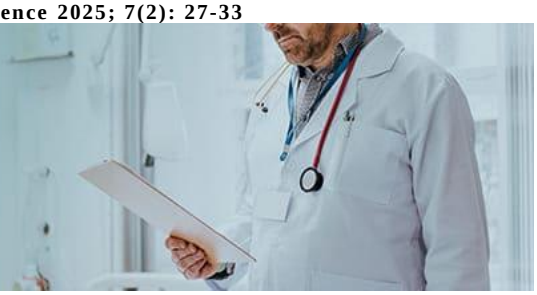
International Journal of Research in MEDICAL SCIENCE



ISSN Print: 2664-8733
ISSN Online: 2664-8741
IJRMS 2025; 7(2): 27-33
www.medicalpaper.net
Received: 17-05-2025
Accepted: 20-06-2025

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Development and validation of a UPLC method for the quantification of related substances in chlordiazepoxide hydrochloride and clidinium bromide capsules

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DOI: https://www.doi.org/10.33545/26648733.2025.v7.i2a.130

Abstract
Objective: To investigate the degradation behavior of Clidinium Bromide, a key component of the Librax formulation, under various stress conditions and to develop a validated Ultra Performance Liquid Chromatography (UPLC) method for its simultaneous estimation with Chlordiazepoxide Hydrochloride.
Methods: An innovative UPLC method was optimized to analyze both active pharmaceutical ingredients with high resolution and sensitivity. The mobile phase consisted of 40 mM phosphate buffer (pH 3.2) as Mobile Phase A and acetonitrile: methanol (70:30 v/v) as Mobile Phase B, delivered in gradient mode through an Acquity UPLC BEH C18 column (150 × 2.6 mm, 1.7 µm) at a flow rate of 0.3 mL/min. Stress conditions included acid, base, peroxide, humidity, thermal, aqueous, and UV exposure. Validation followed ICH guidelines for specificity, precision, and robustness.
Results: The method demonstrated exceptional specificity in detecting Clidinium Bromide degradation products. Formation of related compound A and Benzilic acid was confirmed under particular conditions. All validation parameters met ICH requirements, underscoring the method's reliability and reproducibility.
Conclusion: This study offers a scientifically sound and validated UPLC approach for monitoring the stability of Clidinium Bromide in pharmaceutical formulations. The findings provide a robust analytical foundation for future formulation studies and quality control applications.

Keywords: Librax, chlordiazepoxide hydrochloride, degradation process, analytical precision, benzodiazepines, anti-muscarinic, ultra performance liquid chromatography

Introduction

Gastrointestinal disorders present a pervasive health challenge, affecting millions of individuals worldwide and profoundly impacting their quality of life [1, 2]. Amidst the array of pharmaceutical interventions developed to mitigate the distressing symptoms associated with GI disorders, Librax emerges as a key stone in therapeutic treatment. This medication comprises of the synergistic combination of two vital constituents, i.e. Chlordiazepoxide Hydrochloride and Clidinium Bromide. This medication stands as a beacon of hope for individuals struggling with gastrointestinal discomfort [3].An important constituent of Librax formulation, i.e. Chlordiazepoxide Hydrochloride, is a member of the Benzodiazepines class. It plays a pivotal role as an anti-anxiety medication [4, 5] within Librax medication. Whereas, its counterpart drug Clidinium Bromide is a synthetic quaternary ammonium anti-muscarinic agent, complementing the effect of Librax [6]. Together, both of these components address the intricate interplay of sensitive and somatic factors contributing towards gastrointestinal distress [7]. The components effectively work synergistically and offer relief to patients worldwide. The stability and degradation pathways of Clidinium Bromide within the Librax formulation remain subjects of intense scientific scrutiny [8, 9]. Beyond the realm of academic curiosity, understanding the intricacies of degradation process of Clinidium Bromide assumes paramount importance. This work goes beyond academic endeavours and has significant consequences for patient safety and treatment effectiveness [10]. By unravelling the specific conditions governing the formation of degradation products, such as Clidinium Bromide Related Compound A and Benzilic acid, researchers can boost the medications