

Setting Internal Limits And Its Application For Microorganisms Of Concern In Non-Sterile Pharmaceuticals Products



Ratul Saha

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INTRODUCTION The microbiological presence in non-sterile prescription and over-the-counter drugs products is determined as per Pharmacopeial guidelines. The products are categorized as non-sterile based on their route of administration and intended use [3]. In general, they present lower risk to the user from microbial control standpoint in contrast to parenteral and have allowable microbial limits. The allowable microbial limits are based on the considerations of inherent virulence factors, potential hazard of the organisms, the intended use of the product, the dosage form and its route of administration....

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