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Quantitative Thin-Layer Chromatographic Method for Determination of Amantadine Hydrochloride

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A simple and accurate thin-layer chromatographic (TLC) method for quantitative determination of amantadine hydrochloride (AMD) was developed and validated. The method employed TLC aluminum plates pre-coated with silica gel 60F-254 as a stationary phase. The solvent system used for development consisted of n-hexane-methanol-diethylamine (80: 40: 5, v/v/v). The separated spots were visualized as brown spots after spraying with modified Dragendorff ' s reagent solution. Amantadine hydrochloride was subjected to accelerated stress conditions: boiling, acid and alkaline hydrolysis, oxidation, and irradiation with ultraviolet light. The drug was found to be stable under all the investigated stress conditions. The method was validated for linearity, limits of detection (LOD) and quantitation (LOQ), precision, robustness, selectivity and accuracy. The optical densities of the separated spots were found to be linear with the amount of AMD in the range of $5-40$ µg/spot with good correlation coefficient (r=0.9994). The LOD and LOQ values were 0.72 and 2.38 µg/spot, respectively. Statistical analysis proved that the method is repeatable and accurate for the determination of AMD. The method, in terms of its sensitivity, accuracy, precision, and robustness met the International Conference of Harmonization/Federal Drug Administration regulatory requirements. The proposed TLC method was successfully applied for the determination of AMD in bulk and capsules with good accuracy and precision; the label claim percentages were $99.0 \pm 1.0\%$. The results obtained by the proposed TLC method were comparable with those obtained by the official method. The proposed method is more advantageous than the previously published chromatographic methods as it involved the most simple chromatographic technique; TLC. In addition, method relies on the use of inexpensive equipment, a scanner and software, and not critical derivatizing reagent, thus maximizing the ability of laboratories worldwide to analyze samples of AMD.