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A Review on HPLC-Based Analysis of Active Pharmaceutical Ingredients in Expired and Unexpired Tablet Formulations

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Abstract:

This literature review focuses on the evaluation of active pharmaceutical ingredient (API) stability in expired and unexpired tablet formulations of Albendazole, Azithromycin, and Paracetamol using High Performance Liquid Chromatography (HPLC). The objective of such studies is to assess changes in drug potency, chemical stability, and therapeutic effectiveness following the expiration period. Existing findings indicate that unexpired tablet formulations consistently comply with pharmacopeial standards, maintaining API concentrations within the acceptable range of 90–110%. In contrast, expired formulations exhibit a gradual decline in API content, suggesting ongoing chemical degradation. Among the drugs evaluated, Paracetamol demonstrates comparatively higher stability, with minimal reduction in potency beyond its expiration date. Conversely, Azithromycin and Albendazole show greater susceptibility to degradation, likely due to environmental influences such as temperature, humidity, and light exposure. HPLC is recognized as a reliable and precise analytical technique for the quantification of APIs and detection of degradation products. Overall, the reviewed evidence highlights the critical importance of expiration dates in ensuring drug safety and efficacy. Additionally, it contributes to a broader understanding of degradation patterns in commonly used pharmaceuticals and supports regulatory guidelines for proper storage and usage.

Keywords: Albendazole, Azithromycin, Paracetamol, Active Pharmaceutical Ingredient, Drug Stability, Drug Potency, HPLC

Introduction

Pharmaceutical tablets are designed to deliver a precise dose of active pharmaceutical ingredient (API), and their stability is crucial for ensuring drug safety, efficacy, and quality throughout shelf life. Environmental factors such as temperature, humidity, and light can lead to API degradation, potentially reducing therapeutic effectiveness after expiration [1]. However, studies suggest that API degradation does not always occur immediately after the expiry date and depends on the drug's chemical nature, formulation, and storage conditions [2].

Widely used drugs such as albendazole, azithromycin, and paracetamol represent important therapeutic classes, and their prolonged storage increases the likelihood of post-expiry use. Sub-therapeutic API levels may result in treatment failure and antimicrobial resistance, particularly in antibiotics [2]. Analytical techniques like UV-visible spectrophotometry and high-performance liquid chromatography (HPLC) are commonly used for accurate API quantification due to their reliability and sensitivity. Previous studies have reported variations in API content in expired albendazole formulations, indicating potential loss of potency [2,3].

Stability studies on paracetamol have shown that environmental conditions influence API degradation, emphasizing the need for continuous quality monitoring [4]. Research also indicates that significant API content can be recovered from solid dosage forms using HPLC, demonstrating retained drug potency [11]. Similarly, some expired antibiotics and analgesics have been found to maintain acceptable API levels and physical stability beyond expiry under proper storage conditions [12,13]. However, concerns remain regarding substandard medicines, with studies reporting that approximately 12.4% of essential drugs fail quality tests due to insufficient API content [15]. These findings highlight the importance of evaluating API levels in expired and unexpired formulations for ensuring public health and regulatory compliance.



Literature Review

The determination of active pharmaceutical ingredients (APIs) in finished dosage forms is a fundamental aspect of pharmaceutical quality control, ensuring drug safety, efficacy, and compliance with established pharmacopeial standards. According to regulatory guidelines such as the United States Pharmacopeia (USP) and the International Council for Harmonization (ICH), tablet formulations must contain API levels within specified limits, typically 90–110% of the labeled claim. However, API degradation may occur after the expiration date due to environmental exposure and formulation instability, potentially leading to reduced therapeutic effectiveness or treatment failure [5]. The widespread presence of expired medicines in households and healthcare settings, particularly in developing countries, has increased the importance of evaluating API content in expired versus unexpired formulations.

Analytical techniques play a crucial role in API determination, with High-Performance Liquid Chromatography (HPLC) and UV-Visible spectrophotometry being the most commonly employed methods. HPLC is widely regarded as the gold standard due to its ability to separate, identify, and quantify APIs along with their degradation products. Stability-indicating HPLC methods are especially valuable in expired drug studies, as they distinguish intact drug compounds from degraded forms. Method validation, including parameters such as linearity, accuracy, precision, specificity, and robustness, is generally performed in accordance with ICH Q2(R1) guidelines [6]. In contrast, UV-Visible spectrophotometry is a simpler and more cost-effective technique, commonly used for routine quality control and preliminary API estimation, particularly for drugs like paracetamol that exhibit strong UV absorbance [7]. Several studies have investigated the API content of albendazole tablets in both expired and unexpired conditions. Quantitative analyses using RP-HPLC and UV spectrophotometry have revealed that while some expired samples retain acceptable API levels, others fall below pharmacopeial limits, indicating degradation over time [8]. Additionally, physicochemical evaluations of albendazole tablets have identified instances where certain formulations failed to meet API specifications even prior to expiry, suggesting issues related to manufacturing quality and storage conditions [3]. These findings highlight the variability in API stability and the importance of rigorous quality assessment. Azithromycin, a widely used macrolide antibiotic, has also been studied for its stability characteristics. Due to its complex chemical structure, it is susceptible to degradation under acidic and thermal conditions. Validated RP-HPLC methods have been developed to effectively separate azithromycin from its degradation products, supporting their use in stability-indicating assays. Furthermore, alternative spectroscopic methods, including infrared techniques, have demonstrated accurate and reproducible API quantification, providing additional tools for quality assessment [6,9]. Paracetamol, one of the most commonly used analgesic and antipyretic agents, is generally considered chemically stable; however, prolonged storage and unfavorable conditions can still lead to API degradation. Studies employing RP-HPLC and UV-Visible spectrophotometry have confirmed the reliability of these methods for API estimation, with HPLC offering greater specificity and sensitivity [7,10]. Recent literature has also challenged the assumption that drugs become entirely ineffective after their expiration date. Systematic reviews have reported that many solid dosage forms retain a substantial proportion of their API beyond the labeled expiry date, although variability exists depending on the drug and storage conditions [5]. Overall, these findings emphasize the necessity of validated analytical methods and drug-specific evaluation to ensure pharmaceutical quality and patient safety.



Research Methodology

When we look at studies about how well pharmaceutical formulations last we see that they often use experiments and comparisons to check how much active pharmaceutical ingredient or pharmaceutical formulations is in products that have expired and products that have not expired. These studies usually pick tablet formulations that you can buy in stores making sure they are the strength and brand so that the formulations are similar. The samples are then grouped by whether they have expired or not and stored in a lab under controlled conditions before they are analyzed.

To figure out how much active pharmaceutical ingredient is in these pharmaceutical formulations the studies mainly use techniques that have been tested and proven to work. One of the common methods is called High-Performance Liquid Chromatography or pharmaceutical formulations analysis. This method is very good at detecting small

amounts of pharmaceutical formulations and can separate out different parts of the mixture. Another method that is often used is called UV- spectrophotometry, especially for drugs like paracetamol that absorb a lot of light. This method is simpler and less expensive than pharmaceutical formulations analysis. To get the samples ready for analysis the studies usually involve dissolving the pharmaceutical formulations and the tablet samples in a liquid then using waves to mix them filtering them and making them less concentrated. The pharmaceutical formulations content in the samples is then measured by comparing it to a curve made from known samples. It is very important to make sure that the method used is accurate and reliable so the studies follow guidelines to check things like how well the method works how accurate it is and how precise it is. This ensures that the results are trustworthy and can be repeated.

When the data is analyzed the studies typically use measurements and express the results as an average plus or minus a small amount. The results are then compared to see if there are any differences in the pharmaceutical formulations content, between expired and unexpired pharmaceutical formulations. Overall this approach provides a way to check how stable the pharmaceutical formulations are and make sure they meet the standards set by pharmacopeial authorities for pharmaceutical formulations.

Expected Outcome

Previous studies looking at how pharmaceutical formulations last suggest that tablet formulations of commonly used drugs like albendazole, azithromycin and paracetamol that are not expired usually meet the standards for the amount of active pharmaceutical ingredient or API they contain. This means that these drugs are safe to use and will work as they should. On the hand tablet formulations that are expired can break down in different ways depending on things like the type of drug how long it has been since it expired and how it was stored.

What we see in the literature is that some drugs, like albendazole and azithromycin do not last long as others, like paracetamol. This is because they are more likely to break down over time. As a result when these drugs expire they may not have much API in them as they should which can mean that people do not get the right dose of medicine. This can lead to treatments that do not work well as they should. Studies that use machines like High-Performance Liquid Chromatography or HPLC and UV-Visible spectrophotometry can accurately measure how much API is in a drug. These methods are reliable. Are often used to check how well drugs last and if they are still good after they expire.

When we compare expired and unexpired drugs we often see differences in the amount of API they contain. This shows that the drugs can break down over time. This information is important for deciding if expired drugs are still safe to use or if they should be thrown away. All of these studies help us understand how well different types of drugs last. They also show how important it is to check the quality of drugs even after they have expired. The information we get from these studies is useful for people who make sure drugs are safe for regulators and for guiding people on how to use and get rid of expired drugs, including pharmaceutical formulations, like albendazole, azithromycin and paracetamol.

Conclusion

The reviewed studies show that keeping ingredients in tablets stable is very important for drug safety, efficacy and quality. Many unexpired medicines like albendazole, azithromycin and paracetamol usually meet standards, which means they are reliable for treatment. However medicines past their expiry date can degrade due to their properties how they are made and storage.

Paracetamol stays good but albendazole and azithromycin can degrade quickly so we need to check each drug. To accurately check ingredients techniques like High-Performance Liquid Chromatography and UV-Visible spectrophotometry are used. Expired drugs with active ingredient levels may not work well and can lead to antimicrobial resistance.

Therefore, we need to monitor and evaluate drugs to ensure patient safety and effective healthcare. The stability of pharmaceutical ingredients, APIs is crucial and APIs, in expired drugs should be checked. The use of HPLC and proper storage can help maintain API stability.

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Conflicts of interest

The authors declare that there are no conflicts of interest regarding the publication of this paper.

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