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Review Article

Analytical Techniques for the Assay of Vildagliptin: A Review

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Abstract

Vildagliptin is used to manage type II diabetes mellitus. It inhibits the inactivation of glucagon-like peptide-1 and glucose-dependent insulinotropic poly peptide by dipeptidyl peptidase-4 allowing glucagon-like peptide-1 and glucose-dependent insulinotropic polypeptide to potentiate the secretion of insulin in the beta cells and suppress glucagon release by the alpha cells of the islets of Langerhans in the pancreas. Vildagliptin was approved by the European Medicines Agency in 2007. In the present study the authors have summarised the analytical methods so far developed for the estimation of Vildagliptin in the literature.

Keywords: Vildagliptin; Type II Diabetes Mellitus

Introduction

Vildagliptin (CAS: 274901-16-5) (Figure 1) belongs to dipeptidyl peptidase-4 inhibitor class of drugs [1,2]. It exerts its blood glucose-lowering effects by selectively inhibiting dipeptidyl peptidase-4 enzyme and the duration of dipeptidyl peptidase-4 inhibition by Vildagliptin is dose-dependent [3]. Vildagliptin is chemically (*S*)-1-[*N*-(3-Hydroxy-1-adamantyl) glycyl] pyrrolidine-2-carbonitrile ($C_{17}H_{25}N_3O_2$). It is non-hygroscopic and freely soluble in water and polar organic solvents. Vildagliptin is available with brand names, Galvus, Zomelis, Xiliarx, Jalra etc.

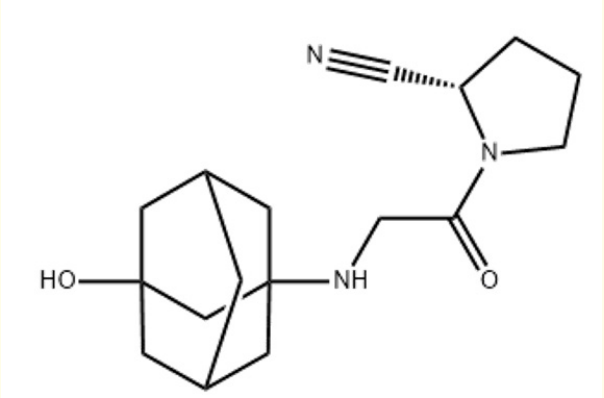

Figure 1: Chemical structure of Vildagliptin.

Different analytical techniques such as spectrophotometry [4-8] (Table 1), RP-HPLC [9-13] (Table 2) and LC-MS/MS [14-18] (Table 3) techniques were developed for the estimation of Vildagliptin in pharmaceutical dosage forms as well as biological fluids.

Table 1: Spectrophotometric methods.

Reagent	Linearity (µg/mL)	λ_{max} (nm)	Ref
Distilled water	5-30	211	[4]
Water	12.5-200	244	[5]
0.1 N HCl (Gastric medium)	5-60	210	[6]
Methanol: Water (1:1)	10-60	217	[7]
Water, 0.1 N HCl, Phosphate buffer (pH 7.4)	2-12	210	[8]

Table 2: Liquid chromatographic methods.

Mobile Phase (v/v)	Detection wavelength (nm)	Column	Linearity (µg/mL)	Ref
Buffer: Acetonitrile (50:50)	220	C18	10-60	[9]
Acetonitrile: Ammonium dihydrogen phosphate (10:90)	200	C18	40-160	[10]
Water: Methanol (70:30)	265	Phenomenex C18	10-50	[11]
Buffer (pH 8.2): Acetonitrile: Methanol (45:48:7)	254	C18	50-90	[12]
0.1 M Phosphate buffer: Acetonitrile (85:15)	210	Agilent XDB-C18	10-150	[13]

Table 3: Mass spectrometric methods.

Mobile Phase (v/v)	Linearity (µg/mL)	Method	Ref
Methanol: 5 mM Ammonium acetate (95:5)	0.010 -1.875	LC-MS/MS	[14]
Acetonitrile: 5 mM Ammonium trifluoroacetate	0.001- 0.852	LC-MS/MS	[15]
Acetonitrile: 2 mM Ammonium acetate (90:10)	0.0016 – 0.501	LC-MS/MS	[16]
Methanol: Water (85:15)	0.44 – 1.46	LC-MS/MS (Impurity Detection)	[17]
Ammonium acetate buffer: Acetonitrile (20:80)	0.071 – 3.024	LC-MS/MS	[18]

Conclusion

The present study represents a detailed review of the analytical methods developed for the estimation of Vildagliptin in pharmaceutical dosage forms as well as biological fluids.

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