



THE EFFECT OF DELAYED STERILIZATION FOR 3 AND 4 DAYS ON STERILITY OF 5% DEXTROSE SOLUTION

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ABSTRACT

Sterilization process plays an important role in pharmaceutical industry. Some problems can cause delayed sterilization. It could affect the sterility and concentration of active ingredients. This study was conducted to investigate the effect of delayed sterilization for three and four days on sterility and the concentration of active ingredient in 5% dextrose solution. Dextrose solutions were divided into two groups. The first group which was directly sterilized consisting of 2 bottles, bottle A for sterility test and bottle B for assay concentration of dextrose. The second group which sterilization process had been delayed for 3 and 4 days, consisting of 3 bottles, bottle C for sterility test before sterilization, bottle D for sterility test after sterilization, and bottle E for assay concentration of dextrose after sterilization. Sterility test was performed by using membrane filtration method, and the number of microorganism should be calculated for Total Plate Count Method. Dextrose concentration was measured by *Luff Schrool* titration method. Based on the results of sterility test, concluded that delay sterilization for three and four days did not affect the sterility of 5% dextrose solution. However, in the solution which had not been sterilized, sterility test result was positive, which Total Plate Count results were respectively 3.2×10^4 CFU/ml and 3.2×10^5 CFU/ml for bacteria and 2.5×10^4 and 2.7×10^4 CFU/ml for fungi. Delayed sterilization for three days and four did not affect the concentrations of dextrose. The dextrose concentrations were from 95.868 to 103.118%. These range were within the range of the applicable requirements.

Keywords : dextrose infusion, sterility, delay, membrane filtration