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Quality by design (QbD)using design-of-experiments (DoE)approach to develop a LC-MS/MS method

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Bioanalytical methods are developed at various stages of the drug development process. Due to the inherent nature of the method development process, redundant efforts take place across an organization, resulting in costly and time-consuming activities. Different approaches are used to develop LC-MS/MS methods, including trial and error, method/column scouting, and software approaches.These approaches suffer from the inability to determine complex interaction effects between method variables or method robustness during the development process.

GLP demands that the analytical method must besuitable for the intended purpose and rugged under the operating environment. Design of Experiment (DoE) is a system of experimental conduct with two important benefits:more information about process output and impact of variables which is available without additional experiments/resources and; compared to One Factor at a Time (OFAT), fewer experiments generate the same amount of data.DoE system output is in the form of mathematical equation where Output is function of input variables like, Y (Output) = f (X1,X2,X3…Xn).Methods developed through DoE are more reproducible and repeatable than those designed with other systems.

A cause and effect diagram, also known as a Fishbone or Ishikawa diagram,is an effective toolfor identifying potential variables for method performance criteria. A decision need regardingthe Constant (C) that must be controlled, which are potential Noise (N) factors and which Variables need to be experimental (X). If a potential Noise (N) is affecting the process output then it should become a Constant(C) or a Variable (X). TheQbD approach with DoE system was used to develop a LC-MS/MS method for quantitating rabeprazole in plasma for pharmacokinetic analysis. This resulted in an optimally performing bioanalytical method while simultaneously applying robustness limits to ensure success in final method validation and ultimately in subject sample analysis.

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