and regulatory compliance in pharmaceutical formulations. Similarly, sitagliptin, another DPP-4 inhibitor, combined with dapagliflozin, a sodium-glucose co-transporter-2 (SGLT2) inhibitor, provides a dual mechanism to control hyperglycemia by increasing insulin secretion and promoting glucose excretion via urine. The primary focus in analytical method development for these FDCs is

to ensure high precision, accuracy, robustness, and environmental sustainability in pharmaceutical analysis. Various chromatographic techniques, such as reverse-phase high-performance liquid chromatography (RP- HPLC) and high-performance thin-layer chromatography (HPTLC), have been extensively employed for their sensitivity, reproducibility, and efficiency in separating drug components. High-performance liquid chromatography (HPLC) has been widely utilized for the simultaneous analysis of these combination drugs due to its precision, accuracy, and reproducibility. For instance, a study on

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sitagliptin and dapagliflozin demonstrated a rapid RP-HPLC method with a correlation coefficient of 0.9999, indicating high reliability [1] The validation of these analytical methods is a crucial aspect, with key parameters such as specificity, precision, and accuracy ensuring their reliability. Studies have shown that the developed methods for these drug combinations have low relative standard deviations, further confirming their robustness [27] Additionally, regulatory compliance plays a significant role in method development, as adherence to standards ensures the acceptability of these methods for market approval and routine quality control [27] While significant advancements have been made in developing efficient analytical methods for these combination drugs, challenges remain in standardizing techniques across different formulations and ensuring their applicability in routine quality control settings. This highlights the need for ongoing research in analytical method development to further enhance the precision, sensitivity, and regulatory acceptance of these techniques.

## 1.1 Drug Profile

### 1. Drug Profile: Sitagliptin

Sitagliptin is a DPP-4 inhibitor that improves glycemic control in T2DM by increasing incretin hormone levels, leading to enhanced insulin secretion and reduced glucagon production. This regulation helps maintain blood glucose balance, particularly after meals. Sitagliptin is commonly prescribed with metformin or other antidiabetic drugs due to its well-tolerated profile and effectiveness in diabetes management.

### Pharmacological Classification

Sitagliptin is classified as a DPP-4 inhibitor that enhances incretin hormone levels, leading to

improved insulin secretion and decreased glucagon levels, thereby contributing to better glycemic control.

### Mechanism of Action

Sitagliptin inhibits the DPP-4 enzyme, prolonging the activity of incretin hormones such as GLP-1 and glucose-dependent insulinotropic polypeptide (GIP). This results in enhanced insulin secretion and reduced glucagon release, improving overall glucose homeostasis.

### Therapeutic Uses

Sitagliptin is primarily used for glycemic control in T2DM and is often prescribed alongside metformin to enhance its effectiveness in lowering blood glucose levels [8]. Sitagliptin is generally well-tolerated but may cause mild gastrointestinal disturbances, headache, and potential allergic reactions [8]

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**Figure 1: Sitagliptin and Dapagliflozin (Source)**

### Market Availability

Sitagliptin is widely available and approved for T2DM treatment, often used in combination with other antidiabetic medications. Fixed-dose combinations of sitagliptin and dapagliflozin are under clinical evaluation for improved efficacy and safety. Dapagliflozin was first approved by the FDA in 2014 for T2DM management and later received approvals for chronic kidney disease (2021) and heart failure (2020, 2023). It is available in multiple countries, including the EU, where it is indicated for both monotherapy and combination therapy with other glucose-lowering agents. [2-5]

**Table 1: Physicochemical Properties of Sitagliptin**

Parameter	Sitagliptin	Authors	Reference
Molecular Formula	C <sub>16</sub> H <sub>15</sub> F <sub>6</sub> N <sub>5</sub> O	Siddiqui et al. (2024) Ravikumar et al. (2023)	[3,5]
Molecular Weight (g/mol)	407.3	Siddiqui et al. (2024)	[5]
Solubility	Soluble in water.	Kang & Kim (2023)	[1]
pKa	7.5	Siddiqui et al. (2024)	[5]
logP (Lipophilicity)	0.4 (Low)	Siddiqui et al. (2024)	[5]

### 1.2 High-Performance Liquid Chromatography (HPLC) and Reverse Phase HPLC (RP-HPLC) in Pharmaceutical Analysis

High-Performance Liquid Chromatography (HPLC) and its variant, Reverse Phase HPLC (RP-HPLC), are widely employed in pharmaceutical analysis for the separation and quantification of active pharmaceutical ingredients. RP-HPLC is particularly effective for analyzing hydrophobic compounds, making it a preferred technique for drug Sitagliptin. Its ability to achieve high sensitivity and selectivity enables accurate quantification in bulk and pharmaceutical formulations.

#### Principle of HPLC/RP-HPLC

HPLC operates on the principle of differential interactions between analytes and the stationary phase (solid) and mobile phase (liquid), facilitating separation. RP-HPLC specifically utilizes a non-polar stationary phase and a polar mobile phase, making it ideal for hydrophobic drug compounds, which are retained longer in the column, enhancing resolution and selectivity (Kumar et al., 2023).[6]

#### Method Parameters

Key RP-HPLC method parameters vary slightly depending on the drug but typically include:

- Mobile Phase: Acetonitrile and phosphate buffer.
- Column Type: Zorbax C18 or BDS Hypersil.
- Flow Rate: Approximately 1 mL/min.

- Detection Wavelength: Between 210 nm and 225 nm.
  - Retention Time: Approximately 2-3 minutes, depending on the compound [7-9]
- Including the combination of antidiabetic drug like sitagliptin, vildagliptin, dapagliflozin various drug studied and understanding the HPLC and other method development techniques following table given in this comparison.

**Table 2: Comparison of Different HPLC Methods in Pharmaceutical Analysis**

HPLC Method	Key Features	Applications	Reference
Conventional HPLC	Utilizes traditional particle-packed columns (e.g., cyano columns).	Effective for stability- indicating assays, such as the simultaneous estimation of bambuterol and terbutaline.	[10]
Reverse Phase HPLC (RP-HPLC)	Uses a C18 column with a mobile phase of acetonitrile and buffer.	Ideal for separating non-polar compounds, widely used in pharmaceutical analysis.	[11]
Normal Phase HPLC (NP-HPLC)	Uses a polar stationary phase (silica-based columns) and a non-polar mobile phase.	Effective for separating non- polar compounds and often used in conjunction with RP- HPLC for comprehensive analysis.	[12-13]
Cation-Exchange HPLC	Considered the gold standard for hemoglobinopathy screening.	Used in clinical applications for hemoglobin variant detection with high accuracy.	[14]
Ultra-Performance Liquid Chromatography (UPLC)	Operates at higher pressures with sub-2- $\mu$ m particles, improving resolution and sensitivity.	Applied in high-speed separations and low-sample- volume analysis in pharmaceuticals.	[13]
High-Performance Thin Layer Chromatography (HPTLC)	Allows simultaneous analysis of multiple samples with minimal sample preparation.	Cost-effective and commonly used for herbal drug analysis and bioactive compounds.	[12-13]
Liquid Chromatography- Mass Spectrometry (LC-MS)	Integrates chromatography with mass spectrometry, offering enhanced detection sensitivity.	Widely used in pharmaceuticals, environmental monitoring, and food safety.	[13]
UV Spectroscopy	Cost-effective and straightforward method for rapid quality control.	Useful for routine applications and quick examination of drug formulations, making it accessible for many laboratories.	[16]
Gas Chromatography- Mass Spectrometry (GC-MS)	Crucial for analyzing volatile compounds and complex mixtures, providing high sensitivity and specificity.	Effective in identifying and quantifying impurities in pharmaceutical products, ensuring quality assurance.	[17]

**Table 3: HPLC Analysis Parameters for Sitagliptin**

Parameter	Sitagliptin	Authors	Reference
Instrument Type	HPLC with UV detection or LC- MS/MS for higher sensitivity.	Deshmukh et al.(2024),	[16-18]
Column	Hypersil Gold C18 (250 $\times$ 4.6 mm), Zorbax Eclipse Plus C18 (150 mm $\times$ 4.6 mm), Kromosil® C18 (4.6 x 150 mm).	Deshmukh et al.(2024),	[17-18]



<b>Mobile Phase</b>	Acetonitrile: Water (40:60 v/v, pH adjusted), 10 mM ammonium acetate buffer + methanol + acetonitrile, Acetonitrile + Sodium Hydrogen Phosphate (30:70).	Deshmukh et al.(2024),	[16-18]
<b>Flow Rate</b>	Ranges from 0.6 to 0.9 mL/min depending on the method.	Deshmukh et al.(2024),	[17-18]
<b>Retention Time</b>	Not explicitly mentioned.	Deshmukh et al.(2024),	[18]
<b>Detection Wavelength</b>	213 nm, 220 nm, 224 nm.	Deshmukh et al.(2024),	[17-18]
<b>Validation Parameters</b>	Linearity ( $R^2 > 0.999$ ), Precision (%RSD < 2%), Recovery (~100%).	Deshmukh et al.(2024),	[18]
<b>Alternative Methods</b>	LC-MS/MS for enhanced sensitivity and specificity, particularly in complex matrices like plasma.	Vatsavayi & Revu (2024)	

**Table 4: Drug Combination of Sitagliptin**

Combination	Column Specification	Mobile Phase Composition	Flow Rate (mL/min)	Detection Wavelength (nm)	Retention Time (min)	Citation	Reference
Sitagliptin + Dapagliflozin	Zorbax Eclipse Plus C18 (150 mm x 4.6 mm, 5 $\mu$ m)	Ammonium acetate buffer: Methanol: Acetonitrile	0.6	224	Not Specified	Thummar et al., 2024	[19]
Sitagliptin + Metformin	Monolithic C18 (100 $\times$ 4.6 mm, 5 $\mu$ m)	Potassium dihydrogen phosphate buffer: Acetonitrile (70:30 v/v)	0.8	210	Not specified	Balamurugan Krishnan et al. (2020) Rao et al., 2023	[20,28]
Sitagliptin + Gliclazide	Xterra Symmetry C8 (100 $\times$ 4.6 mm, 5 $\mu$ m)	Phosphate buffer (pH 3.5):Acetonitrile (60:40 v/v)	1.0	210	2.5, 3.5	Ehab F Elkady et al. (2015)	[29]

**Table 5: Comparison of HPTLC and GC-MS in Stability Studies**

Parameter	HPTLC	LC-MS	GC-MS	Authors	Reference
<b>Principle</b>	Separation on silica-coated plates followed by UV densitometry.	Combines liquid chromatography (C18/C8 column) with mass spectrometry for molecular identification.	Uses gas chromatography for separation and mass spectrometry for identification of volatile compounds.	Sen et al. (2023), Shantikumar et al. (2015), Patel & Kaushal (2023), Reddy et al. (2020), Uçaktürk (2015).	[21-25]



<b>Methodology</b>	Sample spotting on silica gel plates, development in solvent system, drying, and UV scanning.	Sample injection into HPLC system, separation in mobile phase, detection using electrospray ionization-MS.	Requires derivatization for non-volatile compounds, followed by gas chromatographic separation and MS detection.	Sen et al. (2023), Shantikumar et al. (2015), Patel & Kaushal (2023).	[21-25]
<b>Applications</b>	Stability studies, impurity profiling, and rapid screening of pharmaceutical drugs.	High-sensitivity drug quantification, pharmacokinetics, impurity profiling, and metabolite analysis (e.g., Sitagliptin, Rosuvastatin).	Analysis of volatile compounds, degradation studies, forensic drug detection, and complex mixture analysis	Sen et al. (2023), Reddy et al. (2020), Uçaktürk (2015).	[21-25]
<b>Advantages</b>	Cost-effective, allows simultaneous sample analysis, requires	High sensitivity and selectivity, suitable for non-volatile drugs, enables both qualitative and	Excellent for volatile compounds, provides high-resolution	Sen et al. (2023), Patel & Kaushal (2023), Shantikumar et al. (2015), Uçaktürk (2015).	[21-25]
	minimal sample preparation, and uses lower solvent volumes.	quantitative analysis.	separation, and allows structural elucidation via fragmentation patterns.		[21-25]
<b>Limitations</b>	Lower sensitivity compared to LC-MS, limited to UV-active compounds, requires manual optimization of mobile phase.	Expensive instrumentation, complex method development, requires extensive sample preparation, and matrix interferences may affect results.	Requires volatile or derivatized samples, longer analysis times, and expertise in spectral interpretation.	Reddy et al. (2020), Patel & Kaushal (2023), Uçaktürk (2015).	[21-25]

### Summary of Analytical Methods for Drug Combinations

The development of analytical methods for Sitagliptin is essential for ensuring accurate quantification, stability assessment, and regulatory compliance in pharmaceutical formulations. Various chromatographic and spectrophotometric techniques have been employed to ensure high sensitivity, precision, and reproducibility in their analysis. Among these, High-Performance Liquid Chromatography (HPLC) and its widely used variant Reverse Phase HPLC (RP-HPLC) have been established as the most reliable techniques due to their high efficiency in separating and quantifying active pharmaceutical ingredients (APIs). The use of C18 columns and acetonitrile-

phosphate buffer mobile phases has been commonly adopted, with detection wavelengths ranging from 210 nm to 244 nm. The retention times for these drugs vary between 2.9 and 8.34 minutes, depending on the formulation, with validation parameters confirming linearity ( $R^2 > 0.999$ ), precision (relative standard deviation  $< 2\%$ ), and recovery ( $\sim 100\%$ ), ensuring their suitability for routine pharmaceutical quality control. Apart from HPLC, High-Performance Thin Layer Chromatography (HPTLC) has been widely utilized due to its cost-effectiveness, rapid analysis time, and minimal solvent consumption. [9,18,26]



## CONCLUSION

The analytical evaluation Sitagliptin is essential for ensuring their efficacy, safety, and regulatory compliance. HPLC, particularly RP-HPLC, has emerged as the most reliable technique for their quantification due to its high sensitivity, precision, and reproducibility. Alternative methods such as HPTLC, LC-MS/MS, and UV spectrophotometry also offer advantages in terms of cost-effectiveness, rapid analysis, and environmental sustainability. Validation in accordance with ICH guidelines further ensures the accuracy and robustness of these methods.

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