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Cleaning validation: Methods to determine residue of cleaning agents

T Bhaskar, Shashi Kumar and **A Sambasiva Rao**
Sri Indu Institute of Pharmacy, India

Cleaning validation procedures are carried out in order to assure that residues of cleaning agents are within acceptable limits after the cleaning process. Cleaning agents often consist of a mixture of various surfactants which are in a highly diluted state after the water rinsing procedure has been completed. This makes it difficult to find appropriate analytical methods that are sensitive enough to detect the cleaning agents. In addition, it is advantageous for the analytical methods to be simple to perform and to give results quickly. In this study, four different analytical methods are compared: visual detection of foam, pH, conductivity measurements, and analysis of total organic carbon (TOC). TOC was used as a reference method when evaluating the other three potential methods. The analyses were performed on different dilutions of the cleaning agents Vips Neutral™, RBS-25™, Debisan™ and Perform™. The results demonstrated that the most sensitive method for analysis of Vips Neutral™, Debisan™ and Perform™ is visual detection of foam, by which it is possible to detect concentrations of cleaning agents down to 10 μg/mL. RBS-25 was not detected below 200 μg/mL, probably because it is formulated with lowfoaming surfactants. TOC analysis is less sensitive but has the advantage of being a quantitative analysis, while visual detection of foam is a semi-quantitative method. Visual detection of foam is easy to perform, gives a quick result, and requires no expensive instrumentation. The sensitivity of each method was found to be dependent upon the type of cleaning agent that was analyzed.

bhaskar.tejavath1@gmail.com

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