



Efficiency Evaluation of Different Types of Packaging In The Protection of Three Drugs Using Photostability Tests

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Abstract

The aim of this study is to investigate if an inappropriate drug package could cause any significant degradation of the active ingredient. As indicated in the European Pharmacopoeia [1], a drug should be opportunely protected from light exposure because it can lead to a reduction of concentration of the active ingredient with a consequent loss of its pharmaceutical efficiency. Furthermore, photodegradation products could be more toxic than the starting reagents not only for humans, but also for flora and fauna present in the environment.

Pursuing the ICH guidelines, photostability tests were performed on three commercial Italian products (Voltaren 50, Prostide and Momendol) in order to evaluate the efficiency of marketing package and blister package in protecting from photodegradation processes drugs contained therein. For this purpose a special lamp reproducing the sunlight was used to irradiate the drugs in solid dosage form (tablets inside the blister pack, without package and in dust form) and the concentration of pharmaceutical active substances was analysed by a HPLC method.

Introduction

The right storage of drugs is important in order to maintain their characteristics, their stability and their suitable pharmacological activity. From a pharmaceutical point of view, the "period of stability" can be defined as the period between the time spent for the preparation of the drug and the time when it no longer fulfils certain requirements or properties. The presence of degradation products (even in trace) could be considered unacceptable if they have toxic effects on human health, even when the active ingredient had almost maintained intact its concentration. Stability tests are conducted according to the internationally accepted guidelines indicated by ICH (International Conference on Harmonization) [2] and by FDA.

Materials & Methods

The pharmaceutical solid forms were purchased from pharmacies: Prostide (containing 5 mg Finasteride), Voltaren 50 (containing 50 mg of Diclofenac sodium) and Momendol 220 (containing 220 mg of Naproxen sodium).

In order to carry out photodegradation tests, an Osram Ultra-Vitalux Sun Lamp was used in our experiment. The lamp has a double source of electromagnetic radiation: the emission is generated by a tungsten filament lamp and by a discharge mercury one, and the bulb is made of a special glass that allows only the passage of some types of radiation which are able to simulate the natural sunlight. The drugs were irradiated simultaneously in their respective packages, as simple tablets and as pulverized tablets for a period of 90 hours.

A chromatographic analysis was carried out using a HPLC system[3-5] with an Alltech reversed phase column (Alltima C8 250x4.6 mm I.D., 5 μ m) and chromatograms were analysed with PeakFit software. The percentages of degradation were obtained by comparing the concentrations of active principles in degraded drugs with those of not irradiated tablets.

The temperature was constantly maintained at 25°C using a thermostatic bath where the column was immersed.

Results

The analysis of samples showed the following experimental results (fig 1). Naproxen has the fastest rate of photodegradation in all of the tested situations (as active ingredients inside drugs and as pure active principle) Moreover tablets inside the plastic blister package have undergone a considerable degradation (about 26%). Diclofenac behaves similar but the tablet inside the plastic blister package was better protected from UV-Visible radiation (percentage of photodegradation about 5%). Finally

Finasteride shows a greater resistance to photodegradative processes with a good protection coming from the blister package. In all of three cases the marketing package has effectively protected the content from degradation. The use of solutions of pure active principles permits to determine the stability of the molecules themselves and allows a comparison even in a closed market/blister package.

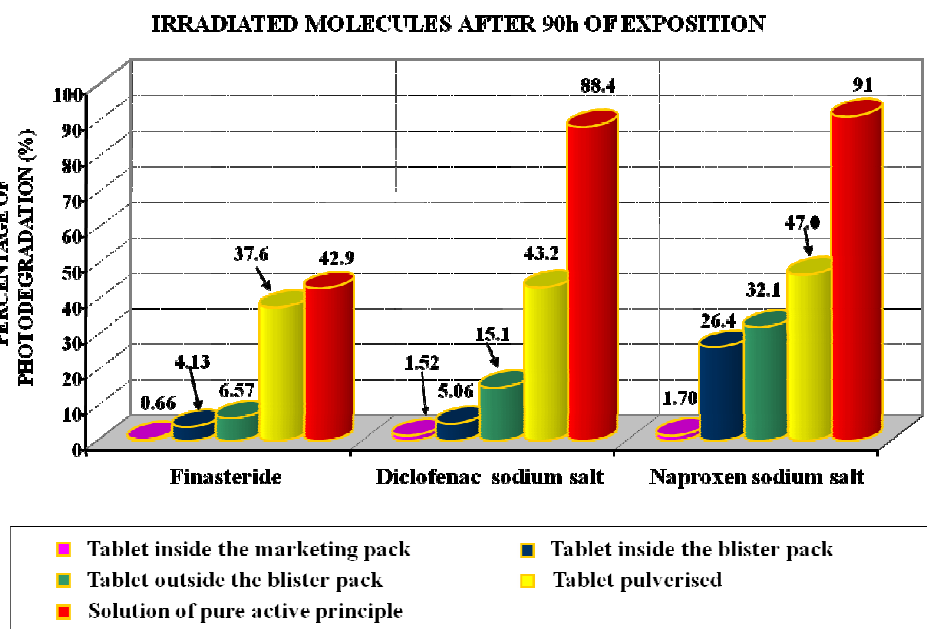


Fig. 1; Comparative graph showing the percentage of degradation of the three drugs in different exposure conditions.

Conclusions

From figure 1 becomes evident that the tests performed on drugs contained in the marketing package, lead to a reduction of the active ingredient less than 5%, as required by European Community laws, so they performed the function of protection against UV-Visible radiation. On the other hand, the plastic blister has proved to be imperfect in protecting the medicinal contents, allowing a certain degree of degradation of the active principle as in the already mentioned case of Naproxen. Plastic blister should be equipped with UV-blocker filters in order to assure an additional protection from radiation. In addition, it could be useful the presence of a "stability indicator" that could show deterioration due to temperature, photolysis or irradiation and that highlights counterfeiting or expiring of drugs in order to increase public safety and to protect the image of pharmaceutical companies.

References

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