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Perspective

Authentication of Modern Raman Spectroscopy Methods for Pharmaceutical Analysis

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DESCRIPTION

The first general chapter on Raman spectroscopy included a description of the equipment, features of sample preparation, control of the instrument's performance, and applications for both qualitative and quantitative approaches. After a lengthy period of revision, the chapter was fully updated in the 8.7 in 2016, adding hand-held Raman spectrometers and their use as Process Analytical Technology (PAT) for the observation of biological and chemical reactions, synthesis, crystallization, granulation, mixing, drying, lyophilization, extrusion, encapsulation, and coating. Raman spectrometers are utilized more often in the pharmaceutical industry as a result of technical advancements in instrumentation. A new section on spectral resolution has also been added, and the significance of having access to, an overview of, and the ability to understand Raman measurement details, including data and spectra in particular, as well as any verifications, instrument settings, and measurement parameters, has been emphasized.

Due to the Optical method ability to measure liquid, solid, and gaseous substances with small sample sizes, extremely quickly and non-invasively, without previous sample preparation and destruction, directly in containers, it has been recognized in several pharmacopoeias throughout the world. Additionally, the use of portable Raman devices is useful since it enables measurements optical method that offers information on all monographic features of pharmaceuticals and excipients, including identification, purity, and amount as well as chemical composition and molecular structure, in accordance with the monographs of pharmacopoeias across the world. Although Raman spectroscopy was suggested in general chapters of the edition as a substitute technology to monitor microbiological quality, polymorph, crystallinity, and chemical imaging, the Raman no one particular monograph for the characterization of chemicals or formulations mentions procedure. The preferred technique for identifying and quantifying compounds under controlled circumstances is Infrared Spectroscopy (IR). Raman and IR spectroscopy are thought to complement one another their sensitivity to various functional groups varies. Raman spectroscopy has the benefit of being able to detect aqueous solutions since water only shows mild Raman scattering, whereas IR spectra are greatly impacted.

Spectroscopy is effectively incorporated into several stages of the life cycle and value-added chain of medicinal products in industrial pharmaceutical manufacture, from drug discovery on laboratory scale through production under Good Manufacturing Practice (GMP) guidelines. Active pharmaceutical ingredients (API) reaction analytics, release testing, and statistical process control were made possible in particular by the possibility of real-time measurements. A special emphasis was placed on cutting-edge concepts like flow or continuous manufacturing, which required ongoing real-time quality assurance. This is consistent with the PAT, which the US Food and Drug Administration (FDA) has described as an approach to design, evaluate, and regulate pharmaceutical manufacturing processes by the monitoring of essential process parameters that impact critical quality characteristics, in a timely way. Online or in line is preferred. Rapid testing approaches that establish the authenticity, safety, and efficacy of medicinal items aftermarket entrance are also becoming increasingly necessary. Future challenges will be more complex, including ensuring the quality of biological drugs as well as Non-Biological Complex Drugs (NBCD), like nanomaterial's, because of their more intricate structures and cutting-edge production methods that frequently involve more steps than the creation of conventional drug delivery systems. To bridge the analytical gap of heterogeneous sample matrices or complicated biologicals like the mRNA vaccine technology actually utilized to combat the SARS-CoV2 epidemic, chemometrics aided Raman spectroscopy may be a key tool.

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