# Analytical Methods For Estimation Of Sitagliptin For Bulk Tablet And Dosage Form

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**ABSTRACT**

Sitagliptin is a dipeptidyl-peptidase inhibitor (DPP-4 inhibitor) Synonyms of sitagliptn is sitagliptina that has recently been approved for the therapy of type 2 diabetes. Like other DPP-4 inhibitors its action is mediated by increasing levels of the incretin hormones glucagon-like peptide-1 (GLP-1) and gastric inhibitory polypeptide. Sitagliptin is effective in lowering HbA1c, and fasting as well as postprandial glucose in monotherapy and in combination with other oral antidiabetic agents. It stimulates insulin secretion when hyperglycemia is present and inhibits glucagon secretion. Absorption of Sitagliptin is 87% orally bioavailable and taking it with or without food does not affect its pharmacokinetics[4]. Sitagliptin reaches maximum plasma concentration in 2 hours. Route of elimination Approximately 79% of sitagliptin is excreted in the urine as the unchanged parent compound. 87% of the dose is eliminated in the urine and 13% in the feces .A new simple and precise reverse phase high performance liquid chromatographic method has been developed and subsequently validated for the estimation of Sitagliptin phosphate monohydrate in bulk and its pharmaceutical dosage form. The assay of Sitagliptin was found to be 99.89 %. The results of the study showed that the proposed RP-HPLC method is simple, rapid, precise, reliable, accurate and economical which is useful for the routine determination of Sitagliptin phosphate in bulk and its pharmaceutical dosage form. This assessment encompasses various analytical methods such as spectrometry and spectrophotometric , ultra performance liquid chromatography (UPLC), high performance thin layer chromatography (HPTLC) and gas chromatography-mass spectrometry (GC-MS) for the estimation of sitagliptin in single and/or in combination.

**Keywords :** Sitagliptin Phosphate, Analytical methods, Type-2 d,iabetes, method validation.

## INTRODUCTION

Sitagliptin phosphate is an oral anti hyperglycemic of the dipeptidyl peptidase-4 (DPP-4) inhibitor class. This enzyme-inhibiting drug is used either alone or in combination with other oral anti hyperglycemic agents (such as metformin or a thiazolidinedione) for treatment of diabetes mellitus type 2. Sitagliptin works to competitively inhibit the enzyme DPP-4. This enzyme breaks down the incretins GLP-1 and GIP, gastrointestinal hormones released in response to a meal. By preventing GLP-1and GIP inactivation, they are able to increase the secretion of insulin and suppress the release of glucagon by the pancreas. This drives blood glucose levels towards normal. The Absolute Bioavailability of SITA is approximately 87%. The benefit of this medicine is its lower side effect like less hypoglycemia and less weight gain. it is used alone or in combination with metformin or simvastatin to trat diabetes.

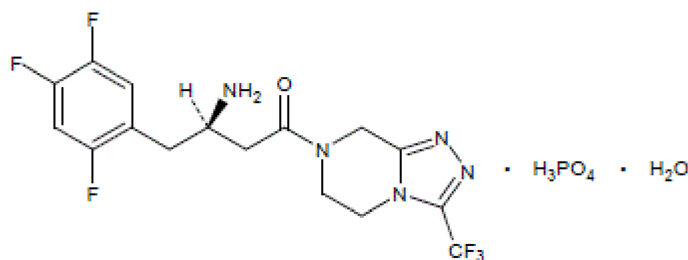


**Figure : structure of Sitagliptin**

SITA is a white to off white, crystalline, non-hygroscopic powder and has a molecular formula of C16H15F6N5O.H3PO4.H2O. The molecular weight is 523.32. The absolute bioavailability of SITA is approximately 87%. The coadministration of high fat meal with SITA has no effect on the pharmacokinetics. It may be administered with or without food.1 Approximately 80% of the SITA excreted unchanged in urine. The fecal route accounts for 13% of elimination.5 It is soluble in water and N, N-Dimethyl formamide , slightly soluble in methanol, very slightly soluble in ethanol, acetone and acetonitrile, and insoluble in isopropanol and isopropyl acetate. Literature survey reveals the availability of various analytical methods for the analysis of sitagliptin in biological samples by RP- HPLC1,2 and few Spectrophotometric methods are available for estimation of sitagliptin in bulk and pharmaceutical dosage form.3-7 There is one RP-HPLC method is also available for this sitagliptin formulation.[8] The reported RP-HPLC method was not economical in terms of mobile phase composition, flow rates and less efficient. Hence there is a need to develop an RPHPLC method for the estimation of sitagliptin in the tablet formulations. The aim of the present analytical research is to develop simple, precise, accurate, rapid and economical RP-HPLC method for the assay of sitagliptin phosphate in tablet formulation And also Different Techniques like spectrometry, high performance liquid chromatography (HPLC),liquid chromatographymass spectrometry (LC-MS),ultra performance liquid chromatography (UPLC), high performance thin layer chromatography (HPTLC) and gas chromatography-mass spectrometry (GC-MS) have been used for analysis of SITA.

## Sample Preparation

### Solubility

According to biopharmaceutical classification system (BCS), the SITA falls in BCS class-I, meaning high solubility and high permeability.6 The pH of a saturated water solution of SITA is 4.4. The partition coefficient is 1.8 and pKa is 7.7 7The solubility of the drug was tested in solvents routinely used for analytical methodology.

## MATERIALS AND METHOD

Sitagliptin phosphate gift sample was provided by MSN labs, Hyderabad. A commercial Janumet tablets containing Sitagliptin phosphate 100 mg was purchased from local market, Hyderabad. All other chemicals used were of HPLC grade.

### Selection of wavelength of detection

Sitagliptin standard solution of 100 ppm was scanned at 200-400 nm and UV Spectrum was recorded. By observing the spectrum of standard solution, λmax of 267 nm was taken for trails to develop the proposed method.

### Instrumentation and Chromatographic Conditions

High performance liquid chromatography Agilent 1200 series equipped with PDA detector and Zorbax Eclipse XDB C18 (150 mm × 4.6 mm) containing 5 µm particle size column was used. Mobile phase comprising of 0.01M

Phosphate buffer :methanol in a ratio 50:50 % v/v at pH 2.5 adjusted with 0.2 % orthophosphoric acid at a flow rate of 0.7 ml/min and the effluent was detected at 267 nm. The Column temperature was maintained at ambient and the volume of injection is 10 μL.

## Preparation of buffer

Phosphate buffer was prepared by dissolving 0.68 gm of potassium dihydrogen orthophosphate in 500 mL of double distilled water. PH was adjusted to 2.5 with 0.2% ortho phosphoric acid and solution was filtered through 0.45 μ Millipore Nylon filter.

## Mobile phase preparation

0.01M Phosphate buffer adjusted to PH 2.5: methanol in a ratio 50:50 % v/v was taken, sonicated for 15 minutes and filtered through 0.45μ Millipore Nylon filter under Vacuum filtration. The prepared solution was used as Mobile phase.

Diluent 1: Water

Diluent 2: Mobile phase

## Preparation of solutions

## Standard stock solution:

10 mg of Sitagliptin was accurately weighed and dissolved in diluent1 in a 100 ml volumetric flask and the solution was made up to 100 mL with diluent 1to obtained concentration of 100 μg/ml.

## Working Standard solution:

1mL of standard stock solution was pipetted into 10 mL volumetric flask and diluted up to the mark with diluent 2 and filtered through 0.45μ Millipore Nylon filter to obtained concentration of 10 μg/ml.

## Sample stock solution:

20 tablets were weighed and average weight of tablet was calculated. The tablets were crushed into a fine powder using mortar and pestle. 42 mg of tablet powder equivalent to 10 mg of Sitagliptin phosphate monohydrate was weighed accurately and transferred into a 100 mL clean and dry volumetric flask. Then 70 ml of diluent 1 was added, sonicated for 15 min. and then volume was made up to the mark with the diluent 1 to obtained concentration of 100 μg/ml. Further1 mL of above sample stock solution was pipetted into a 10 mL volumetric flask and diluted up to the mark with diluent 2, filtered through 0.45 μ Millipore Nylon filter to obtained final concentration of 10 μg/ml.

## Method validation

The method was validated in terms of the following parameters; linearity, specificity, accuracy, precision, and system suitability parameters as per the ICH guidelines.

## Specificity

To determine specificity, a volume of 10μl of working standard, sample and blank solution were injected separately and the chromatograms were recorded and shown are figure 3 and 4.

## Linearity

A series of working standard solutions of Sitagliptin phosphate monohydrate were prepared in the concentration range from 5 to 30(μg/mL) and injected into the chromatographic system. A calibration graph is plotted between

concentration of Sitagliptin phosphate monohydrate (µg/mL) and chromatographic peak area (mV). The results are tabulated in Table no.1 and linearity graph was shown in Fig 5.

## Accuracy studies

A known amount of working standard at three different levels i.e. 50%, 100%, and 150% were added to pre analyzed sample solution of 100% concentration and injected each three times in to the chromatographic system. From this % recovery was calculated. Results of the recovery studies are shown in Table no.2

## Precision Studies

### System precision:

The system precision was established by injecting six replicate injections of working standard solution into the chromatographic system and the results are shown in table no.3

### Method Precision:

The method precision was established by injecting six freshly prepared sample solutions into the chromatographic and the results are shown in table no.4 **:**

## Sensitivity

The sensitivity of Sitagliptin by the use of proposed method was estimated in terms of the limit of quantitation (LOQ) and the limit of detection (LOD). The LOQ and LOD were found to be 0.6 µg/ml and 1.9 µg/ml.

# Results and Discussions

The proposed method was developed and validated as per the ICH guidelines. Linearity was observed over a concentration range of 5 to 30 µg/ml. System suitability parameters were satisfactory and the theoretical plates were obtained above 2000. Tailing factor was found below 2. %RSD also found below 2%. The assay of Sitagliptin was found to be 99.89% and the low % RSD value confirms the robustness of the method.

**Table 1**: Data linearity study

| SI. NO. | Concentration ( µg/ml) | Peak Area | Statistical Analysis |
|---|---|---|---|
| 1 | 5 | 32500 | Slope =6326<br>Intrcept = 945.7<br>Correlation Coefficient= 0.999 |
| 2 | 10 | 66306 | |
| 3 | 15 | 99201 | |
| 4 | 20 | 122467 | |
| 5 | 25 | 156734 | |
| 6 | 30 | 193693 | |

**Table : 2** Data of Accuracy (Recovery Studies)

| SI.NO. | Spiked level | Amount of drug from Formulation (µg/mL) | Amount added (µg/mL) | Amount found (µg/mL) | % Recovery | Statisticali Analysis |
|---|---|---|---|---|---|---|

| | | | | | | Mean ± SD (n=3) | % RSD |
|---|---|---|---|---|---|---|---|
| 1 | 50% | 10 | 5 | 15.1 | 100.7 | 100.6±0.374 | 0.37 |
| | | | | 15.02 | 100.1 | | |
| | | | | 15.15 | 101 | | |
| | 100% | 10 | 10 | 19.91 | 99.5 | 99.84±0.251 | 0.25 |
| | | | | 20.02 | 100.1 | | |
| | | | | 19.98 | 99.92 | | |
| 3 | 150% | 10 | 15 | 25.34 | 101.3 | 100.4±0.923 | 0.97 |
| | | | | 24.78 | 99.14 | | |
| | | | | | | | |

**Table 3**: Data of system precision

| **Injection** | **Retension time ( min)** | **Peak area** |
|---|---|---|
| Injection -1 | 3.073 | 66287 |
| Injection -2 | 3.1 | 67736 |
| Injection -3 | 3.173 | 66286 |
| Injection -4 | 3.113 | 66262 |
| Injection -5 | 3.2 | 67585 |
| Injection -6 | 3.173 | 67591 |
| Mean ± S.D % RSD | 3.138±0.045 | 66957±681.3 |
| | 1.43 | 1.01 |

**Table 4:** Data of method precicion

| **Injection** | **Retension time ( min)** | **Peak area** |
|---|---|---|
| Injection -1 | 3.12 | 71511 |
| Injection -2 | 3.113 | 72575 |
| Injection -3 | 3.113 | 71676 |
| Injection -4 | 3.12 | 71946 |
| Injection -5 | 3.16 | 71106 |
| Injection -6 | 3.12 | 71851 |
| Mean ± S.D | 3.124±0.016 | 488.1 |
| % RSD | 0.512 | 0.679 |

**Table 5 :** Summary of Validation Parameter

| **S.No.** | **Parameter** | **Results** |
|---|---|---|
| 1 | Limit of Linearity | 5-30 ±/mL |
| 2 | Regression equation | y = 6326x+945.7 |
| | Slope | 6326 |
| | Intercept | 945.7 |
| | Correlation coefficient (r2) | 0.999 |
| 3 | Accuracy (%) | 99.8-100.6 |
| 4 | Precision (%cv) | |
| | System precision | 1.22 |

| | | |
|---|---|---|
| | Method precision | 0.59 |
| 5 | LOD (µg/mL) | 0.6 |
| 6 | LOQ(µg/mL) | 1.9 |

## Analytical Methods

### *Spectrometry*

In the literature about 25 methods were reported for the estimation of SITA using spectrometry, of which 11 methods are for determination of SITA alone, while the others are for quantifying SITA in combination with other drug substances. The summary of reported spectrometric methods indicating the basic principle, λmax, solvent and limit of detection (LOD) is shown in table 1(2, 9-32)

**Table 1:** Summary of spectrometric methods for the analysis of SITA

| Compounds | Methods | ¾λmax (nm) | Solvent /Procedure | LOD(µg/mL) | Ref. |
|---|---|---|---|---|---|
| SITA | First order derivative | 275 | Water | 2.38 | 2 |
| SITA | Method A Method B | 267-275 | Method & Water | 0.09636 0.4125 | 9 |
| SITA | - | 267 | Methanol | 6.03 | 10 |
| SITA | Method A (Abs. ratio) Method B (AUC) | 267 261- 270 | Water | 11.85 14.05 | 11 |
| SITA | Extractive Visible Method A-BTB Visible Method BBCG | 412 419 | Methanol | _ | 12 |
| SITA | - | 267 | Water | 0.2269 | 13 |
| SITA | Method for dissolution study | 267 | 1 M HCL/ 2 USP apparatus 1( basket) | _ | 14 |
| SITA | Zero order, First order, Second order derivative | 26,72,13,276 | Methanol | 6.03,4.14,3.43 | 15 |
| SITA | - | 267 | 0.1 N HCL | 0.139 | 16 |
| SITA | Visible method | 430 | Water/Primary amino group of SITA with acetyl acetone & HCHO gives yellow color | 1.947 | 17 |
| SITA | Visible method | 338 | Water/SITA with OPA, NAC 7 borate buffer gives chromogen. | 1.1 | 18 |

**Table 2: Spectophotometric (UV/VIS)** methods for the analysis of **Sitagliptins** and in bulk materials and formulations

| Sr. No. | Drug | Sample | Description | Detection wave length (nm) | Ref. No. |
|---|---|---|---|---|---|
| 1 | Sitagliptin | Bulk substance and Tablet dosage form | Solvent : Methanol<br>Linearity : 20 – 60 µg/ml with r2 = 0.991<br>LOD : 6.03 µg/ml<br>LOQ : 18.28 µg/ml | 267 | 44 |

## U.V Spectrophotometric method simultaneous estimation of Sitagliptin Phosphate

In derivative spectral method [6-8], UV spectrum of drug can be recorded at 200-400 nm and processed to get derivative spectrum. At the zero crossing point of one drug, the second drug would be measured which gives a reasonable or estimating drug without interference of additives or impurities Thus a derivative spectrum shows better resolution of overlapping bands than the fundamental spectrum and may permit the accurate determination of the λmax of the individual bands.

## HPLC

**HPLC Conditions:**
Mobile phase 60:40 v/v acetonitrile: water was used. It is filtered before use through a 0.45 micron membrane filter, and pumped from the respective solvent reservoirs to the column at a flow rate of 1.0 ml/min. The run time was set at 8 min and the column temperature was ambient. Prior to the injection of the drug solution, the column was equilibrated for at least 30 min with the mobile phase flowing through the system. The eluents were monitored at 272 nm.

**Preparation of Mobile Phase:**
500 ml of acetonitrile and 500ml of double distilled water was taken, filtered through 0.45 micron membrane filter paper and sonicated for 5 min.

**Preparation of Standard Stock solution:**
10 mg of Sitagliptin phosphate was accurately weighed and dissolved in 2ml of acetonitrile in 10 ml volumetric flask. The volume was made up to 10ml with Acetonitrile to obtain standard concentration of 1 mg/ml (stock 1).

**Working Standard solution:**
1ml of stock solution was pipetted out into 10 ml volumetric flask and volume was made up to 10 ml acetonitrile to produce 100 mcg/ml concentration solution.

**Preparation of Sample solution:**
20 tablets of Sitagliptin phosphate (Januvia) were weighed and tablet powder of 420.7 mg (equivalent to 100 mg of Sitagliptin phosphate) was transferred and dissolved in 20ml of acetonitrile in 100 ml volumetric flask. The volume was made up to 100 ml with acetonitrile. Solution was kept 25 minutes for sonication. The solution was filtered through 0.45 micron membrane filter, from the above filtered solution 10ml was pipetted out in 100 ml volumetric flask and volume was made up with acetonitrile to produce a concentration of 100 mcg/ml of Sitagliptin phosphate.

**Linearity:**
Aliquots of standard Sitagliptin phosphate stock solution were taken in different 10 ml volumetric flasks and diluted up to the mark with the acetonitrile such that the final concentrations of Sitagliptin phosphate are in the range of 20-120 mcg/ml. Each of these drug solutions (20 l) was injected three times into the column and peak areas and retention times

were recorded. Evaluation was performed with PDA detector at 272 nm and a Calibration graph was obtained by plotting peak area versus concentration of Sitagliptin phosphate (Fig3).

The plot of peak area of each sample against respective concentration of Sitagliptin phosphate was found to be linear in the range of 20–120µg/ml with correlation coefficient of 0.9998. Linear regression least square fit data obtained from the measurements are given in table I. The respective linear regression equation being Y=6552.4x+7903.9. The regression characteristics, such as slope, intercept, and %RSD were calculated for this method and given in Table I.

| **Table I: Linear Regression Data for Calibration curves.** | |
|---|---|
| **Drug** | **Sitagliptin phosphate** |
| Concentration range (µg/ml) | 20-140 mcg/ml |
| Slope (m) | 6552.397143 |
| Intercept (b) | 7903.866667 |
| Correlation coefficient | 0.9998 |
| % RSD | 0.32% |

**Assay:**

20 µl of sample solution was injected the injector of liquid chromatograph. The retention time was found to be 5.062 minutes. The amount of drug present per tablet was calculated by comparing the peak area of the sample solution with that of the standard solution. The data are presented in Table II.

**Table II: Results of HPLC assay and Recovery studies.**

| **Sample** | **Amount claim [mg/ tablet]** | **Amount found by the Proposed method.** | **% recovery of sample** |
|---|---|---|---|
| 1 | 100mg | 60.03 | 100.05% |
| 2 | 100mg | 79.92 | 99.91% |
| 3 | 100mg | 100.04 | 100.04% |

**Recovery Studies:**

Accuracy was determined by recovery studies of Sitagliptin Phosphate, known amount of standard was added to the preanalyzed sample and subjected to the proposed HPLC analysis. Results of recovery study are shown in Table II. The study was done at three different concentration levels.

**RESULTS AND DISCUSSION:**

The system suitability tests were carried out on freshly prepared standard stock solution of Sitagliptin phosphate Parameters that were studied to evaluate the suitability of the system are given in Table II

**Table III: Validation Summary**

| **Validation Parameter System Suitability** | **Results** |
|---|---|
| Theoretical plates (N) | 51771 |
| HETP | 19.31 |
| Symmetry factor/Tailing factor | 1.262 |
| Retention time in minutes. | 5.062 |
| LOD (µg/ml) | 0.125µg/ml |
| LOQ (µg/ml) | 0.375µg/ml |

**Limit of Detection (LOD) and Limit of Quantification (LOQ):**
The limit of detection (LOD) and limit of quantification (LOQ) for Sitagliptin phosphate were found to be 0.125µg/ml and 0.375µg/ml respectively. The signal to noise ratio is 3 for LOD and 10 for LOQ.

From the typical chromatogram of Sitagliptin phosphate as shown in fig 2, it was found that the retention time was 5.062 min. A mixture of ACN: WATER in the ratio of (60:40) v/v was found to be most suitable to obtain a peak well defined and free from tailing. In the present developed HPLC method, the standard and sample preparation required less time and no tedious extraction were involved. A good linear relationship (r=0.9998) was observed between the concentration range of 20-120 µg/ml. Low values of standard deviation are indicative of the high precision of the method. The assay of Sitagliptin tablets was found to be 99.5%. From the recovery studies it was found that about 100 % of Sitagliptin phosphate was recovered which indicates high accuracy of the method. The absence of additional peaks in the chromatogram indicates non-interference of the common excipients used in the tablets. This demonstrates that the developed RP-HPLC method is simple, linear, accurate, sensitive and reproducible. Thus, the developed method can be easily used for the routine quality control of bulk and tablet dosage form of Sitagliptin phosphate within a short analysis time.

**Fig 2: Typical chromatogram of Sitagliptin phosphate showing retention time 5.062 min.**

## HPTLC

a HPTLC method for simultaneous estimation of SITA and SIMV. A precoated silica gel 60 F254 (0.2 mm thickness) on aluminium sheets was employed to carry out the separation. Chloroform: methanol in the ratio of 8:2 v/v was used as mobile phase. The developing chamber was run up to 8 cm. The Rf values were found to be 0.13 and 0.75 for SITA and SIMV. The plate was scanned and quantified at 217 nm. The linear detector response was observed between 2000 ng/spot to 7000 ng/spot and 250 ng/spot to 750 ng/spot for SITA and SIMV. The LOD and LOQ were found to be 660, 2000 ng/spot and 50, 150 ng/spot, respectively for SITA and SIMV. The Average recovery was found to be 92.80 % and 98.01 % for SITA and SIMV.64

## GC-MS

A simple and rapid GC–MS method for the determination of SITA in human urine was developed. SITA was derivatized by N-methyl-trimethylsilyltrifluoroacetamide prior to GC–MS analysis and converted to its N-TMS amine derivative. It was extracted from urine by using carbonate buffer (pH 9.0) and ether. LOQ was found to be 50 ng/mL. The calibration curve was linear in the range of 50–600 ng/mL with a coefficient of determination ($r^2$) above 0.997. The intra-day and inter-day precisions were less than 8.76%, and the intra-day and inter-day accuracies were found between 0.83 and 4.53%. The method was successfully applied to urine samples obtained from diabetic patients.7

## UPLC

Instrumentation and Chromatographic Conditions

The UPLC system, used for method development, forced degradation studies and method validation was Waters Acquity UPLC™ system equipped with the binary solvent manager, sample manager, column heater module and photodiode array detector . Aquity UPLC BEH C8 (100 × 2.1 mm, 1.7 µm) was used as stationary phase. The mobile phase composition used was the buffer 10mM potassium dihydrogen phosphate and 2 mM hexane-1-sulfonic acid sodium salt (pH adjusted to 5.50 with diluted phosphoric acid) and acetonitrile with gradient program [Time(min)/% acetonitrile): 0/8, 2/8, 4/45, 6/45, 8/8, 10/8]. Prior to use, the mobile phase was filtered by using 0.2 µm filter. The flow rate of the mobile phase was maintained at 0.2 mL $min^{-1}$ and water was used as sample diluent. The column temperature was 25°C and eluents were monitored at 210 nm. The injection volume for samples and standards was 0.5 µL. The total analysis run time was 10 min.[12]

Preparation of Solutions

*Standard Solutions*

A standard solution containing 50 µg $mL^{-1}$ of SP and 500 µg $mL^{-1}$ of MH was prepared by dissolving an appropriate amount of SP and MH in diluent. An impurity blend solution of Metformin impurity-1 & 2 and Sitagliptin impurity with 100 µg $mL^{-1}$ concentration was prepared in diluent.

**Sample preparation**

To prepare the sample stock solution, tablets of Junumet™, each containing 50 mg of SP and 500 mg of MH, were accurately weighed and transferred into a clean and dry mortar, crushed to a fine powder. An appropriated amount was transferred into a 100mL volumetric flask, diluted to volume with diluent and sonicated for 10 min obtaining the final concentration of 50 µg $mL^{-1}$ of SP and 500 µg $mL^{-1}$ of the active pharmaceutical ingredient. The solution was filtered through 0.45 µm Millipore PVDF filter.

## CONCLUSION

This review aimed at focusing various analytical methods reported for the assay of SITA. A broad range of techniques are available for the estimation of SITA in biological samples and pharmaceutical dosage forms. The analysis of published data revealed that spectrometric methods are the simple and economical methods for estimation of SITA in pharmaceutical formulations. For analysis of SITA, HPLC-UV provides accurate results and low cost compared to advanced detection techniques. HPLC with PDA detection was extensively used for the development of stability indicating assay methods for separation and quantification of SITA in presence of degradation products. The proposed RP-HPLC method was found to be simple, accurate, precise, linear, robust and specific for quantitative estimation of Sitagliptin phosphate in bulk and its formulation. The proposed RP-HPLC method was cost effective and less time consuming. The values for system suitability parameters showed feasibility of this method for routine pharmaceutical application. the present RP-HPLC method is suitable for routine assay of Sitagliptin phosphate in bulk and tablet dosage form in the quality control laboratories. The described HPLC method provides simple, precise, sensitive and reproducible quantitative method for routine analysis of Sitagliptin phosphate in conventional dosage form such as tablets. These methods are adequate to analyse the drugs in single component formulation as well as combination preparation. Also, TLC/HPTLC AND SITA using HPLC with sensitive MS detection has become an indispensible tool for quantification of SITA in biological fluids and pharmacokinetic studies.

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