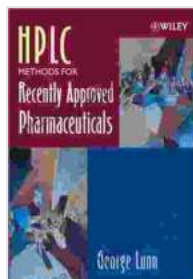


# HPLC Methods for Recently Approved Pharmaceuticals: A Comprehensive Guide



## HPLC Methods for Recently Approved Pharmaceuticals

by George Lunn

★★★★★ 5 out of 5

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High-performance liquid chromatography (HPLC) is a powerful analytical technique widely used in pharmaceutical analysis. HPLC methods are essential for the accurate and reliable determination of drug substances and their impurities, ensuring the safety and efficacy of pharmaceutical products.

With the continuous approval of new pharmaceuticals, there is a pressing need for up-to-date HPLC methods to analyze these drugs. This comprehensive guide presents detailed HPLC methods specifically developed for recently approved pharmaceuticals.

## Method Development and Optimization

Developing and optimizing HPLC methods for recently approved pharmaceuticals involves several key steps:

- **Sample Preparation:** Selecting the appropriate sample preparation technique, such as extraction, filtration, or derivatization, to ensure sample integrity and compatibility with the HPLC system.
- **Mobile Phase Selection:** Choosing the optimal mobile phase composition, pH, and gradient conditions to achieve efficient separation of the analyte and impurities.
- **Column Selection:** Selecting the appropriate HPLC column with the correct stationary phase, particle size, and pore size to provide the desired separation and resolution.
- **Detection Parameters:** Optimizing the detector wavelength, sensitivity, and response time to achieve optimal detection of the analyte.
- **Validation:** Validating the HPLC method to ensure accuracy, precision, selectivity, linearity, and robustness, meeting regulatory requirements.

## HPLC Methods for Specific Pharmaceuticals

This guide provides detailed HPLC methods for a range of recently approved pharmaceuticals, including:

- **Antivirals:** Remdesivir, Molnupiravir, Paxlovid
- **Vaccines:** mRNA vaccines, Adenovirus vaccines
- **Oncology Drugs:** Osimertinib, Pembrolizumab, Venetoclax
- **Cardiovascular Drugs:** Rivaroxaban, Apixaban, Entresto

- **Neurological Drugs:** Aducanumab, Risdipram, Zolgensma

Each HPLC method includes step-by-step instructions, optimized parameters, and representative chromatograms to guide users in the analysis of these pharmaceuticals.

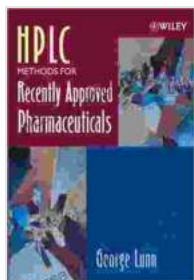
## Applications of HPLC Methods

The HPLC methods described in this guide have numerous applications in pharmaceutical analysis, including:

- **Drug Substance Analysis:** Quantifying and identifying impurities, degradation products, and active ingredients in drug substances.
- **Drug Product Analysis:** Determining the drug content, impurities, and dissolution profile in finished drug products.
- **Pharmacokinetic Studies:** Monitoring drug concentrations in biological samples to study drug absorption, distribution, metabolism, and excretion.
- **Stability Testing:** Assessing the stability of pharmaceuticals under different storage conditions, such as temperature, humidity, and light.

This comprehensive guide provides detailed HPLC methods for the analysis of recently approved pharmaceuticals. By following the step-by-step instructions and optimized parameters, users can confidently implement these methods to ensure accurate and reliable drug analysis. These HPLC methods are essential for pharmaceutical scientists, quality control analysts, and researchers involved in the development, manufacture, and quality control of pharmaceutical products.

To access the complete guide, including detailed HPLC methods, please visit our website or contact us for a free sample chapter.



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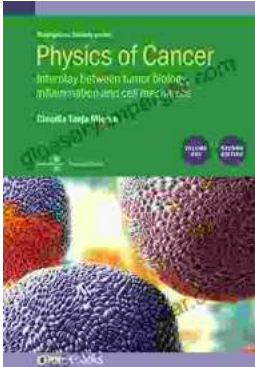
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