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Abstract

CHAPTER 5

QbD Considerations for Analytical Development

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1 INTRODUCTION

Very recently, the Food and Drug Administration (FDA) has approved a few new drug applications (NDAs) with regulatory flexibility for quality by design (QbD)-based analytical approach. The concept of QbD applied to analytical method development is known now as analytical quality by design (AQbD). It permits the analytical method for movement within method operable design region (MODR). Unlike current methods, analytical method developed using AQbD approach reduces the number of out-of-trend (OOT) results and out-of-specification (OOS) results due to the robustness of the method within the region. It is a current trend among pharmaceutical industry to implement AQbD in the method development process as a part of risk management, pharmaceutical development, and pharmaceutical quality system (ICH Q10). Owing to the lack explanatory reviews, this paper has been communicated to discuss different views of analytical scientists about implementation of AQbD in pharmaceutical quality system and also to correlate with product QbD and pharmaceutical analytical technology (PAT).

QbD is a systematic approach consolidated with quality risk management and using different designing tools along with statistical analysis to yield a quality product (Fig. 1).

In the year 2011, the FDA correlated the analytical method to risk management (ICH Q9) where risk factor for the quality of product depends on (a) severity of drug on patients due to lack of efficacy, (b) chance of failure on uncertainty of new process or products, and (c) poor detectability due to inappropriate analytical method.[1,2] Subsequently, the FDA has also granted regulatory flexibility for few analytical procedures based on AQbD. In pharmaceutical industry, QbD (Fig. 2) has become mandatory for process and product design and analytical procedure optimization.[3] As per International

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