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Analysis of Different Brands of Dapagliflozin (10mg) Tablets Usinghigh Performance Liquid Chromatographic (HPLC) Method

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ABSTRACT
The study involves quantitative analysis of 2 differentbrands (samples) of DAPAGLIFLOZIN (10mg) tablets used in Vadodara (India),usingandHigh-PerformanceLiquidChromatographic methods,The mobile phase was prepared by mixing acetonitrile and 0.1% triethylamine (pH-5.0) in ratio50:50%v/v. The prepared mobile phase was sonicated and filtered through 0.45µm membrane filter. There is no any official method available so as per EU criteria this method is validated as well as performed. Instrument- SHIMADZU HPLC - LC-2030, Software-Lab Solutions used for performing the analysis.at flow rate of 1mL/min and detection wavelength of 224nm. There is no official standard of dapagliflozin is available so here 10 mg of api takes as a standard, in the analysis for sample- 1 RT found 3.894 for 2nd sample RT time found-3.964, both the samples found suitable for market as well as complies the %label claim.

Key words- DAPAGLIFLOZIN, API, TABLETS, MARKETED FORMULATION, HPLC.

I. INTRODUCTION

The purpose ofAnalysis is to identify substances, purify them, separate them, quantify them, determine the molecular structures of chemical compounds that make up pharmaceuticals, and determine how these compounds are combined to make up a pharmaceutical product[1].It's Mainly done by Chemical analysis of drug molecules or agents and their metabolites.[2]

Dapagliflozin is mainly used to treat type 2 diabetes. It can also be used to treat heart failure. Dapagliflozin is especially wont to treat sort two polygenic disorder. It can even be wont to treat failure. Dapagliflozin was approved by EU in 2012 to treat DM-2 and vessel connected illness. Dapagliflozin was approved for medical use within the us in Jan 2014.By inhibiting SGLT2, dapagliflozin blocks organic process of filtered aldohexose within the urinary organ, increasing urinary aldohexose excretion and reducing blood sugar levels. Its mechanism of action is freelance of exocrine gland exocrine gland cell perform and modulation of hypoglycemic agent sensitivity.[3]dapagliflozin structure mainly contains C-glycosyl comprising beta-D-glucose in which the anomeric hydroxy group is replaced by a 4-chloro-3-(4-ethoxybenzyl) phenyl group.3

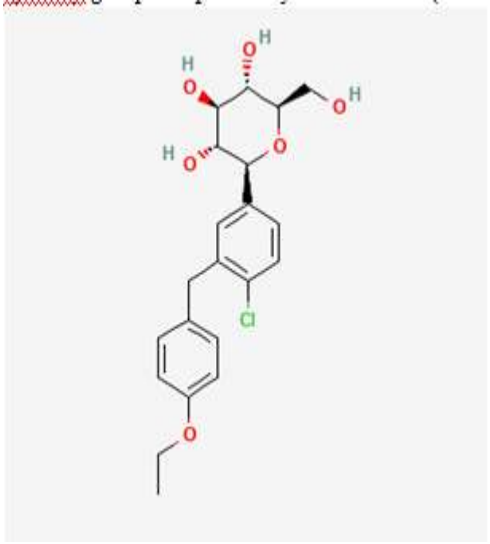

Fig 1 structure of dapagliflozin

Methodology: - There are no many methods available for dapagliflozin but for accuracy and validation HPLC prefers due to its high potency to detect and sensitivity. Assay of Dapagliflozin (Marketed Tablets) are found by using HPLC.

Sample Collection: Here, two Different Sample of Dapagliflozin Taken from Pharmaceutical shop both contain 10 mg of dapagliflozin. For authenticity of tablets bill was taken.(VADODARA)

Avg wait of different samples are given below.

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Table 1: Showing the Average Weight of Tablets from DifferentBrands

Samples	Weight(mg)
SAMPLEA	10.4
SAMPLEB	10.6

Analysis Study

1.High Performance Liquid Chromatography

Instrument- SHIMADZU HPLC -LC-2030, Software-Lab Solutions

Procurement of API Sample of Dapagliflozin procured from Zydus life science Ltd, Ahemdabad, Gujarat.

Preparation of mobile phase[4]

The mobile phase was prepared by mixing acetonitrile and 0.1% triethylamine (pH-5.0) in ratio

50:50%v/v. The prepared mobile phase was sonicated and filtered through 0.45µm membrane filter.

Preparation of standard stock solution.

- An accurately weighed 10.0mg of DAPA was transferred in a 10.0mL volumetric flask, dissolved in sufficient quantity of diluent to prepare a standard stock solution of 1000µg/mL of DAPA. The working standard solution of 50µg/mL was prepared by appropriate dilution of the stock solution with mobile phase.
- 100ml of the mobile phase was measured and added to each of the volumetric flask, and was put on to a sonicator for five minutes, for the drug molecules to dissolve.
- After sonicating for five minutes, the solutions were then filtered through a filter paper into clean beakers.
- 10ml of each filtrate was taken and put into different 100ml volumetric flask, and the mobile phase was added to make up the volume.
- From the above solutions, small portion of each was then put into different chromatographic sample vial, and the vials were put into the machine at different locations**.**
- The Peak area obtained for prepared concentration of different brands of DAPAGLIFLOZIN Shows below.

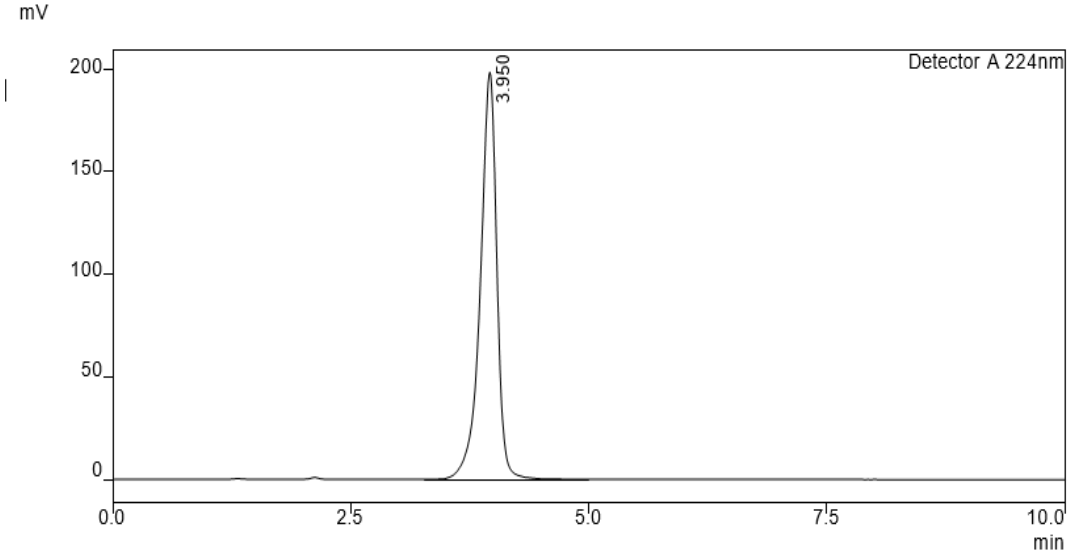

Fig-2 Standard Chromatogram of DAPAGLIFLOZIN(API,10mg)

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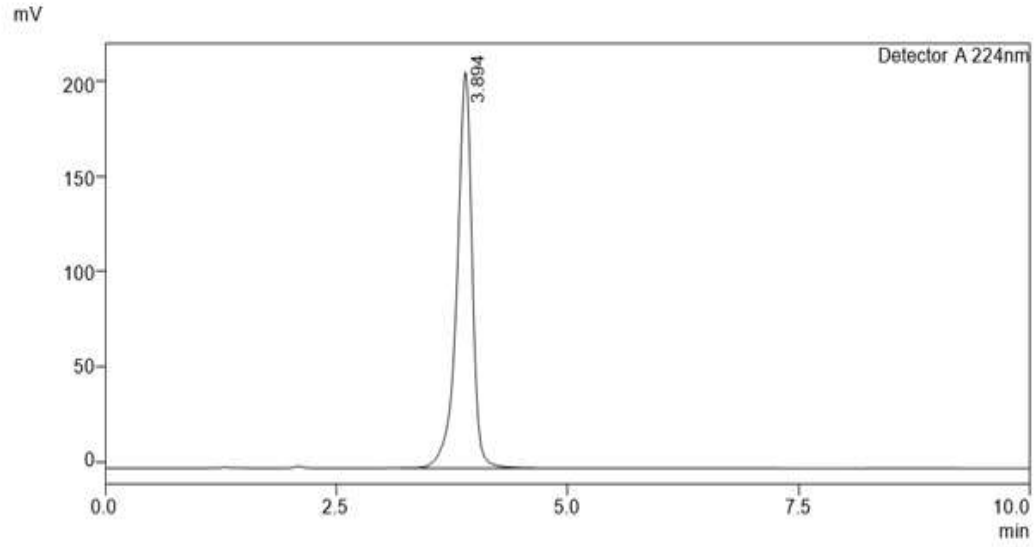

Fig-3 Chromatogram of Type -A tablet of Dapagliflozin

Table-.2 HPLC study of sample -A tablet

Peak#	Ret.Time	Area	Height	Unit	Name
1	3.894	2403723	207849	mg/L	Dapagliflozin
Total		2403723	207849		

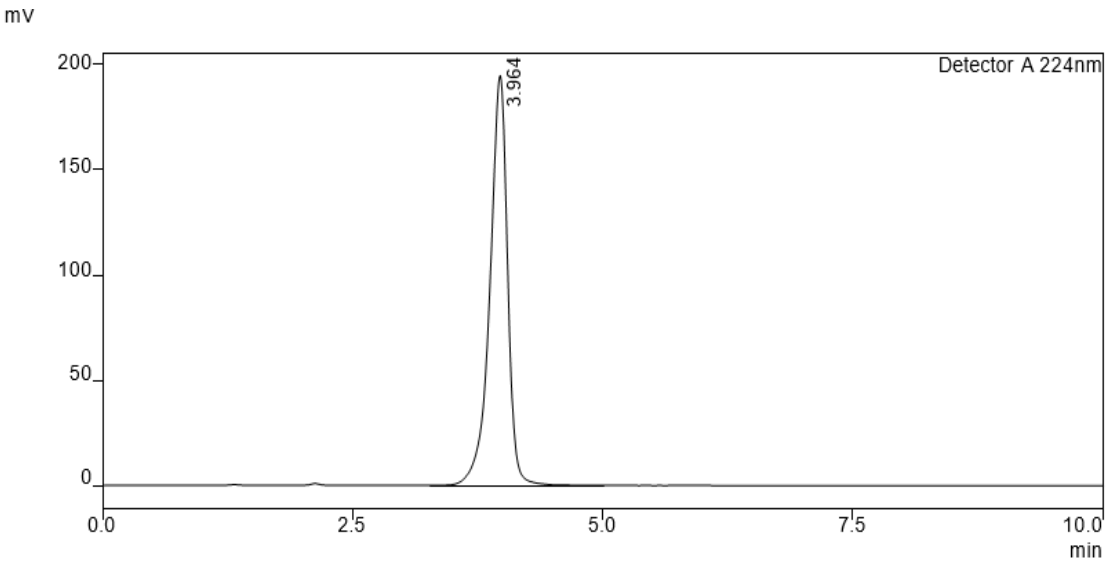

Fig-4 Chromatogram of sample -B tablet of Dapagliflozin

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Table-3 HPLC study of Type -B tablet

	Ret.Time	Area	Height	Unit	Name
1	3.964	2406301	194248	mg/L	Dapagliflozin
Total		2406301	194248		

Result and discussion

Table 4: Showing the Results Obtained Using HPLC Method

Sample solution	Concentration(mg/ml)	Peak Area	%Content	Content(mg)
A	0.014	2403723	100.61	10.1
B	0.0.12	2406301	97.96	9.9

Dapagliflozin was found to be highly soluble in methanol and stable acetonitrile: 0.1% triethylamine(pH-5.0) mixture. Using these solvents working standard solutions were prepared of desired concentration forRP-HPLC estimation of Dapagliflozin. The mean percentage amounts of Dapagliflozin estimated from tabletformulation using RP-HPLC method was found to be 96%.
%label claim is within the limit of the range provided by the EU guideline, the result of estimate of dapa given below

II. DISCUSSION:

According to the EU, Dapagliflozin tablet should contain not less than 90%and not more than 110%. it canbe seen that samples, A, B, both passed since all of them are within the limit specified by the EU. From the results obtained using the Chroma to-graphic (HPLC) method shows that A, BBoth passes as per the criteria.

III. CONCLUSION:

It can thus conclude that all the brands A, B, are within limit as laid down by EU and HPLCmethod. That the HPLC method is slightly more suitable for assay of Dapagliflozin tablets than UV method because its procedure required less dilution. Both brands of dapagliflozin successfully comply limit of EU. And suitable for market Usage.

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