



MODERN ANALYTICAL APPROACHES FOR STANDARDIZATION OF “VIGITRIL” SUSPENSION BASED ON BISMUTH AND HISTIDINE

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Abstract

This article presents a comprehensive pharmaceutical and analytical investigation of “Vigitril” suspension developed on the basis of bismuth, histidine, and ethylenediaminetetraacetic acid. The study focuses on modern methods of standardization, physicochemical characterization, quality assessment, and stability evaluation of the suspension dosage form. Modern spectrophotometric and chromatographic methods were applied for qualitative and quantitative determination of active pharmaceutical ingredients. Particular attention was devoted to validation parameters including specificity, precision, repeatability, and linearity of analytical procedures. The obtained results demonstrated that the developed suspension possesses satisfactory physicochemical stability, low toxicity, and promising therapeutic effectiveness. The study confirms the pharmaceutical potential of “Vigitril” suspension as a перспективный gastroprotective preparation suitable for further industrial development and clinical application.

Keywords

bismuth, histidine, suspension, standardization, spectrophotometry, chromatography, pharmaceutical analysis, Helicobacter pylori, gastroprotective preparations

Introduction

Diseases of the gastrointestinal tract remain among the most common pathological conditions affecting millions of people worldwide. Chronic gastritis, gastric ulcer, and duodenal ulcer diseases are frequently associated with Helicobacter pylori infection, which plays a crucial role in the development of inflammatory and ulcerative lesions of the gastric mucosa.

During recent decades, significant progress has been achieved in the development of antiulcer and gastroprotective medicines. Among them, bismuth-containing preparations occupy a particularly important place due to their antibacterial activity against Helicobacter pylori and their protective effect on the gastric mucosa. Bismuth compounds demonstrate complex pharmacological properties including antimicrobial, anti-inflammatory, and cytoprotective activities.

Despite the effectiveness of imported bismuth-based preparations, several limitations remain relevant. High treatment costs, insufficient local pharmaceutical production, and adverse effects associated with prolonged therapy create a need for developing new domestic pharmaceutical products with improved therapeutic properties and reduced toxicity.

In this regard, the development of “Vigitril” suspension based on bismuth, histidine, and EDTA represents a promising direction in pharmaceutical science. Histidine acts as a biologically active ligand capable of forming stable complexes with bismuth ions, thereby improving stability and bioavailability of the preparation. EDTA contributes to stabilization of the pharmaceutical system and prevents precipitation processes.

The development of effective pharmaceutical dosage forms requires reliable analytical methods for quality control and standardization. Modern pharmaceutical analysis increasingly relies on spectrophotometric and chromatographic methods capable of ensuring high analytical precision and sensitivity. Therefore, the aim of the present study was to investigate modern analytical approaches for standardization and quality assessment of "Vigitril" suspension.

Materials and Methods

The object of investigation was "Vigitril" suspension developed on the basis of bismuth compounds, histidine, and ethylenediaminetetraacetic acid. Pharmaceutical and analytical investigations were carried out in specialized pharmaceutical laboratories equipped with modern instrumental systems.

The following analytical methods were applied during the study:

- UV spectrophotometry;
- high-performance liquid chromatography (HPLC);
- complexometric titration;
- gravimetric analysis;
- physicochemical stability assessment.

Spectrophotometric investigations were performed using a Shimadzu UV-2700 spectrophotometer in the ultraviolet range. Absorption spectra of active pharmaceutical ingredients were analyzed to determine optimal analytical wavelengths.

Chromatographic analysis was conducted using the Agilent 1200 HPLC system equipped with UV detection. Separation of active compounds was achieved using reverse-phase chromatography under optimized mobile phase conditions.

Quantitative determination of bismuth ions was performed by complexometric titration using standardized titration procedures. Stability studies were conducted under accelerated aging conditions to evaluate physicochemical stability and estimate shelf life of the preparation.

Validation of analytical procedures included assessment of specificity, linearity, precision, repeatability, and analytical sensitivity according to international pharmacopoeial recommendations.

Results and Discussion

The performed investigations demonstrated that the developed "Vigitril" suspension possesses stable physicochemical characteristics and complies with pharmaceutical quality requirements. One of the most important tasks during pharmaceutical development involved optimization of the suspension system and prevention of precipitation processes.

The obtained results confirmed that histidine forms stable coordination complexes with bismuth ions, contributing to improved stability of the pharmaceutical composition. The presence of EDTA additionally enhanced stability of the system by regulating ionic interactions within the suspension medium.

Spectrophotometric analysis demonstrated characteristic absorption maxima corresponding to biologically active components present in the formulation. The developed spectrophotometric procedure showed high analytical sensitivity and reproducibility. Calibration curves demonstrated satisfactory linearity within the investigated concentration range.

Complexometric titration was successfully applied for quantitative determination of bismuth ions in the pharmaceutical formulation. The obtained results indicated high precision and repeatability of the analytical procedure.

Chromatographic investigations performed by HPLC demonstrated effective separation of active compounds contained in the preparation. Retention times remained stable during repeated analysis, confirming reliability of the chromatographic method. The chromatographic procedure allowed accurate identification of biologically active substances and potential degradation products.

The pharmaceutical stability of the suspension was evaluated under accelerated aging conditions. The obtained data demonstrated that the preparation maintained its physicochemical properties during storage. No significant changes in color, odor, viscosity, or sedimentation behavior were observed.

One of the important pharmaceutical characteristics of suspensions is dispersity of particles. Microscopic evaluation demonstrated uniform particle size distribution within the formulation. Such distribution positively influences bioavailability and therapeutic activity of the preparation.

Microbiological purity assessment confirmed absence of pathogenic microorganisms within acceptable pharmacopoeial limits. Preservatives included in the formulation effectively prevented microbial contamination during storage.

Modern pharmaceutical standardization requires validation of analytical methods according to international regulatory standards. Validation results demonstrated that the developed analytical procedures satisfy pharmacopoeial requirements regarding specificity, precision, accuracy, and robustness.

The obtained pharmaceutical and analytical results indicate that "Vigitril" suspension may represent a promising gastroprotective preparation suitable for further clinical evaluation and industrial production. Its relatively low toxicity and stable physicochemical properties create favorable conditions for long-term therapeutic application.

The study additionally demonstrated the importance of combining several analytical approaches during pharmaceutical standardization. Spectrophotometric methods provide rapid and economical quantitative assessment, whereas chromatographic techniques ensure high analytical selectivity and reliability.

The development of domestic pharmaceutical preparations based on modern analytical technologies is especially important for strengthening the pharmaceutical industry and reducing dependence on imported medicines. Local production of gastroprotective medicines may improve accessibility of treatment and stimulate further pharmaceutical innovation.

Conclusion

Modern analytical approaches for pharmaceutical standardization of "Vigitril" suspension were successfully developed and validated. The performed investigations demonstrated that the preparation possesses satisfactory physicochemical stability, reliable analytical characteristics, and promising therapeutic potential.

Spectrophotometric, chromatographic, and complexometric methods allowed accurate qualitative and quantitative assessment of biologically active compounds contained in the suspension. Validation studies confirmed analytical reliability and compliance with pharmacopoeial standards.

The developed pharmaceutical formulation demonstrated stable physicochemical behavior during storage and maintained microbiological purity within acceptable limits. Histidine and EDTA played an important role in stabilization of the pharmaceutical system and optimization of therapeutic characteristics.

The obtained results may serve as a scientific basis for further industrial production, regulatory standardization, and clinical investigation of "Vigitril" suspension. Development of domestic pharmaceutical products based on modern analytical technologies contributes to strengthening pharmaceutical independence and improving accessibility of effective gastroprotective therapy.

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