

DEVELOPMENT OF METHOD FOR QUANTITATIVE DETERMINATION OF AMIODARONE HYDROCHLORIDE IN TABLETS

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Introduction. Amiodarone hydrochloride is a member of a new class of antiarrhythmic drugs with predominantly Class III (Vaughan Williams' classification) effects, available for oral administration as pink, scored tablets containing 200 mg of amiodarone hydrochloride. This medication is used to treat certain types of serious (possibly fatal) irregular heartbeat (such as persistent ventricular fibrillation/tachycardia). It is used to restore normal heart rhythm and maintain a regular, steady heartbeat. Amiodarone is known as an anti-arrhythmic drug. It works by blocking certain electrical signals in the heart that can cause an irregular heartbeat. Amiodarone is particularly helpful when other medicines used for the treatment of arrhythmias are unsuitable for some reason.

Aim. In chemical structure amiodarone hydrochloride is a benzofuran derivative: 2-butyl-3-benzofuranyl 4-[2-(diethylamino)-ethoxy]-3,5-diiodophenyl ketone hydrochloride. Its molecular formula $C_{25}H_{29}I_2NO_3 \cdot HCl$, with a molecular weight of 681.77.

Materials and methods. Amiodarone hydrochloride enters in tablets, such as “Cardiodaron-Zdorovye” (“Pharmaceutical firm “Zdorovye” CJSC, Ukraine), “Amiodarone” (“Lekhim – Kharkiv” JSC, Ukraine), “Cordarone” (“Sanofi aventis”, France).

Results and discussion. Official monographs of the European Pharmacopoeia and the National Ukrainian Pharmacopoeia on active pharmaceutical ingredient contain “Identification” by IR-spectroscopy and reaction of Chlorides, “Impurity H” by thin-layer chromatography, “Related impurities” by liquid chromatography and “Assay” by potentiometric titration. According to the United States Pharmacopoeia (USP), “Assay” is conducted by liquid chromatography.

A high-performance liquid chromatography method is described in the USP in official monograph “Amiodarone tablets” for control organic impurities and assay.

The actual necessity to elaborate a simple spectrophotometric method for the analysis of Amiodarone hydrochloride in pharmaceutical formulations. UV-visible spectrophotometry is the technique of choice in research laboratories, pharmacy and pharmaceutical industries due to its low cost and inherent simplicity.

Conclusions. The objective of the work is to develop a new spectrophotometric method for its estimation in bulk and tablet dosage form with good accuracy, simplicity, precision and economy.