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THE COMPLITE REVIEW ON ANALYTICAL AND FORMULATION TECHNIQUES OF GLIPIZIDE

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ABSTRACT: Glipizide is second generation Short acting sulfonylurea prescribed for treatment of type II diabetes Mellitus. It is with short biological half-life of 3.4 ± 0.7 hrs and metabolized in the liver and excreted in the urine largely as inactive metabolites. The clinical and pharmaceutical analysis of drug requires analytical procedures along with pharmacokinetic and pharmacodynamic data with stability study for any analysis of drug. In the present review we have compiled different published analytical methods for determination of glipizide in pharmaceutical methods. The table no 1 indicate Analytical method development and validation of single Glipizide drug by HPLC method; while table no 2 indicates Analytical method development and validation of glipizide with combination of other drugs by HPLC method. In the literature review table no 3 and 4 indicates Analytical method development and validation of glipizide as well as other drugs in combined forms by UV spectrophotometer. This literature review also involved tabulated information about various formulations available of glipizide along with their method of formulation and polymers used in the formulations.

INTRODUCTION: Chemically, Glipizide (GLP) is a substituted aryl-sulphonylurea. Its empirical formula is $C_{21}H_{27}N_5O_4S$, molecular weight is 445.55 gm and IUPAC name is 1-cyclohexyl-3-[[p-[2-(5 methylpyrazinecarboxamido) ethyl] phenyl] sulfonylurea] [1]. GLP is a medium to long acting anti-diabetic drug and commonly used to lower blood glucose level in patients with type two diabetes mellitus [2].

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As GLP is second generation sulfonylurea, which means it undergoes entero-hepatic circulation and act by stimulating the release of insulin from the pancreases and hence reducing blood glucose level in human beings [3]. GLP bind to K_{ATP} channels on the cell membrane of pancreatic β cells of the islets of Langerhans. This leads to increased fusion of insulin granulae with the cell membrane, and therefore increased secretion of insulin [4].

It is a weak acid (pK_a = 5.9) practically insoluble in acid solution but as per biopharmaceutical Classification System (BCS) it is highly permeable [5]. GLP is poor water soluble drug and is practically water-insoluble but, its absolute bioavailability is close to 1 and its dissolution is considered to be rate limiting step (*i.e.*, an effective factor) in its

absorption from gastrointestinal tract [6, 7]. GLP face problem of low bioavailability. Various approaches have been suggested for designing dissolution tests for poorly water-soluble drugs. These include (a) use of large volumes of dissolution medium, (b) removal of dissolved drug, (c) mixed organic aqueous solvents, (d) two phase dissolution media with an upper organic layer, (e) the inclusion of surfactants, (f) pH changes [8].

It is reported to have short biological half-life (3.4±0.7 hr) make it a suitable candidate to be formulated for the sustained delivery system [9]. GLP requires to be administered in 2 to 3 doses of 2.5 to10 mg per day [10, 11]. It exerts side effects such as severe overdose symptoms include low blood sugar, hypoglycemia and gastric trouble, Sweating Shakiness, Extreme hunger, Dizziness, Cold sweats, Blurry vision *etc* [12].

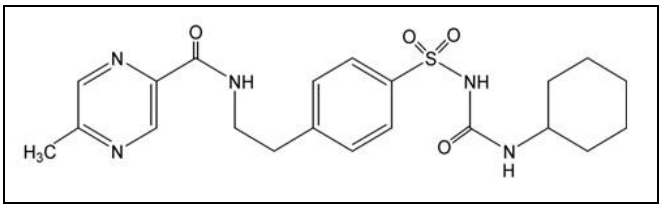

FIG. 1: STRUCTURE OF GLIPIZIDE

This **Table 1** of literature review shows a rapid, simple and sensitive RP-HPLC method for development and validation of single Glipizide drug along with the information like stationary phase and mobile phase used along with their retention time and flow rate with UV detection.

TABLE 1: ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF GLIPIZIDE BY HPLC METHOD

S. no.	Research work	Stationary Phase	Mobile Phase	Detection	Flow Rate (ml/min)	Retention Time (min)	Ref. no.
1	Development and Validation of RP-HPLC Method for Estimation of Glipizide in Bulk Drug and Pharmaceutical Formulation	C18 (ODS 150 mm × 4.6 mm ×3 µm)	Acetonitrile: Water (60:40)	UV at 276 nm	1	2.4	13
2	Development and validation of RP-HPLC-UV method for the determination of Glipizide in human plasma	C18 (ZORBAX ODS,150 mm × 4.6 mm × 5µm)	0.01 M Phosphate buffer (pH 4.25 adjusted by glacial acetic acid): Acetonitrile (65:35)	UV at 275 nm	1.5	10.5	14
3	Development And Validation Of HPLC Method for the Estimation of Glipizide In Pharmaceutical Dosage Forms	C18(Symmetry l50 mm x 4.6 mm × 3.5 µm)	Phosphate buffer (pH 3.5): Acetonitrile (40:60)	UV at 233 nm	1.0	2.82	15
4	Estimation Of Glipizide In Commercial Drugs By RP-HPLC	C18 (Kromosil 250 mm × 46mm × 5 µm)	Methanol: Acetonitrile: Water (40:40:20)	UV at 256 nm	1	3.62	12
5	Glipizide Pharmacokinetics in Healthy and Diabetic Volunteers	C 18 ODS	Acetonitrile: 0.01M KH_2PO_4 buffer(pH 3.5) (35 : 65)	UV at 275 nm	1.5	5.24 ± 0.31	16
6	High Performance Liquid Chromatographic Analysis of Glipizide: Application to In Vitro and In Vivo Studies	C18 (Waters Spherisorb S5 ODS2 (4.6 mm× 250 mm × 5µm)	Acetonitrile: 0.05M KH_2PO_4 (pH 3.5 with *o*-Phosphoric acid (50:50)	UV at 275 nm	1.5	7.87	17
7	Development and Validation of LC Method for the Estimation of Glipizide in Pharmaceutical Dosage Form and Serum	C18(Inertsil ODS, 45 mm ×15mm × 5 µm)	Methanol: Water: 0.01M, KH_2PO_4) (70:25:5)	UV at 270 nm	1.5		18

8	Reverse phase High Performance Liquid chromatography method for analysis of Glipizide in Pharmaceutical dosage forms	C18 (InertsilODS 250mm × 4.6mm × 1µm)	Methanol: 0.05 M KH_2PO_4 (pH 7, adjusted by 1% Triethylamine (85:15)	UV at 225 nm	1	3.21	19
9	Development And Validation of LC Method for the Estimation of Glipizide In Pharmaceutical Dosage Form And Serum	C-18 (Inertsil ODS 250 mm x4.6mm × 5µm)	Methanol: Water: 0.01M KH_2PO_4 (70:25:5)	UV at 270 nm	1.5	3.211	4
10	Development and Validation of RP-HPLC Method for Analysis of Glipizide in Guinea Pig Plasma and its Application to Pharmacokinetic Study	PC-Micra NPS RP18 (33 mm × 4.6 mm × 1.5 µm)	Phosphate Buffer (pH 3.5): Acetonitril (ACN): THF (80:15:5)	UV at 275 nm	0.4	2.01	20
11	Glipizide matrix transdermal systems for diabetes mellitus: Preparation, in vitro and preclinical studies	C 18	20 M KH_2PO_4 in water (pH 3.5 adjusted by Phosphoric acid): Acetonitrile (65:35)	UV at 275 nm	1	6.67	21
12	Development and Evaluation of Swellable Elementary Osmotic Pump Tablet of Glipizide	C18 (ODS250 mm × 4.8 mm ×5µm)	Acetonitrile (ACN): 0.01M Phosphate buffer (pH 3.5) (35:65)	UV at 274 nm	1	8.1	7
13	Development and validation of RP-HPLC method for quantification of glipizide in biological macromolecules	C 18 (Hypersil ODS)	10 mM Phosphate buffer (pH 3.5): Methanol (25:75).	UV at 230 nm	1	7.32	22

This **Table 2** of literature survey reveals that, the spectrophotometric HPLC methods are available for individual Glipizide, with other combined drug like Metformin, Repaglinide and other similar drugs in pharmaceutical preparations and biological formulations along with information like stationary phase and mobile phase used along with their retention time and flow rate with UV detection.

TABLE 2: ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF GLIPIZIDE AND OTHER DRUGS BY HPLC METHOD

S. no.	Research work	Stationary Phase	Mobile Phase	Detection	Flow Rate (ml/min)	Retention Time (min)	Ref. no.
1	Novel RP-HPLC Method For Metformin HCl, Glipizide And Repaglinide Pharmaceutical Drug Products	C18 (Zodiac 150mm x 4.6mm × 3.5µm)	Phosphate buffer(pH 3): Acetonitrile (45:45)	UV at 210 nm	1	3.71	23
2	Development and Validation of RP-HPLC Method for Simultaneous Determination of Glipizide, Rosiglitazone, Pioglitazone, Glibenclamide and Glimepiride in Pharmaceutical Dosage Forms and Human Plasma	C18 (ODS150mm × 4.6 mm ×5 µm)	Phosphate buffer (pH 3.5): Acetonitrile: Methanol (55:15:30)	UV at 248 nm	1	4.51	24
3	Development of a RP-HPLC Method for Simultaneous Determination of Some Antidiabetic Sulfonylurea Drugs in Bulk and Pharmaceutical Dosage Forms	C18 (ODS 150 mm × 4.6 mm × 5 µm)	Methanol: Acetonitrile: Phosphate buffer (pH 3.5) (60:10:30)	UV at 230 nm	1.5	8.0	25

4	Formulation Development and Assessment of Controlled Release Bilayered Osmotic Tablet Carrying Sulfonylurea Class Anti Diabetic Agent & Imperative Factors Imparting Significant Impact on Drug Release	C18 (ODS 15cm × 3.9mm × 4µm)	Phosphate buffer (pH 7.5): Acetonitrile (60:40)	UV at 225nm	1	6.21	26
5	Formulation and evaluation of bilayered gastro retentive floating tablets containing metformin HCl and glipizide	C18 (Symmetry 150 mm × 4.6 mm x 5µm)	Methanol: Phosphate buffer (pH 1.2) (50:50)	UV at 225 nm	0.8	10.0	27
6	Glipizide and Metformin Hydrochloride Tablets	C 18 (ODS 25 cm ×4.6 mm ×5 µm)	Methanol : phosphate buffer (pH 6.0) (1:1)	UV at 260 nm	1	3.0	28
7	Development and Validation of Reverse phase High Performance Liquid chromatography method for Simultaneous Estimation of Glipizide and Metformine in Tablet Dosage Forms	C 18 (ODS 250 mm x 4.5 mm × 5µm)	0.2 M Phosphate buffer (pH 5.8): Acetonitrile (60: 40)	UV at 218 nm	1	7.9	29
8	Simultaneous Determination of Glipizide and Glimepride by RP-HPLC In Dosage Formulations and In Human Serum	C18 (Nucleosil 10 cm × 25 mm × 0.46 µm)	Methanol: Water (80:20)	UV at 230 nm	1	3.13	30
9	Simultaneous Estimation of Metformin and Glipizide By RP-HPLC and its Validation	C 18 (Intersil 250 mm x 4.6 mm × 5 µm)	Phosphate buffer (pH 8.0): ACN (50:50)	UV at 257 nm	2	4.21	31
10	Single and high resolution RP-HPLC method for the determination of six anti diabetic drug products	C18 (ODS 150mm× 4.6mm × 3µm)	Phosphate buffer (pH 3) by H_3PO_4 acid: Acetonitrile (1:1)	UV at 229 nm	0.6	11.43	32
11	Stress degradation study of two oral antidiabetics, gliclazide and glipizide and chemical analysis by LC and LC/MS methods	C18 (Poroshell 120SB 100 mm × 3.0 mm × 2.7 µm)	Phosphate buffer (pH 4.3): Acetonitrile (60:40)	UV at 230 nm	1	3.7	33
12	Separation and Quantification of Eight Antidiabetic Drugs on A High-Performance Liquid Chromatography: Its Application to Human Plasma Assay	C18 (100 mm × 4.6 mm × 5 µm)	0.05 % Formic acid: Methanol (42 : 58)	UV at 234 nm	0.5	7.46	34
13	Development of stability indicating assay method for the simultaneous estimation of metformin hydrochloride and glipizide by RP-HPLC method	C18 (ODS 250 mm × 4.6 mm× 5 µm)	Acetonitrile: Water (70:30)	UV at 222 nm	1.0	4.44	35
14	Validated Stability-Indicating HPLC-UV Method for Simultaneous Determination of Glipizide and Four Impurities	C18 (250 mm × 4.5 mm × 5 µm)	Phosphate buffer (pH 3): Methanol (60 : 40)	UV at 230 nm	0.5	8.0	36
15	Simultaneous Chromatographic Determination of a Critical Combination of Itraconazole, Clonazepam, and Glipizide	C-18 (Hypersil BDS,150 mm x4.6 mm ×5 µm)	Methanol: Water (75:25)	UV at 254 nm	1	2.50	37

16	Simultaneous Method Development and Validation for the Estimation of Metformin HCl and Glipizide in Bulk and Tablet dosage form by RP-HPLC	C18 (Inertsil ODS 250 mm × 4.6 mm× 5µm)	Phosphate buffer (pH 3.5): Methanol (30:70)	UV at 240 nm	1.0	5.76	38
17	RP-HPLC Method for the Quantification and *In-vitro* Studies of Low Dose Oral Hypoglycemic Tablets	C18 (Knauer 250 mm× 4.6 mm × 5µm)	Phosphate buffer (pH 2.8): Acetonitrile (40:60)	UV at 230 nm	1.0	3.8	39

This **Table 3** of literature survey reveals that a simple, accurate, validated and reproducible UV-Spectrophotometric method has been developed for the simultaneous estimation of Glipizide in different pharmaceutical formulations.

TABLE 3: ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF GLIPIZIDE BY UV METHOD

S. no.	Experimental Work	λ_{Max}	Reference
1	Spectrophotometric determination of glipizide in bulk and tablet dosage form by absorption maxima, first order derivative spectroscopy and area under the curve	255 to 295 nm	40
2	A validated new stability indicating densitometric method for quantitative analysis of glipizide in tablets	230 nm	41
3	Ultraviolet spectrophotometric method for determination of glipizide in bulk and tablet dosage formulation	227 nm	42

This **Table 4** of literature survey reveals that a simple, accurate, validated and reproducible UV-Spectrophotometric method has been developed for the simultaneous estimation of glipizide and other drugs in combinations.

TABLE 4: ANALYTICAL METHOD DEVELOPMENT AND VALIDATION OF GLIPIZIDE AND OTHER DRUGS BY UV METHOD

S. no.	Experimental Work	λ_{Max}	Reference
1	Simultaneous UV-Spectrophotometric Estimation of Glipizide and Metformin in Bulk and Its Dosage Form	276 nm	43
2	Simultaneous Estimation Glipizide and Metformin In Bulk and Tablet Dosage Form By Uv-Spectrophotometry	224 nm	44
3	development and validation of UV-visible spectrophotometric method for simultaneous determination of pioglitazone hydrochloride metformin hydrochloride and glipizide in its bulk and pharmaceutical dosage form (Tablet)	226.4 nm	45
4	Simultaneous spectrophotometric estimation of metformin hydrochloride and glipizide in tablet dosage forms	275 nm	46

TABLE 5: VARIOUS FORMULATIONS OF GLIPIZIDE DRUG AVAILABLE

S. no.	Formulation Type	Polymers	Method Used	Reference
1	Buccal Tablets	Methocel K4M, Methocel K15M) and Carbopol 974, Magnesium stearate	Direct Compression	47
2	Controlled Release Drug Delivery System	Spray dried Lactose, PEO (4,000,000) Microcrystalline cellulose, Magnesium stearate, HPMC K100M,HPMC K 4M, HPMC K15M	Direct Compression	48
3	Fast dissolving tablets	MCC, DCP, Crospovidone, Croscarmellose PVP K-30, Pregelatinized Starch, Magnesium stearate, Starch, Aerosil.	Direct Compression	49
4	Floating microspheres	Poloxamer 188, PVP K30, β-cyclodextrin, Gelucire, PEO, HPMC, Magnesium stearate, crospovidone, and lactose	Emulsion solvent evaporation	50
5	Floating Microspheres	Ethylcellulose, HPMC K4M, HPMC K15M, Ethanol, Dichloromethane and Tween80	Emulsion solvent evaporation	51
6	Floating-Bioadhesive Tablets	Chitosan, Hydroxypropylmethyl- cellulose, Carbopol P 934, Polymethacrylic acid, Citric acid and Sodium bicarbonate	Direct compression	52

7	Gastroretentive Floating Tablets	HPMC K100M, Sodium Alginate, Carbopol 940, Poly Vinyl Pyrrolidone K 30, Sodium Bicarbonate, Citric Acid, Magnesium stearate, Starch, Aerosil.	Direct Compression	53
8	Microcrystalliation	PVA, Tween 80, PEG 200	Emulsion solvent diffusion	54
9	Microemulsion	Glipizide, Capmul , MCM (6.5%), Cremophor, EL (25%), Transcutol P (7.5%), Distilled water,	water titration	55
10	Mouth dissolving Tablet	Sodium starch glycolate, Crospovidone, Pregelatinized starch	Direct Compression	56
11	Mucoadhesive Buccal Tablets	HPMC K15M, Sodium alginate, Carbopol 940,Talc, MCC, MG sterate	Direct Compression	57
12	Mucoadhesive microspheres	Carbapol, HPMC K100, Xanthum gum, Guar gum, Calcium Chloride, water, Sodium Alginate	Ionotropic gelation	58
13	Nanoemulsion	Capryol 90 31, Tween 20, Transcutol P, Water	Aqueous Phase Titration	59
14	osmotic tablet	Sucrose, Mannitol, MCC, PVP, Starch, Magnesium stearate, Cellulose acetate, methanol.	Wet granulation	60
15	polymeric nanoparticles	Dichloromethane (DCM), Acetone, PVA, Eudragit RL100	solvent evaporation	61
16	Proniosomes	Maltodextrin, Sorbitol, Mannitol, Span-60	slurry method	62
17	Sustained Release Matrix	Hydroxypropylmethylcellulose (HPMC), Carboxy methyl cellulose sodium, Microcrystalline cellulose	Direct Compression	63
18	Sustained Release Matrix tab	Hydroxypropylmethylcellulose, Ethyl cellulose, Guar gum, Eudragit RS 100 and Xanthan gum.	Direct Compression	64
19	Sustained Release Matrix Tab	HPMC K4M, K15M, K100M, E15, Sodium CMC	Direct compression	65

CONCLUSION: This article includes review of literature for Glipizide, especially it bears analytical and formulation related information, which is cited in **Table 1 - 5**. This tabulated information will be definitely helpful for all researchers who are currently working on research projects with Glipizide.

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