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Cleaning validation in pharmaceuticals

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In the manufacturing of the pharmaceutical products, it is very necessary to reproduce consistently the desired quality of product. The current Good Manufacturing Practice (cGMP) regulations recognize that cleaning is a critical issue to ensure product quality. The control of cross contamination plays a critical role in maintaining the quality of the product. The manufacturing of API and pharmaceutical products involves series of processing steps and use of various equipments. In many cases, the same equipment may be used for processing different products. Residual materials from the previous batch of the same product or from different product may be carried to the next batch of the product, which in-turn may alter the quality of the subjected product. An effective cleaning shall be in place to provide documented evidence that the cleaning methods employed within a facility consistently controls potential carryover of product including intermediates and impurities, cleaning agents and extraneous material into subsequent product to a level which is below predetermined level. The documented evidence of the consistent performance of the cleaning process is given by the validation process. It ensures safety, efficacy and quality of the subsequent batches of the drug product. In this article the various aspects of the cleaning validation such as different types of contaminants, sampling procedures, analytical techniques and regulatory requirements are discussed in detail.

Biography

Rashid Mahmood has completed Master's degree in Analytical Chemistry and in Total Quality Management. He has 13 years of experience of Pharmaceutical Quality Operations and has attended many international conferences as a keynote speaker. Currently he is working as a Senior Executive Manager Quality Operations for Surge Laboratories Pvt. Ltd, Pakistan.

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