Abstract

The aim of this study was to verify method of microbiological examination in pharmaceutical water by microbial limit test that it is suitable for its intended use the microbial limit test including membrane method and pour plate method has been used for microbial monitoring in the pharmaceutical, food and beverage, cosmetics and electronics industrial. According to The United States Pharmacopoeia, European Pharmacopoeia and International pharmacopoeia guidelines, the quality control process should be validated to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from the method validation can be used to judge the quality, reliability and consistency of analytical results. In analytical method verification was studied on critical verification parameters, including accuracy and precision in term of repeatability and intermediate precision. For accuracy test, the percentage recovery was in the range of 89–117% (membrane filtration method) and 75–107% (pour plate method) which complied with acceptance criteria (70–130%). For repeatability and intermediate precision tests, the percentage coefficients of variation were in the range of maximum allowable values 15, 25 or 35 %. All negative controls (peptone water) showed no growth of microorganisms complied with acceptance criteria. All positive controls (*Staphylococcus aureus* subsp. *aureus* ATCC 6538) showed the microorganisms growth complied with acceptance criteria. There was no contamination on negative controls and positive controls complied with acceptance criteria. All Pharmaceutical water samples showed no growth of microorganisms. All analytical method verification tests passed without any deviation and out of specification. The verified method can be applied for microbiological contamination examination in pharmaceutical water and the procedures were written in standard operating procedure of microbiological examination in pharmaceutical water by microbial limit test for routine testing in quality control laboratory.

Keywords: Pour plate method, Membrane filtration method Analytical method validation, Analytical Method Verification