EVALUATION OF MICROBIOLOGICAL SAFETY IN MEDICINAL PRODUCTS MARKETED IN ALBANIA AND COMMONLY USED IN CARDIOVASCULAR DISEASES

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Abstract

The clinical pharmacology of drugs used in cardiovascular diseases, including antihypertensive agents, is an important issue of many recent research activities. Cardiovascular diseases are responsible for more deaths annually than any other disease category. Drug therapy is the most important approach to these diseases and many pharmaceutical products (innovators and generics) are licensed to be used as effective medications. The safety and efficacy of these drugs is strongly related to their chemical structure, pharmacological properties, as well as their microbiology (contamination from raw materials, manufacturing processes, environments, packaging systems, exotoxins from microorganisms, etc.).

Cardiovascular agents are not excluded from microbial contaminations. The microbiological evaluation of several cardiovascular agents, marketed and manufactured in Albanian (brands or generics) has demonstrated specific bacterial and mold contaminations. Specific tests were performed to the medicinal products and their packaging materials - blister packs, plastic bottles, and cardboard boxes. Through morphological and physiological methods, as well as auxanographic techniques, were identified mesophilic molds of *Ascomycetes* and *Basidiomycetes* and were isolated mesophilic and thermophilic bacteria. Comparative results were obtained for the total charge evaluated in cardboard boxes, blisters and tablets. The same bacteria were isolated, while there were identified many different strains of molds. The selected drugs supported the presence and development of molds. Comparative results were obtained taking also in consideration former research scientific publications related to the contaminations observed in liquid medicinal products and their specific package's-glass and plastic bottles, classic and resistant caps, drop counters, etc..

Important conclusions were highlighted: a limited number of microorganisms were evaluated, compared with those in liquid dosage forms; resistant microorganisms were isolated in different types of drugs used for the same purpose; various molds were explored; it was observed a good protective effect in blisters and an increased microbial risk from folding cardboards; the same contaminants were seen both in generics and innovators.

***Key words**: Cardiovascular diseases, Microbial contamination, Branded drugs, Generics, Mesophilic strains, Thermophilic strains.*