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A Concise Comparative Mini Review between HPLC-UV and Spectrophotometric Analysis of Gliptins in Pharmaceutical Formulations

Shereen Mowaka[1-3], Moataz S Hendy[1,3], Mohamed M Elmazar[3,4], Andrew H Hakeem[3,4], Ramzia I Elbagary[5,6], Ehab F Elkady[5], Mirna M Antoun[1,3], Mai M Shaalan[1,3], Sara A Abdel-Wahab[3,7], Mai M Elsemeiri[1], Nourhan K Abdelaziz[1], Alaa E Mohamed[1], Menna H Eltahawy[1], Asmaa M Rashid[1], Rola M Emam[1], Mahmoud M Youssef[1], Muhammad N El-Kattan[1], Marwa A Sayed[1], Ahmed M Kowider[1], Adly H Seha[1], Engy A Rabea[1], Rana M Yakout[1], Rolly H Faried[1], Bassam M Ayoub[1,3*]

[1]Pharmaceutical Chemistry Department, British University in Egypt, El-Sherouk City, Cairo 11837, Egypt
[2]Analytical Chemistry Department, Helwan University, Ein Helwan, Cairo 11795, Egypt
[3]Center for Drug Research and Development (CDRD), British University in Egypt, El-Sherouk City, Cairo 11837, Egypt
[4]Pharmacology Department, British University in Egypt, El-Sherouk City, Cairo 11837, Egypt
[5]Pharmaceutical Chemistry Department, Cairo University, Cairo 11562, Egypt
[6]Pharmaceutical Chemistry Department, Future University in Egypt, Cairo 12311, Egypt
[7]Pharmaceutics Department, Faculty of Pharmacy, Future University in Egypt, Cairo 12311, Egypt

ABSTRACT

The ongoing development of anti-diabetic drugs brings a revolution in the treatment of diabetes mellitus. Dipeptidyl Peptidase-4 (DPP-4) inhibitors are considered a new class of oral anti-diabetic agents used in treatment of type 2 diabetes mellitus. Therefore, the necessity to explore and compare the existing analytical method used for estimation of such drugs either single or in combination is crucial. This review offers an overview of different HPLC-UV and spectrophotometric methods used for determination of DPP-4 inhibitors namely; sitagliptin, vildagliptin, saxagliptin, linaglitpin and alogliptin in a tabulated comparative way. In addition, the present work included stability indicating assays of the drugs and determination of their process related impurities. Spectrophotometric assays showed more facilitated, simple and cost effective methods than the reported chromatographic techniques. Furthermore, the reviewed spectrophotometric methods showed the advantages of low cost solvents, shorter analysis time and simple instrumentation instead of complex details implemented in the chromatographic method development. The developed comparative review should be of interest to the analysts in the area of drug control and can be used by quality control laboratories for the recently approved gliptin combinations.

INTRODUCTION

Diabetes Mellitus (DM) is a chronic condition characterized by high levels of blood glucose due to a defect in insulin production or activity [1]. Oral anti-diabetic drugs are used in case of type 2 DM. Incretin peptides, principally Glucagon-like Peptide (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), regulate islet hormone secretion, glucose concentrations and lipid metabolism [2-4]. The classical mechanism for Dipeptidylpeptidase-4 (DPP-4) inhibitors is that they stimulate glucose-dependent insulin secretion from the beta cells of the pancreas through inhibition of DPP-4 activity in peripheral plasma, which prevents the inactivation of GLP-1 in the peripheral circulation leading to stimulated insulin secretion and inhibited glucagon secretion [5]. The good safety profile of DPP-4 inhibitors has been largely confirmed [6-8]. DPP-4 inhibitors include Sitagliptin (SIG), Vildagliptin (VIG), Saxagliptin (SAG), Linagliptin (LIG) and Alogliptin (ALG).

Many gliptin combinations had been approved by FDA for the treatment of DM. Metformin (MT) was the first line in most of gliptin combinations including Janumet® (SIG and MT), Galvumet® (VIG and MT), Kombiglyze® (SAG and MT), Jentadueto® (LIG and MT) and Kazano® (ALG and MT). In addition, combination of ALG with pioglitazone (PG) marketed as Oseni® tablets and combination of LIG with empagliflozin (EG) marketed as Glyxambi® tablets have been recently approved.

Furthermore, a combination of SIG with simvastatin (SV) marketed as Juvisync® tablets was developed and released in the market. The present review is considered a prominent and reproducible source taking in account the inclusion of the significant spectrophotometric and HPLC-UV methods centralized specifically around the analysis of single and combination gliptins in dosage forms.

Comparative review

HPLC-UV [9-89] and spectrophotometric [90-124] analysis of gliptins were common in the literature (Tables 1 and 2). Based on the aforementioned HPLC-UV literature, various columns with different lengths and particle sizes offering different run times and linearity ranges are mentioned but the most commonly used chromatographic columns were C_{18} and C_8 columns. Concerning mobile phase composition, phosphate buffer was the most common component of the mobile phase with different ratios mixed with organic solvent as acetonitrile, methanol or a combined mixture of them. Isocratic elution is capable to separate the drugs in most of the methods with satisfying results except for those methods including many degradation products and/or impurities that required gradient elution.

It was observed that the chromatographic UV detector was adjusted at SIG λ_{max} range (265-267 nm) for determination of SIG alone however it was adjusted at 270 nm while its determination with PG or at 254 nm while its determination with SV. Determination of SIG and MT required lower λ range (207-232 nm). Most of the developed methods for VIG used wavelength range (205-220 nm) which is close to λ_{max} of VIG either alone or with binary mixture with MT. Wavelength range used for detection of SAG alone or with MT was (208-248 nm). Detection wavelength of (292-296 nm) was used for determination of LIG alone and lower range of (226-237 nm) was mandatory while simultaneous determination of LIG with MT. During determination of ALG alone, the ultraviolet detector was adjusted between 215 nm and 230 nm. In case of the binary mixture of ALG with PG, the UV detection was adjusted at the range of (268-271 nm). Finally, detection was adjusted between 233 nm and 235 nm during the determination of ALG in combination with MT.

In spite of the availability of many HPLC-UV methods for determination of gliptins in pharmaceutical formulations, spectrophotometric analysis exhibited more economic and simple assays either using direct UV determination or by manipulation of the obtained spectra with acceptable Limit of Detection (LOD) and Limit of Quantification (LOQ) values that ensured satisfying sensitivity. Mostly used solvents were distilled/deionized water and methanol. The applications of cost effective spectrophotometric methods have renovated the concept of analysis of gliptins in a highly accurate and precise way with no significant difference than HPLC-UV in case of application to assays of pharmaceutical formulations. This review offers a convenient tool to allow researchers to identify different methods of analysis used for various applications on gliptins. It can be concluded that spectrophotometry is a valuable technique for the analysis of gliptins in spite of the existence of various HPLC-UV methods which differ in the type of column used, mobile phase composition, flow rate, and detector wavelength. The development of new optimized methods is still a necessary requirement in the drug analysis field, so this review may be used as a guide for those interested in analysis of gliptins taking in consideration all the previously developed methods in the literature (Tables 1 and 2).

Table 1: HPLC-UV methods for analysis of gliptins in pharmaceutical formulations

Stationary phase	Mobile phase	Detection wavelength	Applications
C18 column (100 mm × 2.1 mm, 2.2 µm)	Mixture of methanol and water in the ratio of (20:80%, v/v) with pH adjusted to 3.5	220 nm	Assay of SIG and MT in Janumet® tablets [9]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 6.8) and methanol in the ratio of (40:60%, v/v)	265 nm	Assay of SIG in Januvia® tablets [10]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of water and acetonitrile in the ratio of (40:60%, v/v)	253 nm	Assay of SIG and gliclazide in tablets [11]
C18 column (150 mm × 4.6 mm, 5.0 µm)	Mixture of acetonitrile and 0.01 N potassium dihydrogen phosphate buffer (pH 5) in the ratio of (70:30%, v/v)	269 nm	Assay of SIG in Januvia® tablets [12]
C8 column (250 mm × 4.6 mm, 5 µm)	Mixture of methanol and water in the ratio of (70:30%, v/v) with 0.2% of n-heptane sulfonic acid (pH 3.0)	253 nm	Assay for SIG and SV in Juvisync® tablets [13]
C18 column (50 × 2.1 mm, 1.7 µm)	Gradient elution using 10 mM ammonium format (pH 6.4) and acetonitrile	267 nm	Stability indicating assay of SIG in Januvia® tablets [14]
C18 (2.1 × 100 mm, 1.7 mm)	Mixture of phosphate Buffer (pH 4.0) and acetonitrile in the ratio of (30:70%, v/v)	213 nm	Assay for SIG and SV in Juvisync® tablets [15]
C18 column (50 mm × 4.6 mm, 5 µm)	Mixture of (10 mm sodium dihydrogen phosphate and 10 mm sodium dodecyl sulphate, pH 5.5) and acetonitrile in the ratio of (64:36%, v/v)	208 nm and 228 nm	Stability indicating assay of SIG, VIG, LIG and MT in Janumet®, Galvumet® and Jentadueto® tablets [16]
C18 column (100 mm, 4.6 mm, 5 µm)	Gradient elution using phosphate buffer (pH 3.0) and acetonitrile	232 nm	Assay of SIG, VIG, SAG, LIG and MT in dosage forms [17]
Gold column (150 mm × 4.6 mm, 5 µm)	Mixture of buffer and methanol in the ratio of (30:70%, v/v). Buffer containing 1% conc. nitric acid 65% & 2% conc. ammonia 28-32%, pH 8.5)	254 nm	Assay of SIG, MT and atorvastatin in tablets [18]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of orthophosphoric acid buffer and methanol in the ratio of (60:40%, v/v)	228 nm	Assay of SIG and MT in Janumet® tablets [19]
C18 column (100 mm × 4.6 mm, 5.0 µm)	Mixture of potassium dihydrogen orthophosphate (pH 8.5) and methanol in the ratio of (50:50%, v/v)	215 nm	Assay of SIG and MT in Janumet® tablets [20]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of 0.02 M Potassium dihydrogen phosphate pH (4.0) and acetonitrile in the ratio of (60:40%, v/v)	252 nm	Assay of SIG and MT in Janumet® tablets [21]

C8 column (250 mm × 4.6 mm, 5 µm)	Mixture of methanol and water in the ratio of (45:55%, *v/v*) containing 0.2% (w/v) n-heptanesulfonic acid and 0.2% (v/v) triethylamine, pH 3.0	267 nm	Stability indicating assay of SIG and MT in Janumet® tablets [22]
C18 column (150 mm × 4.6 mm, 3.5 µm)	Mixture of phosphate buffer (pH 3.5) and acetonitrile in the ratio of (30:70%, v/v)	254 nm	Assay for SIG and SV in Juvisync® tablets [23]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of 10 mM phosphate buffer (PH 3.5) and acetonitrile in the ratio of (60:40%, v/v)	260 nm	Stability indicating assay of SIG in Januvia® tablets [24]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of acetonitrile and phosphate buffer 0.03 M (pH 3.5) in the ratio of (70:30%, v/v)	218 nm	Assay of SIG and MT in Janumet® tablets [25]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of 0.025 M phosphate buffer (pH 6.8) and acetonitrile in the ratio of (60:40%, v/v)	267 nm	Stability indicating assay of SIG in Januvia® tablets [26]
C18 column (250 mm × 4.6 mm, 5 µm)	Gradient elution of acetonitrile and 10 mM potassium dihydrogen phosphate buffer (pH 3.0)	270 nm	Assay of SIG and PG in Oseni® tablets [27]
C18 column (75 mm × 4.6 mm, 5.0 µm)	Mixture of acetonitrile and 0.05 M ammonium acetate buffer (pH 4) in the ratio of (40:60%, v/v)	253 nm	Assay for SIG and SV in Juvisync® tablets [28]
C8 column (100 mm × 2.1 mm, 1.7 µm)	Gradient elution of (potassium dihydrogen phosphate buffer 10 mM and 2 mM hexane-1-sulfonic acid sodium salt, pH 5.5) and acetonitrile	210 nm	Assay of SIG and MT in Janumet® tablets [29]
C8 column (100 mm × 4.6 mm, 3 µm)	Mixture of phosphate buffer solution (pH 9), acetonitrile and methanol in the ratio of (35:45:20%, v/v/v)	260 nm	Assay of SIG and MT in Janumet® tablets [30]
C18 column (250 mm × 4.6 mm, 5 µm)	Gradient elution of 0.03 M potassium dihydrogen phosphate in water (pH 3.2) and acetonitrile	207 nm	Assay of SIG and MT in Janumet® tablets [31]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer (pH 4.6), acetonitrile and methanol in the ratio of (30:50:20%, v/v/v)	220 nm	Stability indicating assay of SIG and MT in Janumet® tablets [32]
C18 column (250 mm × 4.6 mm, 5 µm)	Gradient elution of 0.05% ammonia solution (pH 9) and mixture of methanol-acetonitrile (50:50%, v/v)	210 nm	Identification of impurities and degradation product with VIG [33]
C18 column (4.6 × 150 mm, 5 µm)	Mixture of 10 mM phosphate buffer (pH 4.6) and acetonitrile in the ratio of (85:15%, v/v)	210 nm	Assay of VIG in Galvus® tablets using an e × perimental design [34]
Cyano column (250 mm × 4.6 mm, 5 µm)	Mixture of 25 mM ammonium bicarbonate buffer and acetonitrile in the ratio of (65:35%, v/v)	207 nm	Stability indicating assay of VIG and MT in Galvumet® tablets [35]
C18 column (50 mm × 4.6 mm, 5 µm)	Mixture of acetonitrile and (sodium dihydrogen phosphate with sodium dodecyl sulphate, 10 mM at pH 4.5) in the ratio of (30:70%, v/v)	208 nm	Assay of VIG and MT in Galvumet® tablets [36]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of 0.1 M Phosphate buffer and acetonitrile in the ratio of (85:15%, v/v)	210 nm	Assay of VIG in Galvus® tablets [37]
C8 column (150 mm × 4.6 mm, 5 µm)	Mixture of acetonitrile and a solution of triethylamine 0.3%, pH 7.0 in the ratio of (15:85%, v/v)	207 nm	Assay of VIG in Galvus® tablets [38]
C8 column (150 mm × 4.6 mm, 5 µm).	Mixture of acetonitrile and disodium hydrogen phosphate (pH 7.0) ion the ratio of (40:60%, v/v)	263 nm	Assay of VIG and MT in Galvumet® tablets [39]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 9.5) and methanol in the ratio of (60:40%, v/v)	210 nm	Assay of VIG in Galvus® tablets [40]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of orthophosphoric acid solution (pH 2.6) and acetonitrile in the ratio of (72:28%, v/v)	266 nm	Assay of VIG in Galvus® tablets [41]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of 0.02 M phosphate buffer (pH 4.6) and acetonitrile in the ratio of (80:20%, v/v)	210 nm	Assay of VIG in Galvus® tablets [42]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 6.5) and acetonitrile at the ratio (50:50%, v/v)	220 nm	Assay of VIG in Galvus® tablets [43]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 8.2), methanol and acetonitrile in the ratio of (45:7:48%, v/v/v)	254 nm	Assay of VIG in Galvus® tablets [44]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of 0.1% phosphoric acid (pH 3.0) and methanol in the ratio of (70:30%, v/v)	225 nm	Stability indicating assay of SAG in Onglyza® tablets [45]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of 0.02 M Potassium dihydrogen phosphate (pH 4.3), acetonitrile and methanol in the ratio of (50:25:25%, v/v/v)	240 nm	Assay of SAG and MT in Kombiglyze® tablets [46]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 5.0), acetonitrile and methanol in the ratio of (75:15:10%, v/v/v)	225 nm	Assay of SAG and MT in Kombiglyze® tablets [47]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of sodium dihydrogen phosphate (pH 3), methanol and acetonitrile in the ratio of (45:20:35%, v/v/v)	220 nm	Assay of SAG in Onglyza® tablets [48]

Cyano column (250 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer (pH 4.6) and acetonitrile in the ratio of (15:85%, v/v)	208 nm	Assay of SAG and MT in Kombiglyze® tablets [49]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 2.5) and acetonitrile in the ratio of (70:30%, v/v)	229 nm	Stability indicating assay of SAG and MT in Kombiglyze® tablets [50]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 6.8) and acetonitrile in a ratio of (94:6%, v/v)	248 nm	Assay of SAG and MT in Kombiglyze® tablets [51]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate and methanol in the ratio of (60:40%, v/v)	248 nm	Stability indicating assay of SAG and MT in Kombiglyze® tablets [52]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate (pH 5.0), acetonitrile and methanol in the ratio of (25:50:25%, v/v/v)	211 nm	Stability indicating assay of SAG and MT in Kombiglyze® tablets [53]
C8 column (250 mm × 4.6 mm, 5 µm)	Gradient elution of 1.20 g/l of sodium dihydrogen phosphate (pH 5.0) and acetonitrile	210 nm	Stability indicating assay of SAG in Onglyza® tablets [54]
Cyano column (250 mm × 4.6 mm, 5 µm)	Gradient elution of methanol and 50 mM phosphate buffer (pH 2.7)	225 nm	Stability indicating assay of SAG in Kombiglyze® tablets [55]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer (pH 4.6), acetonitrile and methanol (40:30:30%, v/v/v)	208 nm	Stability indicating assay of SAG in Onglyza® tablets [56]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen orthophosphate buffer (pH 3.4) and acetonitrile in the ratio of (80:20%, v/v)	213 nm	Stability indicating assay of SAG in Onglyza® tablets [57]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer and methanol in a ratio of (55:45%, v/v)	208 nm	Assay of SAG and MT in Kombiglyze® tablets [58]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of acetonitrile and 0.02 M phosphate buffer (pH 5.0) in the ratio of (35:65%, v/v)	225 nm	Assay of LIG and MT in Jentadueto® tablets [59]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 4.5) and acetonitrile in the ratio of (60:40%, v/v)	280 nm	Stability indicating assay of LIG and MT in Jentadueto® tablets [60]
C18 column (125 mm × 4 mm, 5 µm)	Mixture of methanol and 0.05 M potassium dihydrogen orthophosphate (pH 4.6) in the ratio of (70:30%, v/v)	267 nm	Assay of LIG and MT in Jentadueto® tablets [61]
C18 column (50 mm × 2.1 mm, 1.8 mm)	Mixture of 0.01 M potassium phosphate (pH 4) and acetonitrile in the ratio of (30:70%, v/v)	292 nm	Assay of LIG in Tradjenta® tablets [62]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture (pH 4.1) of acetonitrile, water and methanol in the ratio of (25:50:25%, v/v/v)	243 nm	Stability indicating assay of LIG and MT in Jentadueto® tablets [63]
Cyano column (150 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer (pH 4.6) and acetonitrile in the ratio of (20:80%, v/v)	299 nm	Assay of LIG in Tradjenta® tablets [64]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture (pH 6.4) of acetonitrile, water and methanol in the ratio of (25:50:25%, v/v/v)	238 nm	Assay of LIG in Tradjenta® tablets [65]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture (pH 3) of water and methanol in the ratio of (60:40%, v/v)	238 nm	Assay of LIG in Tradjenta® tablets [66]
C18 column (100 mm × 2.5 mm, 3 µm)	Mixture of methanol and 0.1% orthophosphoric acid in the ratio of (70:30%, v/v) with (pH 6.4)	296 nm	Assay of LIG in Tradjenta® tablets [67]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 3), methanol and acetonitrile in the ratio of (45:25:30%, v/v/v)	237 nm	Assay of LIG and MT in Jentadueto® tablets [68]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer and acetonitrile in the ratio of (40:60%, v/v)	250 nm	Assay of LIG and MT in Jentadueto® tablets [69]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 5.6), methanol and acetonitrile in the ratio of (65:10:25%, v/v/v)	231 nm	Assay of LIG and MT in Jentadueto® tablets [70]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of methanol and phosphate buffer (pH 4.9) in the ratio of (70:30%, v/v)	218 nm	Stability indicating assay of LIG in Tradjenta® tablets [71]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer and acetonitrile in the ratio of (40:60%, v/v)	236 nm	Assay of LIG and MT in Jentadueto® tablets [72]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture (pH 4.1) of methanol and water in the ratio of (83:17%, v/v)	241 nm	Assay of LIG in Tradjenta® tablets [73]
C18 column (100 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 3.4) and acetonitrile in the ratio of (70:30 %, v/v)	240 nm	Assay of LIG in Tradjenta® tablets [74]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 5.6), methanol and acetonitrile in the ratio of (40:5:55%, v/v/v)	233 nm	Assay of LIG and MT in Jentadueto® tablets [75]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of 0.02 M potassium dihydrogen hosphate (pH 5.0) and acetonitrile in the ratio of (70:30%, v/v)	226 nm	Assay of LIG in Tradjenta® tablets [76]

Cyano column (150 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer pH (4.6) and acetonitrile in the ratio of (20:80%, v/v)	215 nm	Assay of ALG in Nesina® tablets [77]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of 0.2 triethylamine buffer (pH 6.0) and methanol in the ratio of (30:70%, v/v)	254 nm	Assay of ALG and MT in Kazano® tablets [78]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer (pH 4.0) and acetonitrile in the ratio of (70:30%, v/v)	235 nm	Assay of ALG and MT in Kazano® tablets [79]
C18 column (250 mm × 4.6 mm, 5 µm)	Gradient elution of (0.1% perchloric acid pH 3 - acetonitrile in the ratio of 90:10, v/v) and (0.1% perchloric acid, pH 3-acetonitrile in the ratio of 40:60%, v/v)	224 nm	Characterization of process-related impurities including forced degradation products of ALG [80]
Cellulose column (250 mm × 4.6 mm, 5 µm)	Mixture of ethanol and diethylamine in the ratio of (100:0.5%, v/v)	230 nm	Method for the enantiomeric purity of ALG [81]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer and acetonitrile in ratio of (45:55%, v/v)	215 nm	Stability indicating assay of ALG and PG in Oseni® tablets [82]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture (pH 6.8) of methanol and double distilled water in the ratio of (80:20%, v/v)	222 nm	Assay of ALG in Nesina® tablets [83]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 3.5) and methanol in the ratio of (70:30%, v/v)	271 nm	Assay of ALG and PG in Oseni® tablets [84]
]C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of Phosphate buffer (pH 3.6) and acetonitrile in the ratio of (35:65%, v/v)	268 nm	Assay of ALG and PG in Oseni® tablets [85]
Cyano column (250 mm × 4.6 mm, 5 µm)	Gradient elution of (water, acetonitrile and trifluoroacetic acid in the ratio of 1900:100:1, v/v/v) and (acetonitrile, water and trifluoroacetic acid in the ratio of 1900:100:1, v/v/v)	278 nm	Determination of ALG and its potential impurities in bulk drug and Nesina® tablets [86]
C18 column (150 mm × 4.6 mm, 5 µm)	Mixture of potassium dihydrogen phosphate buffer (pH 3), methanol and acetonitrile in the ratio of (20:60:20%, v/v/v)	290 nm	Assay of ALG and MT in Kazano® tablets [87]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of phosphate buffer (pH 4.8) and acetonitrile in the ratio of (48:52%, v/v)	210 nm	Assay of ALG and MT in Kazano® tablets [88]
C18 column (250 mm × 4.6 mm, 5 µm)	Mixture of methanol and phosphate buffer (pH 3) in the ratio of (80:20%, v/v)	269 nm	Assay of ALG and PG in Oseni® tablets [89]

Table 2: Spectrophotometric methods for analysis of gliptins in pharmaceutical formulations

Method	Detection wavelength	Linearity (µg/ml)	Solvent	Application
Ratio difference	202-222 nm	2-25	Deionized water	Assay of SIG and MT in Janumet® tablets [90]
Ratio subtraction	202 nm	2-25	Deionized water	Assay of SIG and MT in Janumet® tablets [90]
Amplitude modulation	208 nm	2-25	Deionized water	Assay of SIG and MT in Janumet® tablets [90]
Direct UV	267 nm	7-27	Methanol	Assay of SIG with Gliclazide [91]
Direct UV	580 nm	15-65	DMSO	Assay of SIG in Sitacretin® and Gliptin® tablets [92]
Direct UV	267 nm	2-10	Distilled water	Assay of SIG in Januvia® tablets [93]
Direct UV	267 nm	5-40	0.1 N HCl	Assay of SIG in Januvia® tablets [94]
Absorbance maxima	266 nm	25 - 225	Distilled water	Assay of SIG and MT in Janumet® tablets [95]
Area under the curve	244-279 nm	25-225	Distilled water	Assay of SIG and MT in Janumet® tablets [95]
First derivative	267-275 nm	10-60	Distilled water	Assay of SIG in Januvia® tablets [96]
Direct UV	267 nm	50-300	Methanol	Assay of SIG in Januvia® tablets [97]
First derivative	275 nm	50-300	Methanol	Assay of SIG and MT in Janumet® tablets [98]
Hantzsch method	430 nm	5-25	Distilled water	Assay of SIG in Januvia® tablets [99]
Dual wave length	225-248 nm	50-150	Methanol	Assay for SIG and SV in Juvisync® tablets [100]
Simultaneous equation	267 nm	10-50	Methanol	Assay for SIG and SV in Juvisync® tablets [101]
Direct UV	267 nm	20-70	Methanol	Assay of SIG in Januvia® tablets [102]
First derivative	275 nm	20-70	Methanol	Assay of SIG in Januvia® tablets [102]
Direct UV	267 nm	20-60	Methanol	Assay of SIG in Januvia® tablets [103]
First derivative	213 nm	20-60	Methanol	Assay of SIG in Januvia® tablets [103]
Second derivative	276 nm	40-80	Methanol	Assay of SIG in Januvia® tablets [103]
Direct UV	267 nm	20-100	0.1 N HCl	Assay of SIG in Januvia® tablets [104]
Absorbance ratio	267 nm	20-160	Distilled water	Assay of SIG in Januvia® tablets [105]
Area under the curve	261-270 nm	20-160	Distilled water	Assay of SIG in Januvia® tablets [105]
Derivative ratio	216 nm	5–50	Methanol	Assay of VIG and MT in Galvumet® tablets [106]
Charge transfer	520 nm	20-250	Acetonitrile	Assay of VIG in Galvus® tablets [107]
Charge transfer	535 nm	25-400	Acetonitrile	Assay of VIG in Galvus® tablets [107]
Charge transfer	842 nm	20-500	Acetonitrile	Assay of VIG in Galvus® tablets [107]
Derivative ratio	265.8 nm	4–24	Methanol	Assay of VIG and MT in Eucreas® tablets [108]
Ratio subtraction	204.4 nm	4–24	Methanol	Assay of VIG and MT in Eucreas® tablets [108]
Reaction with picric acid	410 nm	3-32	Chloroform	Assay of VIG in Galvus® tablets [109]
Simultaneous equation.	233 nm	30-70	0.1 NaOH	Assay of VIG and MT in Galvumet® tablets [110]
Direct UV	210 nm	10-120	Distilled water	Assay of VIG in Galvus® tablets [111]
Reaction with Bromocresol green	423 nm	10-50	Chloroform	Assay of VIG in Galvus® tablets [112]

Reaction with Bromothymol blue	415 nm	5-50	Chloroform	Assay of VIG in Galvus® tablets [112]
Direct UV	244 nm	12.5-200	Distilled water	Assay of VIG in Galvus® tablets [113]
Charge transfer	530 nm	100-850	Distilled water	Assay of SAG in Onglyza® tablets [114]
Direct UV	208 nm	5-40	Methanol	Assay of SAG in Onglyza® tablets [115]
Reaction with NQS	475 nm	30-320	Distilled water	Assay of SAG in Kombiglyze® tablets [116]
Absorbance ratio	211 nm	5-30	Distilled water	Assay of SAG in Onglyza® tablets [117]
Dual wavelength	240-280 nm	5-30	Distilled water	Assay of SAG in Onglyza® tablets [117]
Area under curve	204-241 nm	5-30	Distilled water	Assay of SAG in Onglyza® tablets [117]
Direct UV	277 nm	2-6	Methanol	Assay of LIG in Gly × ambi® tablet [118]
Direct UV	294 nm	5-25	Methanol	Assay of LIG in Tradjenta® tablets [119]
Direct UV	241 nm	10-35	50% Methanol	Assay of LIG in Tradjenta® tablets [120]
Direct UV	276 nm	5-35	Methanol	Assay of ALG in Nesina® tablets [121]
Simultaneous equation	224 nm	0.5-18	Methanol	Assay of ALG and MT in Kazano® tablets [122]
Absorption ratio	251 nm	0.5-18	Methanol	Assay of ALG and MT in Kazano® tablets [122]
First derivative	222 nm	2-16	0.1 M HCl	Assay of ALG in Nesina® tablets [123]

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