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Review Article

A Review On Chromatographic and Spectrophotometric Methods for Estimation of Dapagliflozin and Glimepiride In Bulk and In Different Dosage Forms

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ABSTRACT

Dapagliflozin and Glimepiride are very effectively used as type II diabetes. They very potent inhibit renal glucose reabsorption and inhibiting sodium glucose transport protein 2 and its called SGLT2 inhibitors. They used to enhance glycemic control as well as reduce body weight and systolic & diastolic blood pressure. They are generally administered as tablets. This review entails different methods developed for determination of the Dapagliflozin and Glimepiride like UV-spectroscopy and liquid chromatography.

Key-words: Dapagliflozin, Glimepiride, UV Spectroscopy, Liquid Chromatography, SGLT2 Inhibitors.

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INTRODUCTION:

Dapagliflozin and Glimepiride drugs are a class of pharmaceutical that inhibit renal glucose reabsorption and therefore lower blood glucose. They act by inhibiting sodium-glucose transport protein 2 (SGLT2), and are therefore also called SGLT2 inhibitors. Dapagliflozin and Glimepiride used in the treatment of type2 diabetes. As studied on Dapagliflozin and Glimepiride enhance glycemic control as well as reduce body weight and systolic and diastolic blood pressure [1].

SGLTs are responsible for mediating glucose reabsorption in the kidneys, as well as in the gut and the heart. SGLT-2 is primarily expressed in the kidney on the epithelial cells lining the S1 segment of the proximal convoluted tubule. It is the major transport protein that promotes reabsorption from the glomerular filtration glucose back into circulation and is responsible for approximately 90% of renal glucose reabsorption. By inhibiting SGLT-2 it prevents renal re-uptake from the glomerular filtrate and subsequently lowers the glucose level in the blood and promotes glycosuria [2, 3].

Selective and potent inhibition of SGLT-2 and its activity is based on each patient's underlying glycemic control and renal function. The results are decreased renal reabsorption of glucose, glycosuria effect increases with higher level of glucose in the blood circulation. Thereby Dapagliflozin and Glimepiride reduces the blood glucose concentration with a mechanism that is independent of insulin secretion and sensitivity, unlike many other anti-diabetic drugs. Functional β-cells are not necessary for the activity of the drug so it is convenient for patients with diminished β-cell function [2, 3]. Sodium and glucose are co-transported by the SGLT-2 protein into the tubular epithelial cells across the brush-border membrane of the proximal renal tubule. This happens because of the sodium gradient between the tubule and the cell, thereby it provides a secondary active transport of glucose. Glucose is later reabsorbed by passive transfer of endothelial cells into the interstitial glucose transporter protein. Different methods have been developed for determination of like UV-spectroscopy, liquid chromatography (HPTLC and HPLC) [2, 3].

Reported methods are categorized depending on the following considerations:

1. Single component analysed by UV-spectroscopy methods and chromatographic method.
2. Analysis of Dapagliflozin and Glimepiride from combination formulation by UV-spectroscopy methods and chromatographic method.

Table: 1 Analysis of dapagliflozin from combination formulation by liquid chromatography

Sr. No.	DRUGS	METHOD	DESCRIPTION	Ref. No.
1	Dapagliflozin API	UV Spectrophotometric Method	**Wavelength-**237 nm **Solvent**-Water **Linearity range-**0.5-0.9 µg/ml **Correlation co-efficient**-0.994 **LOD**-0.0925 µg/ml **LOQ**-0.00129 µg/ml	4
2	Dapagliflozin in Bulk and Pharmaceutical dosage form	UV Spectrophotometric Method	**Wavelength**-233 nm **Linearity range**-10-35 µg/ml **Correlation co-efficient**-0.999 **LOD**-1.24 **LOQ-**3.62	5
3	Simultaneous estimation of Dapagliflozin and Metformin HCL in synthetic mixture	UV Spectrophotometric Method	**Wavelength-**225-237 nm **Solvent-**Methanol **Correlation co-efficient-**0.993 for Metformin and 0.991 for Dapagliflozin **% RSD-**1.102 of Metformin and 1.353 of Dapagliflozin	6
4	First derivative for simultaneous estimation of Dapagliflozin and Metformin HCL in synthetic mixture	UV Spectrophotometric Method	**Wavelength** **-**Dapagliflozin-235 nm -Metformin HCL-272 nm **Solvent-**Methanol **Linearity range** **-**Dapagliflozin-0.5-2.5 µg/ml	7

			-Metformin-25-125 µg/ml **Correlation co-efficient** **-**Dapagliflozin-0.980 -Metformin HCL-0.982 **LOD** -Dapagliflozin-0.009 -Metformin HCL-0.013 **LOQ** -Dapagliflozin-0.039 -Metformin HCL-0.041	
5	Dapagliflozin API	RP-HPLC	**Mobile Phase** -Ortho phosphoric acid: Acetonitrile (45:55 v/v) **Stationary Phase** **-**BDS Column (250×4.5 mm,5µ) **Solvent-**Methanol **Flow rate=** 1 ml/min **Wavelength-**245 nm **Linearity range** **-** 25-150 µg/ml **Retention time-**2.963 min **Correlation co-efficient-**0.999 **LOD-**0.6 µg/ml **LOQ-**1.8 µg/ml **% Recovery-**99.8%	8
6	Dapagliflozin and Metformin HCL in bulk drug and tablet	RP-HPLC	**Mobile Phase** -Triethylamine : Acetonitrile (50:50 % v/v) **Stationary Phase** **-**Hypersil BDS C_{18} (250×4.6 mm,5µ Particle size) **Solvent-**Methanol **Flow rate=** 1 ml/min **Wavelength-**240 nm **Linearity range** **-**85-510 µg/ml for Metformin and 0.5-3.0 µg/ml for Dapagliflozin **Correlation co-efficient** **-**0.99995 for Metformin and 0.99978 for Dapagliflozin	9

Table: 2 Analysis of Glimepiride from combination formulation by liquid chromatography

Sr. No	Drug	Method	Description	Ref No
1	Glimepiride in pharmaceutical dosage form	UV Spectrophotometric Method	**Detection wavelength :** 249 nm **Linearity range**: 5-30 µg/ml **Correlation coefficient:** 0.999732 **Precision:** 0.159437 **Limit of Detection:** 0.4 µg/ml **Limit of Quantification:** 1.2 µg/ml	10

2	Glimepiride in tablet dosage form	RP-HPLC Method	**Detection wavelength:** 210 nm **Mobile Phase:** Acetonitrile: 0.05M monophasic potassium phosphate (pH 6.0) (40:60) (v/v). **Stationary Phase:** Hypersil C_{18} column (15x3.9mm) **Retention time:** 7.8 min **Flow rate**: 1.5 ml/min **Recoveries** : 99-101%	11
3	Glimepiride in tablet formulation	Stability indicating RP-HPLC Method	**Detection wavelength:** 228nm **Mobile Phase:** potassium phosphate buffer (pH 6.5; 27.5 mmol/L)-methanol (34 + 66, v/v) **Stationary Phase:** C18 column (250 x 4.6 mm, 5.0 pm) **Flow rate:** 1 ml/min **Retention time:** 9 min **linearity** 2 to 40 mg/L **LOD** : 0.315 mg/L **LOQ** : 1.050 mg/L	12
4	Glimepiride in supersaturatable Self Nano-emulsifying (SNE) formulation	RP-HPLC Method	**Detection wavelength:** 228nm **Mobile Phase:** potassium di-hydrogen phosphate buffer(pH-4): Acetonitrile (50:50 v/v) **Stationary Phase:** Kromasil C18 column (150 x 4.6 mm; 5µ) **Retention time:** 0.9152 min **Flow rate:** 1.0ml/min	13
5	Pioglitazone and Glimepiride in bulk and combine dosage form	UV Derivative(1^{st} order) Spectrophotometric Method	**Detection wavelength:** Pioglitazone :225 nm Glimepiride: 248 nm **Solvent:** 0.1 N HCL **Linearity range:** Pioglitazone **:**5-30µg/ml Glimepiride : 4-20 µg/ml **Correlation coefficient:** Pioglitazone **:** 0.9912 Glimepiride : 0.9964 **Limit of Detection:** Pioglitazone **:** 0.0187 µg/ml Glimepiride : 0.132 µg/ml **Limit of Quantification:** Pioglitazone **:** 0.056µg/ml Glimepiride : 0.40µg/ml	14
6	Pioglitazone and Glimepiride in tablets	RP-HPLC Method	**Detection wavelength:** 225 nm **Mobile Phase:** Phosphate buffer(pH-4.5): Acetonitrile (45:55 v/v) **Stationary Phase:** Inertsil ODS (250x4.6mm, 5µm in particle size)	15

			Retention time: Pioglitazone: 4.6 min Glimepiride: 7.7 min **Flow rate:** 1.0ml/min **Linearity range:** Pioglitazone **:**5-50 µg/ml Glimepiride : 5-25 µg/ml	
7	Metformin HCL and Glimepiride in bulk and tablet dosage form	Simultaneous UV Spectrophotometric Method	**Detection wavelength:** Metformin : 236 nm Glimepiride: 228 nm **Solvent:** Methanol **Linearity range:** 5-25µg/ml	16
8	Metformin HCL and Glimepiride in combined tablet dosage form	RP-HPLC Method	**Detection wavelength:** 285 nm **Mobile Phase:** Ortho-phosphoric acid (pH -9.2) Methanol(60:40 v/v) **Stationary Phase:** Water symmetry shielde Rp 18 column(250x4.6mm, 5µm in particle size) **Retention time:** Metformin: 2.344min Glimepiride: 3.725 min **Flow rate:** 1.0ml/min	17
9	Metformin HCL and Glimepiride in Fixed-Dose Combination	Stability-Indicating RP-HPLC Method	**Detection wavelength:** 230nm **Mobile Phase:** an aqueous phase (20 mM phosphate buffer, adjusted to pH 3.0) and an organic phase (methanol:acetonitrile;62.5:37.5) in the ratio of 80:20 **Stationary Phase:** JASCO Finepak SIL (250 mm × 4.6 mm i.d. 5 µm) **Retention time:** Metformin HCL:2.75 min Glimepiride: 5.87 min **Flow rate:** 1 ml/min	18
10	Glimepiride and Metformin in Human Plasma	HPLC Method	**Detection wavelength:** 231nm **Mobile Phase:** Methanol: Water (90:10%v/v) **Stationary Phase:** C18 column20 (250 x 4.6 mm; 5µ) **Retention time:** Glimepiride: 4.286 min Metformin HCL :2.262 min **Flow rate:** 1 ml/min **Linearity:** Glimepiride:0.2-1microg/ml Metformin HCL: 1-5microg/ml **Correlation coefficient:** Glimepiride: 0.9998 Metformin HCL: 0.9999 **%Recovery :** Glimepiride: 99.98%	19

			Metformin HCL: 99.9% **Assay**: % Purity Glimepiride: 98.05 Metformin HCL: 99.69	
11	Pioglitazone and Glimepiride in tablet-Dosage form	UV By multi wavelength Spectroscopy	**Detection wavelength:** 280nm and 238nm **Solvent :** 0.1 N NaOH **Linearity range:** Pioglitazone **:**10-50 µg/ml Glimepiride : 1-5 µg/ml **% RSD**: Pioglitazone **:** 0.74 Glimepiride : 0.96 **% Recovery:** Pioglitazone **:** 101.0 Glimepiride : 100.9	20
12	Rosuvastatin Calcium and Glimepiride in Tablet Dosage Form	UV Spectrophotometric Method	**Detection wavelength:** 241nm and 231nm **Solvent :** 0.1 N NaOH **Linearity range:** Rosuvastatin calcium & Glimepiride **:**10-22µg/ml **Accuracy (% Recovery):** Rosuvastatin calcium : 99.04% Glimepiride **:** 100.94%	21
13	Glimepiride in self-Nano emulsifying powder (SNEP) formulation	RP-HPLC method and its dissolution study	**Detection wavelength**: 228 nm using PDA detector. **Mobile Phase**: Acetonitrile:0.2 M phosphate buffer (pH = 7.4) 40:60 *v/v* **Stationary Phase:** Octadecylsilane (ODS) column (250x4.6mm, 5µm in particle size) **Flow rate**: 1.0ml/min **Linearity range**: Glimepiride : 0.2-2 µg/ml **Correlation coefficient:** Glimepiride: 0.999 **Limit of Detection:** Glimepiride : 0.38 µg/ml **Limit of Quantification:** Glimepiride : 1.17 µg/ml	22
14	Rosiglitazone and Glimepiride in combined dosage forms and human plasma	RP-HPLC method	**Detection wavelength:** 235 nm using nicardipine as an internal standard. **Mobile Phase:** Acetonitrile : 0.02M Phosphate buffer(pH5) (60:40 v/v) **Stationary Phase:** C18 column (150 x 4.6 mm; 5µ) **Retention time:** Rosiglitazone: 3.7 min Glimepiride: 4.66 min Nicardipine : 6.37 min. **Flow rate:** 1.0ml/min **Linearity range:**	23

			Rosiglitazone **:**0.10-25 µg/ml Glimepiride : 0.125-12.5 µg/ml **Limit of Detection:** Rosiglitazone & Glimepiride : 0.04µg/ml **Limit of Quantification:** Rosiglitazone **:** 0.13µg/ml Glimepiride : 0.11µg/ml	
15	Pioglitazone and Glimepiride in pharmaceutical dosage form	RP-HPLC Method	**Detection wavelength:** 230nm **Mobile Phase:** Acetonitrile: KH_2PO_4 buffer(pH6) (60:40 v/v) **Stationary Phase:** Phenomenex Luna (150x4.6mm, 5µm in particle size) **Retention time:** Pioglitazone: 4.4min Glimepiride: 2.7 min **Flow rate:** 1.5ml/min **Linearity range:** Pioglitazone **:** 240-360µg/ml Glimepiride :32-48 µg/ml	24
16	Glimepiride, Pioglitazone, and Metformin In Pharmaceutical Dosage Forms	RP-HPLC Method	**Detection wavelength:** 228nm **Mobile Phase:** Buffer(pH5) : Acetonitrile : Tetrahydrofuran**:** (40 : 50 : 10) **Stationary Phase:** Inertsil ODS-3V (250 mm × 4.6 mm, 5 µm) **Resolution Run time:** Glimepiride: 5 min Pioglitazone: 3.9min Metformin:1.3 min **Flow rate:** 1.7 ml/min **Linearity** : 150%, 125%, 100%, 75%, and 50% solutions	25
17	Metformin, Voglibose, Glimepiride in Bulk and Combined Tablet Dosage Form	Gradient RP-HPLC	**Detection wavelength:** 230nm using Photodiode array detector. **Mobile Phase:** 0.02M phosphate buffer (pH 2.5): Acetonitrile (v/v) **Stationary Phase:** Inertsil ODS 3V (150x4.6mm, 5µm in particle size) column in a gradient mode. **Retention time:** Metformin: 2.423min Voglibose : 8.191min Glimepiride: 11.708min **Flow rate:** 1.0ml/min **Linearity range:** Pioglitazone **:** 240-360µg/ml Glimepiride :32-48 µg/ml **Gradient programming :** 18 min **%Assay :** Metformin: 99.92% Voglibose : 99.32% Glimepiride: 99.72% **Linearity range :** Metformin: 200-600 µg/ml Voglibose : 0.08-0.24 µg/ml	26

			Glimepiride: 0.8-2.4 µg/ml **Regression coefficient :** 0.999 for all the three drugs	
18	Glimepiride and sildenafil citrate in rat plasma	RP-HPLC method And application to pharmacokinetic studies	The drug samples were extracted by liquid-liquid extraction with 300 µl of acetonitrile and 5 ml of diethyl ether. **Detection wavelength:** 230nm **Mobile Phase:** Methanol: Water (85:15 v/v) **Stationary Phase:** C18 column **Retention time:** Glimepiride: 2.5min Sildenafil : 4min **Flow rate:** 1.0ml/min **Total run time :** 7 min	27
19	Metformin, pioglitazone, and glimepiride in pharmaceutical dosage forms	Liquid chromatography	**Detection wavelength:** 240nm using a UV-SPD-10AVP detector **Mobile Phase:** Methanol : Acetonitrile: 15 mM potassium di-hydrogen phosphate (pH 4) 40:35:25 (v/v) **Stationary Phase:** Phenomenex-ODS-3 (C-18) column (250 × 4.60 mm, 5 µm) **Retention time:** Metformin : 2.85 ± 0.03 min Pioglitazone: 4.52 ± 0.03 min GLIMEPIRIDE: 7.08 ± 0.02min **Flow rate:** 1.0ml/min **Linearity Range :** Metformin : 0.2–50 µg/ ml Pioglitazone & Glimepiride : 0.2–30 µg/ml **Precision :-** Metformin : Intra-day % RSD : 1.01–3.24 Inter-day % RSD : 1.54–4.09 Pioglitazone: Intra-day % RSD : 1.03–2.09 Inter-day % RSD : 2.26–3.10 Glimepiride: Intra-day % RSD : 1.00–3.15 and Inter-day % RSD : 1.58–3.07 **Accuracy :-** Metformin : 99.66 ± 0.14 Pioglitazone: 98.46 ± 0.40 Glimepiride: 98.62 ± 0.39	28
20	Sildenafil and Glimepiride in Rat Plasma	LC-Ms Method and their Applications in Pharmacokinetic	**Mobile phase:** A mixture of 70% methanol, 30% of 0.1% formic acid in water **Stationary phase:** ACE 5 C18 column	29

		Interactions	**Flow rate:** 0.5 mL/min **Auto sampler injection volume:** 5 µL, **Internal standard:** Clarithromycin **%Accuracy:** Glimepiride: 99.7% Sildenafil: 98.9% **Correlation coefficient:** 0.994 to 1	
21	Glimepiride in tablets	UV-derivative spectrophotometric method	**Detection wavelength:** Using a wavelength interval of 8 nm in the range of 220-300 nm. **Solvent :** 5×10^{-3} mol L^{-1} NaOH **Linearity range :** 2 to 40 mg L^{-1}	30
22	Glimepiride In Pure And Tablet Dosage Forms	Direct spectrophotometric method Through Ion-Pair Complex Formation Using Bromo-cresol Green	**I_{max} :** 416 nm **Concentration range :** 0.981-9.812 µg/ml **Correlation coefficientR^2 :** 0.9992 **Limit of detection (LOD) :** 0.088 µg/ml **Limit of quantification (LOQ) :** 0.29 µg/ml **Robustness :** 98.9 to 102.4% **(**with average recovers) **Assay of marketed formulations :** 97.8 to 102.4%	31
23	Combination of Metformin HCL, Atorvastatin Calcium and Glimepiride	RP-HPLC Method and Stress Degradation : Application to Nanoparticles	**Detection wavelength:** 230nm **Mobile Phase:** Phosphate buffer (pH 2.9)–organic phase: 70:30. Organic phase :- methanol–acetonitrile (90:10) **Stationary Phase:** 5-µm Qualisil gold, C18 column (4.6 mm × 250 mm). **Flow rate:** 1.0ml/min **Linearity range:** Metformin : 10–60 µg/ ml Atorvastatin calcium : 2-20 µg/ml Glimepiride: 5–30 µg/ml **Correlation coefficient R^2 :** >0.999	32

CONCLUSION:

This review despicts the reported Spectroscopic and Chromatographic methods developed and validated for estimation of Dapagliflozin and Glimepiride. According to this review it was concluded that for Dapagliflozin and Glimepiride different Spectroscopic and Chromatographic methods are available for single and combination also it was found that the mobile phase containing Acetonitrile, water, and Phosphate buffer were common for most of the chromatographic method to provide more resolution. It was observed that most common combination of Dapagliflozin and Glimepiride were with Metformin. For chromatographic method flow rate is observed in the range 1.0-1.5 ml/min to get good resolution time. For most of the Spectroscopic methods common solvent is Methanol. Hence this all methods found to be simple, accurate, economic, precise and reproducible in nature. Most of Methods were of RP-HPLC and UV absorbance detection because these methods provided with best available reliability, repeatability, analysis time and sensitivity.

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