

**Srerility Test Of Sodium Chloride 0.9% Infusion Srerilized By
Bioburden Methol**

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**STERILITY TEST OF SODIUM CHLORIDE 0.9 % INFUSION
STERILIZED BY BIOBURDEN METHOD**

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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 evaluation, 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.

Key words: Sodium chloride 0.9% infusion, Bioburden, Overkill, Sterility test

INTRODUCTION

Sodium Chloride infusion is one of parenterale infusion which is sterile and isotonic solution, can be used for electrolyte replacement therapy (Ansel, 1989) To achieve sterility, the product must be sterilized and tested by sterility test. Infusion can be sterilized by final sterilization generally, especially for compound which is non heat resistant such as sodium chloride (BPOM, 2006). At year of 2007, there was an argumentation about sterility of infusion sterilized by using Bioburden sterilization method, the sterility of product has no fullfill of requirement (Sarnianto,2007). But some researcher have the opposite opinion, the sterility of infusion which is sterilized by bioburden method has the same result which is used by overill sterilization at temperature of 121°C for 15 minutes. Rudi Mantik said, sterile infusion can be sterilized by different kind of sterilization method and must fullfilled the sterility assurance level (SAL) (Tempo Interaktif, 2007). Bioburden Sterilization method need tight monitoring and

controlling for any microba before sterilization process with level of sterility requirement of SAL is 10^{-6} (Lukas, 2006). This method can be done by studying of D value, Study D - value is study for determining of quantity and heat resistency of microorganism in product. D value is time needed in minute for decreasing of microbial population of 90% or one log cycle in certain temperature (Departemen Kesehatan Republik Indonesia, 1995). *Bacillus stearothermophilus* is used as biological indicator because of their heat resistency especially for heat water steam. (Halls, 1994). Based on this introduction, the research of sterility test of Sodium chloride 0.9 % Infusion sterilized by Bioburden method has been carried out

MATERIAL AND METHOD

Material

Alcohol 70 %, Water for Injection sterile and pyrogen free, aquadest, pH indicator universal, carbon active, Sodium chloride, Pyrotell LAL Test (*Single Test*