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Capillary Electrophoresis Development Method for Pharmaceutical Quality Control Analysis

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Opinion Article

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INTRODUCTION

In the early to late stages of research, Capillary Electrophoresis (CE) procedures for pharmaceutical Quality Control (QC) analysis are developed and applied. Early approaches and high-molecular-weight compounds can both benefit from late phase development. For registration stability studies and the release of the Drug Substance (DS) and Drug Product (DP) validation batches, pharmaceutical QC performs late phase method development. These methods are intended to be transferred to the operational QC laboratories for release testing of the production batches and are preferably, developed as such that they are fast, robust, reliable, and transferable methods. As a result, allocating sufficient time, attention, and money to the development of such methods is critical. For QC testing, precise, accurate, durable, dependable, and transferrable methodologies are necessary.

ABOUT THE STUDY

In the classical approach of method development, the methods are constructed in an Analytical Development (AD) lab. The AD lab develops the procedure before transferring it to the QC or stability lab. The development lab often has the ability to speak with the application labs in their quest to build the best approach possible. The application laboratories, on the other hand, are primarily concerned with testing samples, and conversing with the development lab may be regarded a waste of time. As a result, client needs are not taken into account during method development, potentially leading to complications during transfer and even complaints during application. Furthermore, the development lab is unaware of the method's performance during real-world analysis on the customer's end. As a result, complaints are frequently regarded as subjective rather than objective. The real challenge of the method is performed during transfer studies. At this stage, a lot of method-related surprises are common. In more serious circumstances, the transfer fails, and the method must be redesigned, causing delays

that could significantly impair product development timelines and potentially threaten the filing date. CE procedures frequently fail due to poor development and a lack of experience in receiving labs. Recently a more advanced approach towards chromatographic method development was introduced in pharmaceutical product development that also is beneficial for CE methods. In the advanced approach (i) the voice of the "customer" is captured, (ii) key process input variables are identified, (iii) Critical To Quality (CTQ) factors are determined, (iv) several method verification tests are installed, (v) proactive evaluation of method performance during development is performed, (vi) continuous customer involvement and focus is institutionalized, and (vii) method capability assessment is established. The aim of the advanced approach in method development is a first time right development process for late phase methods, with targeted customer focus, robust, reliable, and transferable methods. These methods result in reduced customer complaints, less rework, improved quality of the methods, objectively monitored method performance, improved partnership with the customers, and a high probability for success during method transfer. In contrast to the classical approach, a redesigned process is needed that starts with the generation of a Method Definition Requirement (MDR). This form contains target values that are set for many CTQ's prior to the start of method development process. Design of Experiment (DOE) techniques and Measurement System Analyses (MSA) 3 studies are systematically carried out during the method development process. The performance of the process is continuously monitored by a formal feedback round and improving the quality attributes of methods is the goal, resulting in a reduction of complaints at the customers. This is achieved through continuous involvement with the application labs early in the method development process. The customer's voice is captured early and accounted for during development of the method. General needs are translated into CTQ attributes and treated as such during development. The MDR records product-specific customer requirements. All requirements described in the MDR are considered during method development. Either an intuitive or an experimental design approach may be applied when optimizing methods, resulting in an optimal separation of the main compound and all relevant impurities in a reasonable analysis time using typical CE conditions.

CONCLUSION

The AD lab is in charge of the majority of the development work (Method Development Phase). Before submitting the method it should be evaluated for robustness and daily lab-to-lab application performance (Method Evaluation Phase). Following the development and assessment phases, the final method description is written, fully validated (Method Validation Phase), and transferred to the application labs (Method Transfer Phase). After the thorough evaluation built in the development process, the transfer activities are expected to be carried out seamlessly. Process transfer is almost certain to be successful because the application labs will already be familiar with the method. Each time samples are analysed by the application labs, method performance is monitored (Method Performance Monitoring Phase) and evaluated. The information gathered is provided to the development labs; thereby they are continuously informed about both the good and poor method performance (Performance Feedback). Potential issues are discussed based on objective data and are resolved in close collaboration with each other. The advanced method development approach has proactive controls (method requirement), performance checks (method evaluation), and reactive controls built within the process, allowing to reduce customer complaints, avoid rework, improve method quality, track method performance, involve the customers, and promote partnership.