International Conference & Exihibition on
Analytical and Bioanalytical Techniques 2010
ANANBIOANAL - 2010
Pharmaceutical R & D Summit
doi:10.4172/2155-9872.1000075

A Validated Stability Indicating RP-HPLC Method for the Determination of Amlodipine Besylate and Telmisartan in Pharmaceutical Formulation

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A new Reversed Phase-High Performance Liquid Chomatographic method was developed and validated for the quantitation of Amlodipine besylate and Telmisartan in pharmaceutical formulations. Determination was performed on a HPLC Binary gradient system (Agilent Technologies, 1120 Compact LC HPLC) using a Hypersil-BDS (C_{-18}) column (5 µm, 250 mm 4.60 mm), a mobile phase containing 0.05 M potassium dihydrogen ortho phosphate: acetonitrile (60:40% v/v) in isocratic mode at a flow rate of 1.4 mL/min with UV detection at 237.0 nm. The retention time (t_R) for Amlodipine besylate and Telmisartan were 5.47min and 8.53 min respectively. The response was linear in the concentration range of 1-50 µg mL^{-1} for both Amlo and Tel with regression coefficient (r^2) 0.9987 and 0.999 respectively. The method was validated for precision, accuracy robustness and ruggedness as per ICH guidelines. The LOD and LOQ were found to be 0.03512 µg mL^{-1}, 0.10664 µgmL^{-1} and 0.04663 µg mL^{-1}, 0.14132 µg mL^{-1} for Amlodipine besylate and Telmisartan respectively. The mean recoveries of Amlodipine besylate and Telmisartan were found to be 99.78% and 100.02% respectively. The robustness of the developed RP-HPLC method evaluated by making deliberate variations in the method parameters such as change in flow rate [-0.1 level- 1.3 ml/min; 0.0 level- 1.4 ml/min; +0.1 level -1.50ml/min], ratio of aqueous: organic composition and pH of the mobile phase [+1:-1 level-(61:39/pH-6.41); 0:0 level -(60:40/pH-6.50);-1:+1 level -(59:41/ pH-6.47)] on the retention time, tailing factor and % content indicated that the developed method was unaffected by small changes in method parameters and is robust. The ruggedness of the developed method which was also evaluated by studying the effect of parameters like different analysts and chemicals and solvents (Qualigens- Thermo Fisher Scientific India Pvt. Ltd., Mumbai, India and Universal Labs. Mumbai, India) employed exhibited low % R.S.D values for retention time, tailing factor and % content indicating that the developed method is rugged. The specificity of the method evaluated by forced degradation studies suggest that the method could effectively separate the drugs from its degradation products and can be used for stability-indicating analysis. Due to its simplicity, high precision and accuracy, the proposed RP-HPLC method can be used for the estimation of Amlodipine besylate and Telmisartan in pharmaceutical preparations.