

GMP, GCP & QUALITY CONTROL

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PHARMACEUTICAL REGULATORY AFFAIRS AND IPR

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Quality control and validation

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Quality control is defined as the analysis of an intermediate model to identify aspects that are unusual in some sense and that could, therefore, be a result of errors in the model building or refinement process. Any such errors need to be fixed, if possible, prior to analysis and publication of the model. Validation is the process of assessing the reliability of the final model that is about to be analyzed, published, deposited, and possibly used in follow-up studies. Quality Control is known as QC and focuses on identifying defect. QC ensures that the approaches, techniques, methods and processes are designed in the project are following correctly. QC activities monitor and verify that the project deliverables meet the defined quality standards. Quality Control is a reactive process and is detection in nature. It recognizes the defects. Quality Control must complete after Quality Assurance. A simple, rapid, accurate and sensitive method was developed for quantitative analysis. The method showed adequate precision, the method was validated for the parameters like specificity, linearity, precision, accuracy and robustness. Accuracy is one of the most important parameters of an analytical methodology and it can be expressed as the percent recovery of known amounts of drug added to a sample. The precision refers to the variability of the results in repeated analyses of the sample under identical experimental conditions. The method was validated by evaluating the intra- and inter-day precision. The precision was calculated from an average of ten determinations of a homogeneous sample.

Biography

Chintan V Pandya has his expertise in Quality Control and Validation since last several years. He worked as a Research Associate in research institutes as well as in many industries. He has developed and validated many methods after years of experience in research, evaluation, teaching and administration both in pharmaceutical industries and education institutions. He is the Head and Professor of Chemistry at HVPGR, Kadi – KSV (India). He has an excellent track record in academics at an institution of high repute, in research with more than 10 international research articles and presented his work in national and international conferences. He has published more than 15 research articles and books in reputed and peer reviewed journals and publications. He also associated as reviewer and Editorial Board Member with many reputed publications.

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