

A Validated Reverse Phase HPLC Method for the Determination of Disodium EDTA in Meropenem Drug Substance with UV-Detection using Precolumn Derivatization Technique

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Abstract: This paper deals with development and validation of a high performance liquid chromatographic method for the quantitative determination of disodium EDTA (Ethylenediamine tetraacetic acid) in Meropenem active pharmaceutical ingredient (API). EDTA was derivatized with Ferric chloride solution by heating at 70 °C in water bath for about 20 minutes and the chromatographic separation achieved by injecting 100 µL of the derivatized mixture into a Waters HPLC system with photodiode array detector using a Phenomenex Luna C18(2) column (250 × 4.6 mm), 5 µ. The mobile phase consisting of 5% methanol and 95% of 0.7 g/L solution of Tetra butyl ammonium bromide and 4.6 g/L solution of sodium acetate trihydrate in water (pH adjusted to 4.0 with the help of acetic acid glacial) and a flow rate of 1 milliliter/minute. EDTA eluted at approximately 6 minutes. The method was suitably validated with respect to specificity, linearity of response, precision, accuracy, ruggedness, stability in analytical solution, limit of quantitation and detection and robustness for its intended use.

Keywords: EDTA, HPLC, precolumn derivatization, Meropenem, ferric chloride

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Table of Contents A Validated Reverse Phase Hplc Method For The

1. Understanding the eBook A Validated Reverse Phase Hplc Method For The
 - The Rise of Digital Reading A Validated Reverse Phase Hplc Method For The
 - Advantages of eBooks Over Traditional Books
2. Identifying A Validated Reverse Phase Hplc Method For The
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an A Validated Reverse Phase Hplc Method For The
 - User-Friendly Interface
4. Exploring eBook Recommendations from A Validated Reverse Phase Hplc Method For The
 - Personalized Recommendations
 - A Validated Reverse Phase Hplc Method For The User Reviews and Ratings
 - A Validated Reverse Phase Hplc Method For The and Bestseller Lists
5. Accessing A Validated Reverse Phase Hplc Method For The Free and Paid eBooks
 - A Validated Reverse Phase Hplc Method For The Public Domain eBooks
 - A Validated Reverse Phase Hplc Method For The eBook Subscription Services
 - A Validated Reverse Phase Hplc Method For The Budget-Friendly Options
6. Navigating A Validated Reverse Phase Hplc Method For The eBook Formats

- ePub, PDF, MOBI, and More
 - A Validated Reverse Phase Hplc Method For The Compatibility with Devices
 - A Validated Reverse Phase Hplc Method For The Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of A Validated Reverse Phase Hplc Method For The
 - Highlighting and Note-Taking A Validated Reverse Phase Hplc Method For The
 - Interactive Elements A Validated Reverse Phase Hplc Method For The
 8. Staying Engaged with A Validated Reverse Phase Hplc Method For The
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers A Validated Reverse Phase Hplc Method For The
 9. Balancing eBooks and Physical Books A Validated Reverse Phase Hplc Method For The
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection A Validated Reverse Phase Hplc Method For The
 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
 11. Cultivating a Reading Routine A Validated Reverse Phase Hplc Method For The
 - Setting Reading Goals A Validated Reverse Phase Hplc Method For The
 - Carving Out Dedicated Reading Time
 12. Sourcing Reliable Information of A Validated Reverse Phase Hplc Method For The
 - Fact-Checking eBook Content of A Validated Reverse Phase Hplc Method For The
 - Distinguishing Credible Sources
 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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