

Sampling for Microbiological Analysis: Collection, Storage and Handling

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Background Information

In the pharmaceutical, medical devices and the healthcare industry, sampling is an important quality control activity to ensure product quality through testing. Sampling activity performed at the end of a manufacturing process provides a check on the adequacy of the quality control procedures of the manufacturing department. It is also required by the law (§211.165).

Sampling plan is a detailed outline of which measurement will be taken at what times, on which materials, in which manner, and by whom. Samples should be representative of the batch of materials or products from which they are taken (2). In quality control activity "sampling" is one of the major activities (1). Samples could range from starting materials such as raw materials (including pharmaceutical water), in-process or intermediate samples, finished products, primary and secondary packaging materials, and cleaning and sanitization agents, compressed gas as well as other processing agents (3). Sampling may be required for different purposes for examples: acceptance of batches, clearance of batches, in process controls, stability studies, complaints, performing special tests (3). The sampling personnel require the tools and equipment for collecting the samples (sampling kit). In general, all tools and equipment used for collecting samples either for chemical or microbiological should be kept very clean before use, washed thoroughly with water or suitable solvents and then dried (1, 3). Additionally, tools and containers used for sampling for microbiological analyses are sterilized before use. It is a good practice to keep more than one set of sampling kits available during sampling (1). It is important to follow the manufacturer's instructions for the use of sampling devices (3).

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