Sterility Test Failure Investigations

By Tim Sandle  Nov 14, 2012

INTRODUCTION The pharmacopeial standard applying to sterile products is that sterile products must be capable of passing a test for sterility. The sterility test is an important microbiological test in terms of regulatory expectation rather than probability of detecting gross contamination. It allows for the examination of products purportedly to be sterile. This paper focuses on the conventional sterility test method as set out in the harmonized pharmacopeias (i.e., European, Japanese, and United States). The sterility test is used as a product release test, where the sterility of a product is...

Source URL: http://www.ivtnetwork.com/article/sterility-test-failure-investigations