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A Reviw on Analytical Methods for Determination of Oral Anti-Diabetic Drugs Like Biguanides, Glitazones, Gliptins, Gliflozins and Glimins in Bulk and Pharmaceutical Dosage Forms

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ABSTRACT
The aim of this survey is to approach towards the comprehensive update of different methods for estimation of oral anti-diabetic drug for the treatment of type 2 diabetes mellitus (T2DM) such as biguanides, thiazolidinediones (glitazones), dipeptidyl peptidase 4 (DPP-4) inhibitors (gliptins), sodium/glucose co-transporter 2 inhibitors (gliflozins) and glimins in their bulk and pharmaceutical dosage forms. The review entails about analytical processes like RP-HPLC, HPLC-UV, TLC/HPTLC, LC/MS-MS and UV/VIS. This review approaches toward the information for estimation and separation of mentioned drugs in either in combination or alone.
Keywords: HPLC, UV, TLC/HPTLC, LC/MS-MS,biguanides, glitazones, gliptins, gliflozins and glimins.

INTRODUCTION

High blood sugar levels are a hallmark of type 2 diabetes mellitus (T2DM), a chronic metabolic disorder brought on by either insufficient pancreatic insulin secretion or improper cell response to insulin. It is the most common kind of diabetes, making up around 90% of cases, and usually affects adults, however it is becoming more often found in kids and teenagers. Insulin resistance, or the body's cells becoming less responsive to insulin, is the main characteristic of type 2 diabetes mellitus (T2DM), which raises blood sugar levels. The problem may worsen as the illness develops and the pancreas is unable to make enough insulin. Increased thirst, frequent urination, intense hunger, inexplicable weight loss, exhaustion, hazy vision, and slowly healing wounds are all signs of type 2 diabetes. On the other hand, some T2DM patients may not exhibit any symptoms at first.

Severe consequences from type 2 diabetes might include amputations, heart attacks, strokes, renal problems, visual loss, and nerve damage. Early detection and treatment are therefore essential to avert problems and improve quality of life.

BIGUANIDES

An oral class of antidiabetic drugs called biguanides is used to treat Type 2 Diabetes Mellitus (T2DM). They function by making the body more sensitive to insulin and reducing the amount of glucose produced in the liver. This facilitates better insulin use by the body and lowers blood sugar levels. Metformin is the biguanide that is most frequently used and is regarded as a first-line treatment for type 2 diabetes. It is usually given orally, either before or after meals, and is frequently used in conjunction with insulin therapy or other diabetic drugs.

GLITAZONES

Oral antidiabetic drugs called thiazolidinediones (TZDs), sometimes referred to as glitazones, are used to treat Type 2 Diabetes Mellitus (T2DM). Pioglitazone (Actos) and rosiglitazone (Avandia) are the two primary TZDs. Both drugs are administered orally, and they are usually used in conjunction with insulin therapy or other diabetes drugs. Although TZDs are usually well tolerated, there is a chance of weight gain, fluid retention, and an elevated risk of heart failure as side effects. Rarely, liver issues such as increased liver enzymes and liver failure can also be brought on by TZDs.

GLIPTINS

Oral antidiabetic drugs known as dipeptidyl peptidase-4 (DPP-4) inhibitors are used to treat Type 2 Diabetes Mellitus (T2DM). They function by raising the amounts of specific hormones known as incretins, which promote insulin release and inhibit the liver's synthesis of glucose in order to assist lower blood sugar levels. The DPP-4 inhibitors sitagliptin (Januvia), saxagliptin (Onglyza), linagliptin (Tradjenta), and alogliptin (Nesina) are the ones that are most

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frequently prescribed. These drugs are usually taken orally, with or without food, and are frequently used in conjunction with insulin therapy or other diabetic medications. Although DPP-4 inhibitors are usually well tolerated, adverse effects such headaches, diarrhoea, and upper respiratory tract infections are possible. They may also, in rare instances, result in pancreatitis, and a dangerous inflammation of the pancreas.

GLIFLOZINS

Gliflozins are a class of oral antidiabetic drugs sometimes referred to as sodium-glucose cotransporter 2 (SGLT2) inhibitors. They function by preventing the kidneys from reabsorbing glucose, which causes glucose to be excreted in the urine and lowers blood sugar levels. Canagliflozin (Invokana), dapagliflozin (Farxiga), and empagliflozin (Jardiance) are the three gliflozins that are most frequently prescribed. These drugs are usually taken orally, with or without food, and are frequently used in conjunction with insulin therapy or other diabetic medications. Although gliflozins are usually well tolerated, adverse effects include increased urination, vaginal yeast infections, and urinary tract infections are possible. Rarely, they may also result in ketoacidosis, a dangerous illness marked by elevated blood ketones.

GLIMINS [3]

The first medication in the "glimin" class is imiglimin. A novel class of hypoglycemic medications called glimin is intended to treat individuals with type 2 diabetic mellitus (T2DM). When it comes to how it works, Imeglimin is not like other hypoglycemic medications. It has been demonstrated that Imeglimin improves three important pathogenetic components of type 2 diabetes: 1. elevated gluconeogenesis; 2. insufficient beta cell insulin production triggered by glucose; and 3. peripheral insulin resistance.

TABLE: 1 UV/VIS methods of biguanides, glitazones, gliptins, gliflozins and glimins in bulk and pharmaceutical dosage forms

Sr. No.	Drug	Description	λ (nm)	Ref. No.
1.	Metformin	**Solvent:**Water **Linearity:**10-50 mg mL^{-1}	234nm	4
2.	Metformin	**Solvent:**0.01N NaOH **Linearity:**1-25 µg/ml **LOD:** 0.2226 µg/ml **LOQ:**0.6745µg/ml	233nm	5
3.	Pioglitazone	**Solvent:**phosphate buffer and methanolic solution **Linearity:**1-20µg/ml	268 nm in phosphate buffer and 272nm in methanol.	6
4.	Pioglitazone	**Solvent:**ethyl acetate **Linearity:**2-10µg/ml **LOD:**0.090 µg/ml **LOQ:**0.274µg/ml	269nm	7
5.	Canagliflozin	**Solvent:**MeOH:distill water **Linearity:**10-60µg/ml **LOD:**0.33µg/ml **LOQ:**100µg/ml	224nm	8
6.	Empagliflozin	**Solvent:**ethanol **Linearity:**2-12µg/ml **LOD:**0.02µg/ml **LOQ:**0.07µg/ml	247nm	9
7.	Remogliflozin	**Solvent:**ethanol **Linearity:**100-250µg/ml **LOD:**10.00µg/ml **LOQ:**40.00µg/ml	228nm	10
8.	Linagliptin	**Solvent:** MeOH:distill water	407nm	11

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		Linearity: 5-45µg/ml **LOD:**1.5815µg/ml **LOQ:** 4.7924µg/ml		
9.	Alogliptin	**Solvent:**MeOH:distill water **Linearity:** 5-25µg/ml **LOD:**0.00070µg/ml **LOQ:** 002148µg/ml	277nm	12
10.	Saxagliptin	**Solvent:**MeOH **Linearity:** 5-50µg/ml **LOD:**0.040,0.836µg/ml **LOQ:** 0.121,2.533µg/ml	211nm and 204nm	13
11.	Imeglimin	**Solvent:** double distill water **Linearity:** 2.5-15µg/ml	239nm	14

TABLE: 2 UV/VIS methods of biguanides, glitazones, gliptins, gliflozins and glimins in bulk and pharmaceutical dosage forms in combination with other drugs

Sr. No	**Drug**	**Description**	**λ (nm)**	**Ref. No.**
1.	Metformin+Pioglitazone	**Solvent:** 0.1N NaOH **Linearity:** 5-30 µg/ml MET 2.5-15 µg/ml **LOD:**1.628 µg/ml MET, 0.27 µg/ml PIO **LOQ:**4.884µg/ml MET, 0.71 µg/ml PIO	247.5nm MET and 279.5nm PIO	15
2.	Metformin+Canagliflozin	**Solvent:** MeOH:water (40:60 v/v) **Linearity:** 4-12 µg/ml MET 15-30 µg/ml CANA **LOD:**0.10431 µg/ml MET, 0.3325 µg/ml CANA **LOQ:**0.3161 µg/ml MET, 1.0076 µg/ml CANA	240 nm MET, 319 nm CANA	16
3.	Metformin+Empagliflozin	**Solvent:** MeOH **Linearity:** 20-120 µg/ml **LOD:**At **225nm**0.35µg/ml MET, 0.20 µg/ml EMPA At **237nm**0.19 µg/ml MET, 0.48 µg/ml EMPA **LOQ: At 225nm** 1.06µg/ml MET, 0.59 µg/ml EMPA **At 237nm** 0.58 µg/ml MET, 1.43 µg/ml EMPA.	225nm, 237nm	17
4.	Metformin+Remogliflozin	**Solvent:** Ethanol:water **Linearity:** 2.5-30 µg/ml MET, 1-24 µg/ml REMO **LOD:**0.76 µg/ml MET, 0.31 µg/ml REMO **LOQ:**2.18 µg/ml MET, 0.94 µg/ml REMO	240 MET, 234 REMO	18
5.	Metformin+Linagiptin	**Solvent:** Ethanol **Linearity:** 1-15µg/ml MET, 0.5-9 µg/ml LINA	215-240nm	19
6.	Metformin+Alogliptin	**Solvent:** MeOH **Linearity:** 0.5-18 µg/ml	224nm MET and	20

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			251nm ALO	
7.	Metformin+Saxagliptin	**Solvent:**MeOH:Distill water (1:1) **Linearity:** 2-10µg/ml MET, 50-90 µg/ml SAXA **LOD:**1.2 µg/ml MET, 7.32 µg/ml SAXA **LOQ:**3.6µg/ml MET, 21.62 µg/ml SAXA	231nm MET and 274nm SAXA	21

TABLE: 3 HPLC methods of biguanides, glitazones, gliptins, gliflozins and glimins in bulk and pharmaceutical dosage forms

Sr. No.	Drug	Description	λ (nm)	Ref. No.
1.	Metformin	**Column:** OD-5-100, C_{18} µ-bondapack (0.4x25cm x 0.5 µm) **Mobile phase:** Water:methanol (70:30) **Flow rate:** 0.5mL/min **Retention time:** 4.4min	233nm	22
2.	Metformin	**Column:** Nova-pak silica (150mm x 3.9mm x 4 µm) **Mobile phase:** $NH_4H_2PO_4$buffer:MeOH (21:79 v/v) **Flow rate:** 1.0mL/min **Retention time:** 1.0min	232nm	23
3.	Pioglitazone	**Column:**Hypersil C-8 (250) **Mobile phase:** ACN:water (60:40 v/v) **Flow rate:** 1mL/min **Retention time:** 640 min	266nm	24
4.	Canagliflozin	**Column:** inertsil ODS-3 (250x4.6mm,5µ) **Mobile phase:** 0.02% formic acid:ACN(40:60 v/v) **Flow rate:** 1.2mL/min **Retention time:** 4.4 min	230nm	25
5.	Empagliflozin	**Column:** Develosil ODS HG-5 RPC18 (15cm x 4.6mm, 5µm) **Mobile phase:** phosphate buffer:ACN(45:55 v/v) **Flow rate:** 1.0mL/min **Retention time:** 3.872min	228nm	26
6.	Remogliflozin	**Column:** kromasil C18 (250mm x 4.6mm, 5µm) **Mobile phase:** 0.02M ammonium actatebuffer:ACN:THF (50:45:05 v/v/v) **Flow rate:** 2.0mL/min **Retention time:** 6.2min	228nm	10
7.	Linagliptin	**Column:** symmetry C18 column **Mobile phase:** MeOH:water (83:17 v/v) **Flow rate:** 1.0mL/min **Retention time:** 5.85min	241nm	27
8.	Alogliptin	**Column:** Hypersil gold thermo scientific C18 (250cm x 4.6mm, 5µm) **Mobile phase:** ACN:ammonium carbonate buffer (55:45 v/v)	277nm	28

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		Flow rate: 1.0mL/min **Retention time:** 4.0min		
9.	Saxagliptin	**Column:** Grace C18 (250mm x 4.6mm, 5µm ID) **Mobile phase:** MeOH:Water (80:20 v/v) **Flow rate:** 0.8mL/min **Retention time:** 4.196min	212nm	29
10.	Imeglimin	**Column:** Hypersil ODS (150mm x 4.6mm, 5 µm) **Mobile phase:** buffer pH 3.0:MeOH(75:25 v/v) **Flow rate:** 1.0mL/min **Retention time:** 6.295 min	234nm	30

TABLE: 4 HPLC methods of biguanides, glitazones, gliptins, gliflozins and glimins in bulk and pharmaceutical dosage forms in combination with other drugs

Sr. No	**Drug**	**Description**	**λ (nm)**	**Ref. No.**
1.	Metformin+ Pioglitazone	**Column:** Gemini C18(150mm x 4.6mm, 5 µm) **Mobile phase:** ACN:Ammoniumactate buffer pH-3 (42:58 v/v) **Flow rate:** 0.3mL/min **Retention time:** 5.17 min MET, 8.1 min PIO	255nm	31
2.	Metformin+ Canagliflozin	**Column:** ODS(250mm x 4.6mm, 5 µm) **Mobile phase:** buffer:ACN:MeOH (40:40:20) **Flow rate:** 1.0mL/min **Retention time:** 2.783 min MET, 3.781 min CANA	212nm	32
3.	Metformin+ Empagliflozin	**Column:** Kromosil C18 (250mm x 4.6mm, 5.6 µm) **Mobile phase:** ACN:0.1% OPA (50:50 v/v) **Flow rate:** 1.0mL/min **Retention time:** 2.192 min MET, 3.200 min EMPA	260nm	33
4.	Metformin+ Remogliflozin	**Column:** Zorbax C18(250mm x 4.6mm, 5 µm) **Mobile phase:** MeOH:Phosphate buffer pH-4.2 (80:20 v/v) **Flow rate:** 1.0mL/min **Retention time:** 4.32 min MET, 2.46 min REMO	250nm	34
5.	Metformin+ Linagiptin	**Column:** Water's X-Bridge C18(150mm x 4.6mm, 5 µm) **Mobile phase:** ACN:0.02M phosphate buffer pH-5 (35:65 v/v) **Flow rate:** 1.0mL/min **Retention time:** 1.6 min MET, 4.6 min LINA	225nm	35
6.	Metformin+ Alogliptin	**Column:** Agilent C18 (250mm x 4.6mm, 5 µm) **Mobile phase:** 0.2% TEA:MeOH (30:70 v/v) **Flow rate:** 1.0mL/min **Retention time:** 6.26 min MET, 3.30 min ALO	254nm	36
7.	Metformin+ Saxagliptin	**Column:** Enable C18 G(250mm x 4.6mm, 5 µm) **Mobile phase:** 0.05 M KH_2PO_4 pH-4.5:MeOH:ACN (60:20:20 v/v/v)	220nm	37

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		Flow rate: 0.6 mL/min **Retention time:** 4.38 min MET, 6.92 min SAXA		

TABLE: 5 TLC/HPTLC methods of biguanides, glitazones, gliptins, gliflozins and glimins in bulk and pharmaceutical dosage forms

Sr. No.	**Drug**	**Description**	**λ (nm)**	**Ref. No.**
1.	Metformin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** ammonium sulfate:2-propanol:MeOH (8:1.6:1.6 v/v/v) **Linearity:** 200-1000ng/spot **LOD:**95ng/ml **LOQ:**200ng/ml	238nm	38
2.	Metformin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** MeOH:chloroform:ammonium acetate (6:3:1 v/v/v) **Linearity:** 100-300ng/spot **LOD:**25ng/ml **LOQ:**100ng/ml	236nm	39
3.	Pioglitazone	**Stationary phase:**silica gel 60 **Mobile phase:** chloroform:MeOH(10:1 v/v) **Linearity:** 200-3000ng/spot **LOD:**65.06ng/ml **LOQ:**197.1ng/ml	254nm	40
4.	Canagliflozin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** toluene: ethyl acetate: MeOH (2:2:1 v/v/v) **Linearity:** 10-500ng/spot **LOD:**0.39ng/ml **LOQ:**1.19ng/ml	290nm	41
5.	Empagliflozin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** ethyl acetate: chloroform: ACN (55:25:20 v/v/v) **Linearity:** 20-120µg/ml **LOD:**0.061µg/ml **LOQ:**0.177µg/ml	254nm	42
6.	Linagliptin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** ethyl acetate: chloroform: ACN (55:25:20 v/v/v) **Linearity:** 10-60µg/ml **LOD:**0.028µg/ml **LOQ:**0.087µg/ml	254nm	42
7.	Alogliptin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** ACN: MeOH (4.5: 5.5 v/v) **Linearity:** 500-5000ng/spot **LOD:**2.356ng/band **LOQ:**7.14ng/band	277nm	43
8.	Saxagliptin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** MeOH: chloroform (6:4 v/v) **Linearity:** 400-1200ng/spot **LOD:**7.96ng/spot **LOQ:**26.54ng/spot	222nm	44

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TABLE: 6 TLC/HPTLC methods of biguanides, glitazones, gliptins, gliflozins and glimins in bulk and pharmaceutical dosage forms in combination with other drugs

Sr. No.	Drug	Description	λ (nm)	Ref. No.
1.	Metformin+ pioglitazone	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** butanol: 4-dioxane: glacial acetic acid (5:3:2 v/v/v) **Linearity:** 2000-20000ng/band MET, 60-600ng/band PIO **LOD:**629.89ng/band MET, 8.51ng/band PIO **LOQ:**1908.76ng/band MET, 25.77ng/band PIO	226nm	45
2.	Metformin+ linagliptin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** Acetone: MeOH: toluene: formic acid (4:3:2:1 v/v/v/v) **Linearity:** 400-2000ng/spot MET, 20-100ng/spot LINA **LOD:**20ng/spot MET, 10ng/spot LINA **LOQ:**100ng/spot MET, 20ng/spot LINA	259nm	46
3.	Metformin+ alogliptin	**Stationary phase:**silica Gel 60 F_{254} **Mobile phase:** ACN: MeOH (4.5: 5.5 v/v) **Linearity:** 100-2500ng/band MET & ALO **LOD:**1.26ng/band MET, 0.91ng/band ALO **LOQ:**3.82ng/band MET, 3.03ng/band ALO	253nm	47

TABLE: 7 LC/MS-MS methods of biguanides, glitazones, gliptins, gliflozins and glimins in bulk and pharmaceutical dosage forms in combination with other drugs

Sr. No.	Drug	Description	Ref. No.
1.	Metformin+ pioglitazone	**Column:** PhenomenexSynergi POLAR-RP 80A column (250 3 4.6 mm, 4 mm) **Mobile phase:** acetonitrile:water with 6 mM ammonium acetate and 0.1% formic acid (50:50, v/v) **Flow rate:** 1.0mL/min **Retention time:** 3.0,2.9 MET, 6.1,4.9min PIO	48
2.	Metformin+ canagliflozin	**Column:** C18 analytical column(50mm x 4.6mm, 5 µm) **Mobile phase:** 0.1% formic acid: ACN (60:40 v/v) **Flow rate:** 0.5mL/min **Retention time:** 0.9min MET, 4.5min CANA	49
3.	Metformin+ empagliflozin	**Column:** Bridged Ethylene Hybrid C18 column (50 mm × 2.1 mm, 1.7 µm) **Mobile phase:** 1% Formic acid: ACN (75:25, v/v) **Flow rate:** 0.2mL/min	50
4.	Metformin+ remogliflozin	**Column:** BDS-Hyoersil, C18 (50mm×4.60mm, 5.0µ) **Mobile phase:** 0.10% HCOOH: MeOH: ACN (10:45:45 v/v/v) **Flow rate:** 0.80 mL/min	51

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