

BP-010

STERILITY TESTS OF SODIUM CHLORIDE 0.9% INFUSION STERILIZED BY BIOBURDEN METHOD

Marline Abdassah, Insan Sunan K. And Nurul Safitri

Faculty of Pharmacy, Padjadjaran University
Bandung-Indonesia

ABSTRACT

Sodium chloride 0.9% infusion is one of large volume parenteral that commonly used as a fluid or electrolyte replacement therapy. Infusion can be sterilized by various methods, one of that is bioburden method. Bioburden method consider microbial burden on preparation before sterilization process, and can be carried out under temperature 121°C. Different with overkill method, bioburden method is considered not fulfill applicable standards in achieve sterility assurance level. This research was done to find out the effectiveness and efficiency of bioburden method compared to overkill method of sodium chloride 0.9% infusion. The research was done by determining D value at 115°C, making of sodium chloride 0.9% infusion, determination of contamination in infusion, sterilization of infusion at 115°C for 18.6 minutes, and evaluation of infusion that includes organoleptis evaluation, pH evalution, sterility test and pyrogen test. The results showed that sodium chloride 0.9% infusion is sterilized with bioburden method declared sterile and free of pyrogens, as well as the infusion are sterilized by overkill method. The results also showed that bioburden method is nearly as effective and efficiency as overkill method.

Reproduced with permission of copyright
owner. Further reproduction prohibited
without permission.