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Review Article

METHOD DEVELOPMENT AND VALIDATION OF MENTIONED CARDIOVASCULAR DRUGS BY UV-VISIBLE SPECTROSCOPY –A REVIEW

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ABSTRACT
This review focuses on the development and validation of UV Spectrophotometric methods for the analysis of mentioned cardiovascular drugs. It provides an overview of various UV spectroscopic techniques employed for the estimation of cardiovascular drugs in pharmaceutical formulations. The review discusses the key aspects of method development, including wavelength selection, and optimization of experimental conditions. Additionally, it highlights parameters such as linearity, accuracy, precision, specificity, and robustness. The review aim to provide a comprehensive summary of the UV spectroscopic methods developed and validated for cardiovascular drugs, highlighting their advantages, limitations and applications in pharmaceutical analysis.

Keywords: UV spectroscopy, cardiovascular drugs, method development, method validation pharmaceutical analysis.

INTRODUCTION

Analytical chemistry is a branch of chemistry which deals with identification of components (qualitative) and determination of quantity of components (quantitative) of substances or samples or mixture. There are two types of analysis, one is qualitative analysis and another one is quantitative analysis. In qualitative analysis, there is identification of components or analyte of mixture or sample is carried out. In quantitative analysis, there is determination of a006Dount of components or analyte of mixture or sample is carried out [1]. Analytical method includes use of a specified technique and detailed-stepwise instructions which are used in qualitative, quantitative or structural analysis of a sample for one or more analytes [2]. Method development and validation involve a systematic approach to designing, optimizing, and verifying analytical techniques, such as chromatography and spectroscopy, to quantify and identify drugs in various matrices. Spectroscopy is the branch of science dealing with the study of interaction of electromagnetic radiation with matter. The most important consequence of such interaction is that energy is absorbed or emitted by the matter in discrete amounts called quanta [3]. Cardiovascular diseases are a leading cause of morbidity and mortality worldwide, necessitating the development and validation of robust analytical methods for cardiovascular drugs. These methods are crucial for ensuring the quality, safety, and efficacy of cardiovascular medications. Cardiovascular risk factors

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and related disorders are common among older adults, and use of various classes of cardiovascular (CV) drugs could reduce the risk of cardiovascular disease (CVD) [4]. The aim of this review article is to compile and discuss the analytical method development of various cardiovascular drugs, including: Edoxaban tosylate monohydrate, Amlodipine besylate, Metoprolol, Lignocaine, Nitroglycerine, Losartan potassium, Furosemide, Atenolol, & Simvastatin To develop and validate a UV-Vis spectroscopic method for the mentioned cardiovascular drugs, to discuss the solvents used and wavelength ranges for each cardiovascular drug. And highlight future directions in the research of cardiovascular drugs.

MATERIAL AND METHODS

Edoxaban Tosylate Monohydrate

The chemical names for Edoxaban Tosylate Monohydrate (EDTM) are N-(5-chloropyridin-2-yl)-N-(1S, 2R, 4S)-4-(Dimethyl Carbomoyl)-2-(5 methyl 6, 7 Di hydro 4H-1, 3) thiazolo (5, 4, 1) pyridine-2-carbonyl amino cyclohexyl ox amide 4 methyl benzene sulfuric acid. Therapeutically, EDTM is used to prevent stroke and systemic embolism patients and prevent treating blood clots. It is classified under an oral direct factor Xa inhibitor. It is systemic embolism in patients with non-valvular atrial fibrillation and to treat deep vein thrombosis. EDTM was developed and validated in a spectrophotometric method using the ELICO SL 210 UV double beam spectrophotometer. Containing of two pairs of quartz cells of 1cm thickness using methanol as a solvent. The λ max of EDTM was determined by using CH3OH as a solvent. The maximum absorbance of EDTM was studied at 291.2nm, which was chosen as the detection wave length for the estimation of EDTM. Calibration of the curve of EDTM was done by preparing the stock solution of two µg/ml concentration. The calibration curve was done by plotting the concentration of EDTM on the X-axis and absorbance on the Y-axis. The developed method was validated according to ICH guidelines. The linearity range of EDTM was studied in the range of 2–10 µg/ml with a correlation coefficient of r2 = 0.999. %RSD was less than 2 in intraday precision. The mean percentage recovery at each level should be 99.82–99.99%. This UV method is simple, quick, sensitive. The results proved that this method is successfully ideal for routine quality control testing of EDTM samples. [5]

Amlodipine Besylate

Chemical names for Amlodipine Besylate are 3-ethyl, 5-methyl (4RS)-2-(2- aminoethoxy) methyl)-4-(2-chlorophenyl)-6-methyl -1, 4-dihydropyridinr-3, 5-dicarboxylate benzene sulphonate (3, 5). The solvent used is slightly soluble in water. Amlodipine Besylate Is Freely Soluble in Methanol. Estimation of Amlodipine Besylate was execute the new method based on the UV and HPLC methods. The UV spectroscopy of Amlodipine was recorded using methanol buffer as a solvent. A calibration curve was obtained for Amlodipine Besylate in the range of 5–30 µg/ml. λmax was found to be 281 nm against reagent blank. The method validated was according to ICH Q2B guidelines for validation of analytical procedures to determine the linearity, regression, correlation coefficient, stability, percent recovery studies, and the linearity analytic concentration at 5µg/ml. The correlation coefficient was found to be 0.9996 and the drug solution was found to be stable for 24 hours. The method relies on the use of simple and cheap chemicals and techniques but provides sensitivity comparable to that achieved by a sophisticated and expensive technique like HPLC or HPTLC. It is used as alternatives for rapid and routine determination of bulk samples and tablets. [6]

Metoprolol

The chemical name for Metoprolol Succinate (MPS) is 1-isoproylaminot-3-9p-(2-methoxethyl) phenoxy0-2-propanol succinate (2:1) (salt) is a widely prescribed beta adrenergic blocker. Therapeutically, metoprolol is used to manage hypertension and various cardiovascular disorders like angina pectoris, heart failure and arrhythmias. Metoprolol was developed and validated in UV-visible spectrophotometer model AU-270, featuring a double beam and double detector arrangement with a 1cm matched cell. λax of metoprolol was determined by using methanol as a solvent at the λmax of 280 nm. Which was chosen as the defection wavelength for the estimation of metoprolol. Calibration of the curve of metoprolol was done by preparing the stock solution of 10 µg/ml. The concentration of metoprolol in x axis and absorbance on the y-axis. The developed method was validated according to ICH guidelines, parameters like precision, linearity, precision, accuracy, ruggedness, robustness and LOD and LOQ. The validated method was applied for estimation of metoprolol in a pharmaceutical formulation. The assay method indicated that the amount of drug in the tablet sample was in good with the label drained the formulation. The developed UV spectrophotometric method adheres to ICH guidelines. [7]

Lignocaine

The chemical name of Lignocaine Hydrochloride is (2-(diethyl amino) – N- (2,6-dimethylphenyl) acetamide: hydrochloride. The molecular formula of lignocaine hydrochloride is 270.8gm/mol. Lignocaine hydrochloride in therapeutically lignocaine hydrochloride is used for the treatment of local anesthetic and a cardiac depressant used as an anti-arrhythmia agent. The UV spectrophotometric method for the development and

validation of lignocaine hydrochloride in bulk and semisolid dosage form was used for analytical balance (shimadzu 220) sonicator (microclean -110) and UV-visible spectrophotometer (systronic 2201). The calibration curve in a series of 10 ml volumetric flasks 2–10 ml of the standard solution was pipetted separately. The volume was completed to the mark using Ro water. The absorbance was measured at wavelength 228.8nm against blank solution. The absorption spectrum shows λ max. of lignocaine hydrochloride at 228.8nm in the same gel formulation in lignocaine hydrochloride 10mg equivalent lignocaine hydrochloride gel was heightened and transferred to the 100ml volumetric flask and dissolved in to water as a solvent after that sonicated for 5 min and vortex for 2 min 4ml of above solution was pipetted out and transferred to the 10ml; volumetric flask and make up the volume up to 228.8nm, The proposed method was validated according to ICH Q28 R, guidelines for validation of analytical procedure that determine the five different concentrations of lignocaine hydrochloride were prepared and analyzed at wavelength 228.8nm. The regression coefficient was found to be 0, 9992. The concentration of 20, 40,60mg/ml was taken as 50,100,150% and % recovery was found to be in the range 99–100%. Hence, the parameter was found to be validated. The range is an interval between the highest and lowest concentration limits of the analyte, i.e. 20–100 µg/ml. [8]

Nitroglycerine

The chemical names for Nitroglycerin are 1, 2, 3 Trinitoxypropane, Trinitroglycerol Glycerin tri nitrate. Nitroglycerin is used for the angina pectoris (chest pain), heart failure, myocardial infarction (heart attack), hypertensive emergencies, and controlled hypertension during surgery. Nitroglycerin releases nitric oxide→ activates guanylate cyclase→ increases cyclic GMP→ releases smooth vascular muscles, especially in veins → reduces preload and after load. Improving cardiac output, the development was achieved by using UV Visible Spectrophotometer (Shimadzu UV-1601 PC and UV-1700).15µg/ml of standard solution of nitroglycerin was scanned in the range of 200-400nm and the maximum absorption of nitroglycerin was found to 210nm using methanol as a solvent. Accuracy and precision and specificity of the proposed method studied, the % RSD should be less than 2%the relative standard solution was found to be 0.740%which is indicate that the system is precise to analyze the sample. The developed method was validated as the ICH guideline parameters like linearity robustness and ruggedness the linear curve was prepared by plotting concentration (µg/ml) Vs absorbance and the correlation coefficient was found to be 0.9915 which is within the limit. [9]

Losartan Potassium

The chemical name for the LOSARTAN POTASSIUM is (mono potassium salt) 2 butyl -4 chloro-1-[(2-(1H- tetrazol-5-yl) [1, 1-biphenyl)]-4-yl)]-1H-imidazole-5-methanol. losartan potassium is a member of class 1 antihypertensive agent. It is effectively used for the treatment of hypertension and heart disease. The development was achieved by using UV1800 Spectrophotometry (Shimadzu), double beam spectroscopy losartan was soluble in water and methanol. 10 µg/ml of losartan potassium of stock solution was scanned in the range of 200-400nm using 50% as blank. The developed method was a first derivative spectroscopy a signal at 234nm of the first derivative spectrum was detected sufficient for quantification. The proposed method was validated like ICH guideline, parameters like LOD, LOQ, sensitivity, Linearity, accuracy and precision. The linearity was determined by plot a graph of concentration vs signal 1D234in the range of 4-14 µg/ml and the correlation coefficient value was found to be r^2-0.9996. The recovery studies was performed by mixing a known amount drug to pre analyzed sample and the percentage recovery was calculated, this valuecovering the specific range (80-120%) the method was found to be precise and the % RSD value for intraday 0.102 and inter day 0.18 respectively it was less than 1%. [10]

Frusemide

FRUSEMIDE (fu) chemical name is 5-(aminosulfonyl) -4 – (chloro–2 – [(2-funanyl methyl) amino benzoic acid]. It has the following generic names: frusemide, arsenide, beronold, desmidian, hasilix and others. Therapeutically, frusemide used for hypertension, edema, acute, pulmonary edema and hypocalcaemia is used in the furosemide tablet. The UV spectrum of frusemide (0.01mg/ml) in 0.1N NAOH was scanned from 190 to 400 nm using a DMS 90 spectrophotometer. It exhibited two maxima at 226 and 272nm. The empirical formula is that C12H11C1N2O5OS corresponds to both molecular weights of 330.77.

Frusemide is white to slightly yellow, odorless, almost tasteless crystalline powder, slightly soluble in water, chloroform and ether soluble in acetone, methanol, and diethylformide. The PH of the aqueous solution is in the range 8.9 to 9.3. The validation parameters show that the UV spectrometric methods were found to be accurate, precise and sensitive. A shimadzu (Kyoto, Japan) modal UV -1800 double beam UV –visible spectrometric attached with computer-operated software UV problem 2, 0 with a spectral width of 2nm, wavelength accuracy of 0.5 nm. The method was used in the absorbance maxima method, and the area under curve method [11]. The analytical method development is accuracy, precision, and linearity. The experimental work was for (a) to check the solubility of frusemide (b) to identify the λ max of

frusemide (c) sample preparation for analysis of tablet formulation. The present UV spectrophotometric methods can be preferred in small scale industries and have been successfully applied and suggested for the quantitative analysis of frusemide in pharmaceutical formulation for QC, where economy and time are essential and to assure therapeutic efficacy.

ATENOLOL

ATENOLOL (ATN) chemically 4- (2-hydroxyl-3-isopropyl aminopropoxy) – phenyl acetamide, is an adrenal receptor blocking agent. The things primarily used in hypertension were angina pectoris, myocardial infarction and heart failure. The development was achieved by using UV double-beam jasco uv-2075 spectrometer and spectral bond width of 2nm and a pair of 1cm matched quartz cells was used. Distilled water was selected as a common solvent for developing spectral characteristics of the drug. The selection was made after assessing the solubility of both the drugs in different solvents. The method was the absorbance ratio method. Wavelengths of 232.0nm (iso absorption point) were selected for analysis. The calibration curves of atenolol were plotted in the concentration range of 5.30 μg/ml and 5-30µg/ml at60th the wavelengths respectively. It mainly acts by the inhibition of renin release, angiotensin -2 and aldosterone production. It is reported to lack intrinsic sympathomimetric activity and membrane stabilizing properties. The Indian pharmacopeia describes a non-aqueous titration method for the assay of atenolol. Based on the results obtained, it is found that the proposed methods are accurate, precise, LOD, LOD, recovery reproducible and economical and can be employed for routine quality control of atenolol. A rapid sensitive UV spectrophotometer method for routine evaluation of atenolol in tablets was developed and validated as per ICH guidelines. UV spectrophotometric method was performed on a 226.6nm. solution of phosphate buffer PH 6.8. Correlation coefficient of 0.9988. [12]

SIMVASTATIN

It is a butanoic acid derivative, synthetically termed 2, 2 dimethyl -1, 2, 3,7,8,8 –hexahydra-3,7-dimethyl -8-(2-(tetrahydra-4hydroxy -6-oxa-2H-pyran-2-yl) ethyl)-1-napthalenyl ester. Statins are cholesterol-lowering agents that reversibly inhibit HMG-CoA Reductase, which catalyzes a rate-limiting step in cholesterol biosynthesis. The development was achieved by using the double-beam UV visible spectrophotometer of Shimadzu Corporation, UV -1800 with two identical 1 cm quartz cells. The absorption spectra of both the standard and sample solution were taken over the range of 200–400 mm. A working solution of 10 µg/ml of simvastatin was prepared by using methanol as a solvent. The wavelength of maximum absorption for simvasatin was found to be 238nm using methanol as a solvent. The developed method was validated as per the ICH Q2 (R1) guidelines. The developed method adhered to beers – lamber's law and was shown by a calibration curve in the range 2–12 µg/ml. The correlation coefficient value of the proposed method was determined by graphing the concentration and absorbance. The value was found to be 0.9995. %. The RSD values for intraday and inter-day precision were more than 2%, which indicated that the method was precise. Exceptional recoveries were obtained at each 80%, 100% and 120% levels, which indicated the accuracy of the method. The LOD and LOQ were measured as 0.0703 µg/ml and 0.2130 µg/ml each. The developed method can be used for quantitative estimation of simvastatin in bulk and pharmaceutical dosages form [13].

Table 1: Summary of Wavelength and Maximum Absorption of Cardiovascular Drugs

S.NO	DRUG NAME	SOLVENT	Λ MAX
1.	Edoxaban tosylate monohydrate	Methanol	291.2nm
2.	Amlodipine besylate	Methanol	281nm
3.	Metoprolol succinate	Methanol	280nm
4.	Lignocaine hydrochloride	Water	228.8nm
5.	Nitroglycerin	Methanol	210nm
6.	Losartan potassium	Methanol	234nm
7.	Furesemide	Methanol and water	277nm
8.	Atenolol	Water	272nm
9	Simvastatin	Methanol	283nm

RESULT AND DISCUSSION

In this review article, we investigated the UV-Vis spectroscopic absorption of mentioned cardiovascular drugs (focusing on their maximum absorption in various solvents. The primary objective was to compile recent literature on UV-Vis spectroscopy determination of these cardiovascular drugs. Our findings indicate that UV-Vis spectroscopy plays a vital role in cardiovascular drug development, enabling the determination of maximum absorption. Based on our analysis of collected articles, we concluded that UV-Vis spectroscopic determination of mentioned cardiovascular

drugs yields efficient results in solvents like methanol, methanol water, and water within the wavelength range of 200-400 nm TABLE 1. The methods validated according to ICH guidelines were found to be reliable, true, and precise, making them suitable for further analytical studies of these cardiovascular drugs.

CONCLUSION

The main objective of pharmaceutical analysis is to get consistent, reliable and accurate data for the analysis of a drug. In developing countries where the cost and availability of the resource are limited, the need for sensitive, selective and accurate analytical method is crucial UV- Vis- spectrophotometer is one of the most frequently employed techniques in pharmaceutical analysis which indicator many methods for assay of substances

UV method doesn't require special regent's equipment's and process only needs to dissolve in methanol (solvent) then measure the absorbance

From this current review, we are concluding that the newly developed method and validated spectra photometric was found to be selective, specific, linear, precise, so bust, rugged and stable for determination of mentioned cardio vascular drug. The method was developed using methanol, methanol water and water for mentioned drugs shows maximum absorbance wavelength between 200-400nm.

From the literature survey revealed that analytical methods such as UPLC, HPLC were reported for estimation of many cardio vascular drugs but they were more costly and time consuming. To overcome these disadvantages of reported method newly developed UV Spectrophotometric method is less time consuming cost effective and economic for routine use in the synthetic drug industry.

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