

Master's Thesis in Pharmacy year 2016, Christoph Meier et al.

Name of Student:

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Titel:

Optimization of an Hydrogenperoxide Sterilization Cycle and evaluation of material compatibility

Abstract

During the sterile manufacturing process it's necessary to transfer a lot of starting materials into a clean room environment. A spray- and wipe disinfection with ethanol 70 or 80 % solutions can't guarantee a high sterilization security. To improve patient safety especially for manufacture of parenteral nutrition, a new closed hydrogen peroxide sterilizator based on a gas generator in a closed stainless steel cabinet is used to desinfect the surfaces of starting materials during the night. The goal of the master thesis was the development of a sterilization cycle with a 5-log reduction. The migration of hydrogen peroxide into the primary packaging of the starting materials has to be minimized and any thermal stress for the components to be avoided. Only bags of ethyl vinyl acetate (EVA) have a too high migration rate of hydrogen peroxide and can't be sterilized by this procedure. Using bacterial spores as bioindicators and chemical indicators it could be proved that the developed sterilization cycle can guarantee the sanitization to the requested level.