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(54) Title of the invention : VALIDATION OF REVERSE PHASE HIGH PERFORMANCE LIQUID CHROMATOGRAPHIC METHOD FOR SIMULTANEOUS ESTIMATION OF LIGNOCAINE AND ADRENALINE IN INJECTION

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(57) Abstract :

The present invention relates to new RP-HPLC method was developed for the simultaneous estimation of adrenaline and lignocaine in formulation as well as bulk and it was validated as per ICH guidelines. The chromatogram for was found to be satisfactory on symmetry C-18 (4.6×150mm, 5µ Hypersil column) using mobile phase composed of Methanol-Water (80:20, pH adjusted to 5.0 with orthophosphoric acid) at a flow rate of 0.8 ml/min and the detection wavelength of 254 nm. The retention time of adrenaline was found to be 1.450 min and that of lignocaine was found to be 2.707 min. The system suitability parameters proved that the proposed method is suitable for estimation of both the drugs under study. The theoretical plates for separation were found to be 2985 for adrenaline and 5392 for lignocaine. The linearity for adrenaline was studied from 1 to 5 µg/ml concentrations and for lignocaine was studied from 1-5µg/ml concentrations. The precision of the method was good and the recovery of drugs was found to be within the acceptance limits of 80-120%. The LOD and LOQ for adrenaline were found to be 0.0559µg/ml and 0.169 µg/ml respectively. The LOD and LOQ for lignocaine were found to be 0.015 µg/ml and 0.047µg/ml respectively. The proposed RP HPLC method was found suitable for the estimation of adrenaline and lignocaine in fixed dose combination dosage forms (injection) and is simple, selective, reproducible and accurate with good precision and can be successfully applied to routine analytical purpose

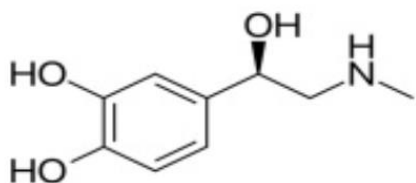


Figure 1 Structure of Adrenaline

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