UV-SPECTROPHOTOMETRIC ASSAY SOTALOL HYDROCHLORIDE IN BULK AND TABLET FORMULATION

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Beta-blockers are used by tens of millions peoples to treat high blood pressure and other heart ailments. They are effective, life-saving medicines with decades of widespread and generally safe use.

Sotalol hydrochloride is a hydrophilic non-selective β-adrenoreceptor antagonist used for treatment of hypertension, cardiac arrhythmias, and angina pectoris. It is a racemic mixture consisting of equal amounts of the D and L forms, with the D enantiomer having solely antiarrhythmic class III effects and the L enantiomer having both antiarrhythmic class III and beta-blocking effects.

In this regard, the aim of our work is to develop the UV spectrophotometric methods of assay of sotalol hydrochloride. In medical practice, sotalol hydrochloride is used in the form of tablets and oral solution. In Ukraine registered tablets under the trade name “Sotalol Sandoz” of 40, 80, 160 mg and “Sotalol APO” Borshchahivskiy HFZ of 80, 160 mg.

Sotalol hydrochloride substance and formulations based on it included many foreign pharmacopoeias. Literature survey revealed that very few methods have been reported for the analysis of sotalol hydrochloride dosage form which includes UV spectroscopy the absorption index, reverse phase high performance liquid chromatography methods, thin-layer chromatography, gas chromatography, infrared spectrum, mass spectrum, colour test (Liebermann's reagent – brown; mercurous nitrate – black).

The aim of our work is to develop methods for the spectrophotometric determination of sotalol hydrochloride for its further use in the analysis of its dosage forms, particularly tablets.

In order to achieve this objective we have removed the ultraviolet spectrum was 0.05% aqueous solution and 0.1 N HCl solution of sotalol hydrochloride, maximum is observed at a wavelength of 228 nm and a shoulder at 261-265 nm region and 0.05% solution of aqueous alkali – 249.0 nm. Therefore, quantitative determination of sotalol hydrochloride in a solvent 0.1 N NaOH. Calculation of the content of the active substance in a quantitative spectrophotometric determination was carried out by standard.

As the results of research, obedience to the law of Bouguer-Lambert observed in the concentration range $5.0 \cdot 10^{-4}$ to $2.0 \cdot 10^{-3}$ g/ml at length wave 249 nm.

Approbation methods performed on the tablets “Sotalol Sandoz” containing 0.08 g of sotalol hydrochloride in one tablet. Found that auxiliary substances do not affect the character of the spectrum.

The developed methods has been used by us determination of sotalol hydrochloride commercial pharmaceutical formulations as tablet “Sotalol Sandoz” were prepared mixture model and determined the content of the active ingredient.