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DESIGN AND CHARACTERIZATION OF LIPOSOMAL LOADED GELS FOR TRANSDERMAL DRUG DELIVERY OF FLUVASTATIN SODIUM

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Abstract:

In the present study, an attempt was made to develop the transdermal drug delivery systems of Fluvastatin sodium using Liposomes incorporated in a gel, which will control the release of drug, increasing the bioavailability of the drug and thus decreasing the dosing frequency of the drug. It was designed by encapsulating the drug in various Liposomal formulations composed of various ratios of Soya Lecithin: Span 80 or Tween 80 or sodium deoxycholate. The Liposomes were prepared by rotary evaporation sonication method. Lipid: surfactant ratio of 90:10 is found to be more effective when compared to other ratios. Experimental results of the present study showed that deformable lipid vesicles improve the transdermal delivery, prolong the release, and improve the site specificity of the Fluvastatin sodium. The drug diffusion studies showed that the prepared liposome vesicles followed zero order kinetics and mechanism of drug diffusion followed peppas model.

Key Words: *Liposomes, Anti-hyperlipidemic, Controlled release, Lipid, Surfactant.*

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DEVELOPMENT AND VALIDATION OF RP-HPLC METHOD FOR SIMULTANEOUS ESTIMATION OF ATORVASTATIN CALCIUM AND RAMIPRIL IN TABLET DOSAGE FORMS

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ABSTRACT

Objective: A New method was established for simultaneous estimation of Atorvastatin calcium and Ramipril by RP-HPLC method. **Methods:** Chromatographic separations were carried using Phenomenex Luna C18 (250 × 4.6 mm, 5µm) column with a mobile phase composition of methanol in addition to phosphate cradle (0.1% v/v triethylamine pH 4.5 well balanced with 0.1% v/v orthophosphoric harsh) have been delivered at a flow rate of 1 ml/min and the detection was carried out using waters HPLC auto sampler, separation module 2695 HPLC system with PDA detector at wavelength 254 nm. The running time 12min. **Results:** The retention time for Atorvastatin and Ramipril were 3.02 and 6.10 minute respectively. The correlation coefficient values in linearity were found to be 0.999 and concentration range 20-70 µg/ml for Atorvastatin and 20-70 µg/ml for Ramipril respectively. For accuracy The total recovery was found to be 99.8 % and 99.8 % for Atorvastatin and Ramipril. LOD and LOQ for Atorvastatin 2.95 and 9.96. LOD and LOQ for Ramipril 3.34 and 10.05. **Conclusion:** The results of study showed that the proposed RP-HPLC method is a simple, accurate, precise, rugged, robust, fast and reproducible, which may be useful for the routine estimation of Atorvastatin calcium and Ramipril in tablet dosage form.

KEYWORDS: Atorvastatin calcium, Ramipril, RP-HPLC, Simultaneous estimation.

INTRODUCTION

Atorvastatin (Lipitor®), is a lipid-lowering drug included in the statin class of medications. By inhibiting the endogenous production of cholesterol in the liver, statins lower abnormal cholesterol and lipid levels, and ultimately reduce the risk of cardiovascular disease. More specifically, statin medications competitively inhibit the enzyme hydroxymethylglutaryl-coenzyme A (HMG-CoA) Reductase,[1] which catalyzes the conversion of HMG-CoA to mevalonic acid. This conversion is a critical metabolic reaction involved in the production of several compounds involved in lipid metabolism and transport, including cholesterol, low-density lipoprotein (LDL) (sometimes referred to as "bad cholesterol"), and very-low-density lipoprotein (VLDL). IUPAC name calcium bis((3R,5R)-7-[2-(4-fluorophenyl) -3-phenyl-4-(phenylcarbamoyl)-5-(propan-2-yl)-1H-pyrrol-1-yl]-3,5-dihydroxyheptanoate).

Chemical formula $C_{66}H_{68}CaF_2N_4O_{10}$. Molecular weight 1155.34. Atorvastatin (calcium salt hydrate) is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide (DMF), which should be purged with an inert gas. The solubility of atorvastatin (calcium salt hydrate) in these solvents is approximately 0.5, 15, and 25 mg/ml, respectively.

Ramipril is a prodrug belonging to the angiotensin-converting enzyme (ACE) inhibitor class of medications. It is metabolized to ramiprilat in the liver and, to a lesser extent, kidneys. Ramiprilat is a potent, competitive inhibitor of ACE, the enzyme responsible for the conversion of angiotensin I (ATI) to angiotensin II (ATII). ATII regulates blood pressure and is a key component of the renin-angiotensin-aldosterone system (RAAS). Ramipril may be used in the treatment of hypertension, congestive heart failure, nephropathy, and to reduce the rate of death, myocardial infarction and stroke in individuals at high risk of cardiovascular events.[2] IUPAC name (2S,3aS,6aS)-1-[(2S)-2-{[(2S)-1-ethoxy-1-oxo-4-phenylbutan-2-yl]amino}propanoyl]-octahydrocyclopenta[b]pyrrole-2-carboxylicacid.

Chemical formula $C_{23}H_{32}N_2O_5$. Molecular weight 416.58. Ramipril is soluble in organic solvents such as ethanol, DMSO, and dimethyl formamide (DMF), which should be purged with an inert gas. The solubility of ramipril in ethanol is approximately 25 mg/ml and approximately 30 mg/ml in DMSO and DMF.