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Commentary

Pharmaceutical Analysis of Quality Control of Drugs

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DESCRIPTION

In drug development, pharmaceutical analysis primarily focuses on methods for identifying and quantifying potential new drug candidates, determining purity, identifying by-products and degradation products in compatibility and stability studies, and determining the drug substance's fate in the organism. These difficult activities necessitate sophisticated methodologies, specialized equipment, and methods run by highly skilled personnel, who often have a strong academic background.

Pharmaceutical quality control presents a variety of obstacles; approaches and methods must be well-established and acknowledged. The key feature to be achieved by laboratories under time and cost pressure utilizing ordinary equipment controlled by varied levels of skilled workers is robustness, not brilliance.

Liquid Chromatography (LC), particularly High-Performance Liquid Chromatography (HPLC), has recently established itself as a crucial analytical technology not only in drug discovery but also in ordinary quality control labs. Although there is a growing tendency toward hyphenated techniques in development analysis, such as LC combined with Mass Spectrometry (MS), the "working horse" in QC laboratories is still HPLC coupled with unspecific Ultra-Violet (UV) or fluorescence detection. Even though diode array has not completely replaced UV detection and Refractive Index (RI), electrochemical, and light scattering detection, they have not been widely adopted. Size Exclusion Chromatography (SEC) is a second extensively used method for determining aggregates in biomolecules, a class of active pharmaceutical components (drug substances) that is rapidly growing in relevance.

The fundamental benefit of LC is that it has been widely used in academics, education, development, and practice for decades, resulting in widely acknowledged and broadly implemented approaches to method development, improvement, and troubleshooting. Pharmacopoeias allow for some adaptation and alterations based on system suitability tests, allowing laboratories to deal with minor changes in the analytical process without having to contemplate complex changes that would require regulatory permission. Furthermore, the adaptability and reproducibility of LC allow for simple or somewhat difficult implementation at many sites with varying analytical conditions.

The continual advancement of sorbent materials has finally culminated in the advent of stationary phases with substantially reduced particle or pore size, resulting in increased selectivity, separation power, and analysis speed, and therefore greater capacity in the ordinary laboratory. However, progress in the development of numerous novel stationary phases has not yet permeated normal applications; in most cases, typical Reversed Phase (RP) 18 material is used.

The significant current trend in LC is miniaturization, which includes instruments, column particle size, and column diameters. The introduction of Ultra Performance Liquid Chromatography (UPLC) coupled to MS using columns with impressing reduced particle sizes of stationary phases, as well as the development of monolithic phases consisting of a single silica monolith with a total porosity of greater than 80%, are the most recent developments. These techniques have already made it into development labs, but they still need to find more common applications.

Peptide digests can also be separated using UPLC or monolithic phases in proteomic and genomic research. It also appears that its rapid adoption has slowed the rise of Capillary Electrophoresis (CE), another high-performance separation technology. CE has long been recognized as an excellent complement to LC due to its distinct separation mechanism, which is mostly based on charge to mass ratio or hydrophobicity variations. CE was regarded a method of choice for fast routine applications because of its advantages as a miniaturized technology with lower solvent and reagent use. However, it became increasingly obvious that miniaturization entails a loss of reproducibility or repeatability; in many situations, it found out that CE procedures lacked the robustness required in a typical laboratory. When it comes to unifying basic end point test procedures, the regulatory authorities of the three areas' stubbornness in preserving local traditions contrasts greatly with Process Analytical Technology's (PAT) vision. This innovative

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strategy aims to replace final product testing with continuous, risk-based monitoring of production processes and subsequent parametric release. Near Infrared (NIR) or mid-IR spectroscopy, as well as Raman spectroscopy, are analytical techniques that would fit into this real-time vision of process surveillance. All of these techniques are not widely used in the pharmaceutical analysis, with the exception of NIR, which has made its way into starting material testing, particularly single container testing. In 2007, there were more symposia, conferences, and education courses on that topic, as well as the documented examples of its implementation in pharmaceutical manufacture, demonstrating that the revolutionary change is still coming. One important roadblock is that developing a meaningful "design space" for simpler variation change control and a meaningful "control space" for PAT necessitates far more information and knowledge about critical process steps and effects than is often available and present during drug development. As a result, this strategy may be more appropriate for established, long-running products rather than new ones, rendering the concept ambiguous. In the foreseeable future, no measurable effects on analytical trends in pharmaceutical quality control can be predicted.