DEFINITION OF LIMIT CONTENT ACCOMPANYING IMPURITIES MULTICOMPONENT MEDICINES

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In the world pharmaceutical market well represented drugs for combination therapy. These drugs contain two or more active substances which potentiate the therapeutic effect or directed to treatment of diseases with different, usually concomitant symptoms while using only one drug.

Stability studies of each active substance are needed in the presence of other active substances and excipients in the production and storage of combined drugs. The main criterion for the stability of the finished product is a dynamics of growth contents accompanying impurities degradation, which can significantly to influence on the effectiveness and safety of the drug.

Analytical method for determining the content limit accompanying impurities creates in the process of the stability studies of pharmaceutical substances and finished products. This method is based on the profile of impurities formed as a result the influence of negative environmental factors: light, oxidation, moisture, temperature, etc. Medicinal product exposes the relevant stress conditions and determines which additives are formed by chemical degradation of the drug. The analytical data allow to determine dynamics of accumulation impurities accompanying drug and concluded about its stability during production and storage.

Purpose of research is detection the least stable among the other active ingredient, degradation of which will be the first in the same conditions for all substances and identify predominant impurity of this substance for the implementation of its control in the actual product.

For the purpose the research was conducted degradation of components of the drug with 1 M solution of hydrochloric acid and sodium hydroxide and 3% solution of hydrogen peroxide.

A specific method was developed for determining the content limit of active substances by HPLC with UV method of detection based on these data. Method of determining allows minimal time, material and human resources to control product quality at the same time by two parameters as “Related substances” and “Assay”.

According to various conditions degradation of drugs were found less stable active substance and the overwhelming impurity of this substance. For confirmation of correctness the proposed method was conducted validation in accordance with the requirements of State Pharmacopoeia of Ukraine.