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A REVIEW ON CHROMATOGRAPHIC AND SPECTROPHOTOMETRIC METHODS FOR ESTIMATION OF GLIFLOZIN IN BULK AND IN DIFFERENT DOSAGE FORMS

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ABSTRACT

Gliflozin are very effectively used as type II diabetes. They very potent inhibit renal glucose reabsorption and inhibiting sodium-glucose transport protein2 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 combination of Gliflozin like UV-spectroscopy and liquid chromatography

Keywords: Gliflozin, UV Spectroscopy, Liquid Chromatography, SGLT2 Inhibitors.

INTRODUCTION:

Gliflozin drugs are a class of pharmaceuticals 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. Gliflozin used in the treatment of type II diabetes. As studied on canagliflozin, a member of this class, Gliflozin 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 reuptake from the glomerular filtrate and subsequently lowers the glucose level in the blood and promotes glucosuria [2,3].

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

S.NO	DRUG	METHOD	DESCRIPTION	Ref. no.
1	**Dapagliflozin** in API	**UV-Spectroscopy**	**Wavelength:** 237 nm **Solvent:** Water **Linearity Range:** 0.5-0.9µg/ml **Correlation Coefficient(r2):** 0.994	**5**
2	**Dapagliflozin** And **Metformin Hydrochloride** In Synthetic Mixture	**UV-Spectroscopy**	**Wavelength:** 225nm & 237nm **Solvent:** Methanol **Correlation Coefficient (r2):** 0.993 for Metformin and 0.991 for Dapagliflozin **%RSD:** 1.102 of Metformin and 1.353 of Dapagliflozin	**9**
3	**Dapagliflozin** and **Metformin Hydrochloride** in Synthetic Mixture	**UV-Spectroscopy**	**Wavelength:** 235nm & 272nm **Solvent:** Methanol **Correlation Coefficient(r2) :** 0.984 for Dapagliflozin and 0.982 for Metformin **Linearity Range :** 25-125 µg/ml for Dapagliflozin and 0.5-2.5 µg/ml for Metformin	**10**
4	**Canagliflozin** in human plasma	**HPLC**	**Mobile Phase:** 20 mm potassium dihydrogen orthophosphate : acetonitrile (45 : 55, v/v) **Stationary Phase:** Nucleodur Isis C18 column **Flow Rate:** 1 mL min−1 **Linearity Range:** 16.13–6000 ng mL−1 **Solvent:** Diethyl ether **Wavelength:** 280 nm	**6**
5	**Canagliflozin** in rat plasma	**UHPLC–MS/MS**	**Mobile Phase:** Acetonitrile-water (80:20, v/v) **Stationary Phase:** BEH C18 column (100×2.1mm, i.d. 1.7µm) **Flow Rate:** 0.3mLmin(-1) **Wavelength:** 283 nm	**8**
6	**Dapagliflozin** In API	**RP-HPLC**	**Mobile Phase:** Ortho Phosphoric Acid : Acetonitrile (45:55 v/v) **Stationary Phase:** BDS column (250×4.5mm, 5µ) **Flow Rate:** 1ml/min **Wavelength:** 245 nm **Linearity Range:** 25-150µg/ml **Retantion Time:** 2.963 min **Correlation Coefficient(r2):** 0.999 **LOD:** 0.6 µg/ml **LOQ:** 1.8µg/ml **%Recovery:** 99.8% **Solvent:** Methanol	**4**
7	**Canagliflozin** in tablet dosage form	**RP-HPLC**	**Mobile Phase:** Water: Acetonitrile (55:45%v/v) **Stationary Phase:** ODS column (4.6 × 150mm, 5µ particle size) column **Flow Rate:** 1.0 ml/min **Wavelength:** 214nm **Linearity Range:** 25-150 ppm **Retention Time:** 2.8 min **Correlation Coefficient(r2):** 0.999 **LOD:** 0.037 **LOQ:** 0.112 **Solvent:** Methanol	**13**

Table 2. Analysis of gliflozin from combination formulation by liquid chromatography (Cont…)

S.NO	DRUG	METHOD	DESCRIPTION	REF. NO.
8	**Canagliflozin** And **Metformin Hydrochloride in bulk and tablet**	**RP-HPLC-DAD**	**Mobile Phase:** Ammonium Acetate : Acetonitrile (65:35, v/v). **Stationary Phase:** Kromasil C18 column (250mm×4.6 mm, 5mm particle size) **Flow Rate:** 1ml/min **Wavelength:** 254 nm **Linearity Range:** 50-300µg/ml for Metformin and 5-30µg/ml for Canagliflozin **Correlation Coefficient(r2):** 0.999 for Metformin and 0.999 for Canagliflozin	**12**
9	**Dapagliflozin** and **Metformin Hydrochloride** in bulk drug and tablet	**RP-HPLC**	**Mobile Phase:** Triethylamine : Acetonitrile (50:50%/v/v) **Stationary Phase:** Hypersil BDS C18 (250 mm × 4.6 mm, 5 µ particle size) column **Flow Rate:** 1ml/min **Wavelength:** 240 nm **Linearity Range:** 85-510 µg/ml for Metformin and 0.5-3.0 µg/ml for Dapagliflozin **Correlation Coefficient(r2):** 0.99995 for Metformin and 0.99978 for Dapagliflozin **Solvent:** Methanol	**11**
10	**Canagliflozin** and **Metformin** in Tablet	**RP-HPLC**	**Mobile Phase:** Buffer **:** Acetonitrile : methanol (40:40:20) **Stationary Phase:** ODS 250mm x 4.6 mm, 5µ **Flow Rate:** 1 ml/min **Wavelength:** 212 nm. **Retention Time:** 2.783 min for Metformin and 3.781 min for Canagliflozin: **% Recovery:** 100.1% for Metformin and 100.2% for Canagliflozin	**7**
11	**Canagliflozin** and **Metformin** in Pharmaceutical Formulation	**RP-HPLC**	**Mobile Phase:** Phosphate buffer : Acetonitrile (65:35%v/v) **Stationary Phase:** Kromosil C_{18} 250 column **Flow Rate:** 1 ml/min **Wavelength:** 248nm **Linearity Range:** 50-300 µg/ml for metformin and 5-30 µg/ml for Canagliflozin **Retention Time:** 2.413min for Metformin and 3.548 min for Canagliflozin	**14**

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, glucosuria effect increases with higher level of glucose in the blood circulation. Thereby Dapagliflozin reduces the blood glucose concentration with a mechanism that is independent of insulin secretion and sensitivity, unlike many other antidiabetic 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 analyzed by UV-spectroscopy methods and chromatographic method.
2. Analysis of Gliflozin from combination formulation by UV-spectroscopy methods and chromatographic method

CONCLUSION:

This review depicts the reported Spectroscopic and Chromatographic methods; developed and validated for estimation of Gliflozin class. According to this review it was concluded that for Gliflozin (Canagliflozin, Empagliflozin, and Dapagliflozin) different Spectroscopic and Chromatographic methods are available for Single component as well as for 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 Gliflozins were with Metformin. For chromatographic method flow rate is observed in the range 0.8-1.5 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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REFERENCES:

1. Haas, b; eckstein, n; pfeifer, v; mayer, p; hass, m d s (2014). "Efficacy, safety and regulatory status of sglt2 inhibitors: focus on canagliflozin". Nutrition & diabetes 4 (11): e143. Doi:10.1038/nutd.2014.40. Issn 2044-4052.
2. Anderson, s. L.; marrs, j. C. (20 march 2012), "Dapagliflozin for the treatment of type 2 diabetes". Annals of pharmacotherapy 46 (4): 590–598. Doi:10.1345/aph.1q538. Pmid 22433611.
3. Li, an-rong; zhang, jian; greenberg, joanne; lee, taeweon; liu, jiwen (april 2011). "Discovery of non-glucoside SGLT2 inhibitors". Bioorganic & medicinal chemistry letters 21 (8): 2472–2475. Doi:10.1016/j.bmcl.2011.02.056.
4. Manasa. Sanagapati, "Development and validation of a RP-HPLC method for the estimation of Dapagliflozin in api", international journal of pharmaceutical sciences and research, vol-5, 2014
5. Manasa. Sanagapati, "Method development and validation of Dapagliflozin api by UV spectroscopy", international journal of pharmaceutical sciences review and research, july – august 2014
6. Muzaffar iqbal, "A simple and sensitive high performance liquid chromatography assay with a fluorescence detector for determination of Canagliflozin in human plasma", royal society of chemistry,2015
7. Nareddy preethi reddy, "RP-HPLC method development and validation for the simultaneous estimation of Metformin and Canagliflozin in tablet dosage form", international journal of pharma sciences, vol. 5, (2015)
8. Muzaffar iqbal, "Rapid determination of Canagliflozin in rat plasma by UHPLC–

MS/MS using negative ionization mode to avoid adduct-ions formation", research gate, 01/2015

9. Jani br , "Development and validation of UV-spectroscopic method for simultaneous estimation of Dapagliflozin and Metformin Hydrochloride in synthetic mixture", international journal of research and development in pharmacy and life sciences , vol. 4, april - may, 2015
10. Jani br, "Development and validation of UV-spectroscopic first derivative method for Simultaneous estimation of Dapagliflozin and Metformin hydrochloride in Synthetic mixture", journal of bioequivalence studies, volume 1, 2015
11. Mohammad yunoos, "A validated stability indicating high-performance liquid chromatographic method for simultaneous determination of Metformin Hcl and Dapagliflozin in bulk drug and tablet dosage form", Asian journal of pharmaceuticals and clinical research, volume-8, 2015
12. Uttam prasad panigrahy, "A novel validated RP-HPLC-DAD method for the simultaneous estimation of Metformin Hydrochloride and Canagliflozin in bulk and pharmaceutical tablet dosage form with forced degradation studies", oriented journal of chemistry, volume 31, 2015
13. Suma Maddu, "RP-HPLC method development and validation for the estimation of Canagliflozin in tablet dosage form", International journal of pharmacy, volume 5(4). Page: 1288-1292, 2014
14. Gaware Deepak, " A validated stability indicating RP-HPLC method for simultaneous determination of Metformin and Canagliflozi n in pharmaceutical formulation", world journal of pharmacy and pharmaceutical sciences, volume 4, 2015

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