Study of the Photostability of Sodium Montelukast Under Controlled Stress Conditions

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ABSTRACT

Montelukast Sodium is a drug widely used in the treatment of respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD). Although its therapeutic efficacy is well established, the stability of the drug under different environmental conditions, especially exposure to light, has raised increasing concerns.

This study evaluated the photostability of montelukast sodium under different wavelengths and light doses. Drug degradation was monitored using UV-Vis spectrophotometry and high-performance liquid chromatography (HPLC). The results provide essential information for optimizing the storage and handling conditions of montelukast sodium, ensuring its efficacy and safety. This study is essential for the development of guidelines to ensure the drug's stability throughout clinical use.

Keywords: photostability; montelukast; light; degradation; stress conditions.

INTRODUCTION

Photostability studies are essential for evaluating the intrinsic stability of an active pharmaceutical ingredient (API) or a finished product when exposed to light, as they help identify potential risks of degradation or unacceptable changes. These studies also allow the determination of degradation patterns and the validation of analytical methods, ensuring that the proposed procedures are appropriate for the drug under investigation, such as montelukast sodium (ICH, 1996; Alsante et al., 2007; Albani, 1997). A photostability study involves subjecting the drug to stress conditions (e.g., in the presence of light), thereby obtaining crucial information about its stability (Anderson, 2004).

The stability of a pharmaceutical product containing a photosensitive drug may be compromised upon light exposure, and it is important to emphasize that each substance reacts uniquely to such exposure. When necessary, the photodegradation products generated during these studies should be identified and quantified using

appropriate and validated methodologies developed specifically for each substance (Azevedo Filho, 2011). In this context, the present project aims to evaluate the photostability of montelukast sodium under different stress conditions, including oxidative, acidic, and basic environments.

The execution of this project will provide systematic knowledge about the photostability of montelukast sodium, allowing the establishment of optimal handling and storage conditions under light exposure.

METHODOLOGY

Photodegradation was monitored using a UV-Vis spectrophotometer and high-performance liquid chromatography (HPLC), ensuring accurate measurement of degradation products. Sodium montelukast solutions were prepared and subjected to distinct stress conditions: acidic (HCl), basic (NaOH), and oxidative (H_2O_2), to evaluate their stability under each scenario. These solutions were exposed to light of different wavelengths (fluorescent and LEDs) and varying intensities to assess the effect of illumination on photodegradation. After exposure, samples were analyzed using UV-Vis spectrophotometry and HPLC to quantify photodegradation and determine the extent of degradation under each stress condition.

RESULTS

To evaluate the photostability of montelukast sodium, a series of experiments was conducted involving exposure of the drug to different light sources and stress conditions. Initially, photodegradation tests were carried out in a montelukast solution under fluorescent light, monitoring absorbance changes over varying exposure periods (Table 1). These results provided a solid foundation for the subsequent stages of the study, where exposure time and concentrations were adjusted in order to assess how different variables affect the drug’s stability.

Table 1. Photodegradation results of montelukast sodium under fluorescent light.

TIME (hours)	DEGRADATION (%)
24 hours	1.37
48 hours	5.7

The analysis in Table 1 indicates that the duration of light exposure is a determining factor influencing the degradation of the active ingredient, highlighting the importance of strictly controlling illumination conditions during the storage and handling of montelukast sodium.

The results obtained demonstrate that the photostability of montelukast sodium is significantly influenced by the duration of light exposure. These findings highlight the necessity of establishing clear guidelines for the storage and handling of montelukast sodium, in order to minimize degradation and ensure its therapeutic efficacy throughout the product's shelf life.

CONCLUSION

Through the stability study of the montelukast sodium drug, with a focus on photodegradation analysis, the results indicate that the substance is susceptible to alterations upon light exposure, which may compromise its therapeutic efficacy and safety. Further studies are needed to fully understand the mechanisms involved in the photodegradation of montelukast sodium, to develop strategies to mitigate these effects, thus ensuring its stability and efficacy over time.

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