

CHAPTER 5

ANALYTICAL TECHNIQUES FOR DRUG FORMULATION

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Abstract

Analytical techniques are the foundation of pharmaceutical formulation, playing a pivotal role in ensuring drug efficacy, stability, safety, and compliance with international regulatory standards. This chapter provides a thorough examination of validated analytical methods, detailing their applications in API characterisation, stability testing, impurity profiling, bioequivalence assessment, and optimisation of drug delivery systems. The significance of regulatory frameworks, including ICH Q2(R1), USP <1225>, FDA, and EMA guidelines, is underscored to highlight the stringent validation requirements for analytical procedures in pharmaceutical research. Furthermore, the chapter explores emerging trends and technological advancements that are revolutionizing drug formulation and analytical science. Nanotechnology-driven analytical methods, such as Dynamic Light Scattering (DLS) for nanoparticle stability assessment and High-Resolution Transmission Electron Microscopy (HR-TEM) for lipid-based drug carriers, have

