Research in Pharmaceutical Sciences, 2012;7(5)
School of Pharmacy and Pharmaceutical Sciences
Isfahan University of Medical Sciences

Method suitability (validation) test for diclofenac sodium inj. 75 mg/3ml in sterility test.

A. Jabari[1], M. Aghajani[1], J. Mahdjouri[2], S. Mobaseri[3,*], N. Jamali[3], H. Ghobadi[3], M. Mohammad Amini[3], H. Rastegar[2], N. Adib[2]

[1]Chemidarou Industrial Company, Tehran, Iran
[2]Food & Drug Control Laboratory Research Center, Tehran, Iran
[3]Chemidarou Industrial Company, Tehran, Iran

Background and Aims: This study was designed to validate sterility test method for Diclofenac sodium inj. 75mg/3ml. It is generally understood that if a product possesses antimicrobial properties because of the presence of a specific preservative or because of its formulation, this antimicrobial property must be neutralized to recover viable microorganisms.
Methods: Membrane-Filtration, rinsing with fluid A and dilution as an additional neutralization method was performed for sterility test and its validation. After transferring the contents of the test samples to the membrane, they were challenged with the addition of a small number of six viable microorganisms (not more than 100 cfu) to the final portion of fluid A and each membrane transferred to the separate portion of specific medium that their volumes were 150 ml.These six microorganisms include: *Bacillus subtilis* ATCC No. 6633, *Candida albicans* ATCC No. 10231, *Aspergillus niger* ATCC No. 16404, for Soybean-Casein Digest Broth medium. *Staphylococcus aureus* ATCC No. 6538, *Pseudomonas aeruginosa* ATCC No. 9027, and *Clostridium sporogenes* ATCC No.19404, for Fluid Thioglycollate medium. In the second stage these six different microorganisms were added directly to the test samples and then they were filtered.
Results: All six organisms recovered under the validation test method when the viable microorganisms were added to the final portion of fluid A. But we could not recovered some of the microorganisms when we inoculated the viable microorganisms directly to the samples.
Conclusions: These finding confirm that the method of sterility test for Diclofenac sodium inj. 75 mg/3ml could be considered valid, as long as the viable microorganisms should be added to the final portion of diluent which is used to rinse the filter, instead of adding directly to the samples.

Keywords: Sterility test; Membrane filtration; Suitability; Microorganisms.