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PRACA ORYGINALNA
ORIGINAL PAPER

Evaluation of photoprotective properties of pharmaceutical packaging containing cefuroxime by total hemispherical reflectance analysis

Ocena właściwości fotoprotekcyjnych opakowań farmaceutycznych zawierających cefuroksym za pomocą analizy hemisferycznej reflektancji całkowitej

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ABSTRACT

INTRODUCTION: Improper protection of an active substance may lead to a loss of its original properties. Many methods can be used to assess the photoprotective properties of drug packaging, including the hemispherical directional reflectance method. The aim of the study is to assess the reflectance value for both the outer and direct packaging containing cefuroxime.

MATERIAL AND METHODS: Two formulations (Ceroxim and Zinnat) of both expired and unexpired packages were tested with a 410-Solar reflectometer. Three types of measurement areas were analyzed: "white" (white areas of the outer cardboard box), "coloured" (coloured areas of the outer cardboard box) and "blister" (the direct packaging made of aluminium/PVC).

RESULTS: The highest reflectance value was found in the 700–1100 nm range for both the unexpired and expired preparations. In the 335–380 nm band, the amount of reflected radiation for the unexpired Ceroxim vs Zinnat packages was as follows: 30% vs 12% from the coloured areas, 39% vs 24% from the white areas and 74% vs 70% from the blisters, respectively. For the expired coloured areas of Ceroxim, the reflectance was significantly higher compared to the unexpired ($p < 0.001$) in all the spectral bands, except 1700–2500 nm. In contrast, the reflectance of the expired white areas of Ceroxim was higher than the unexpired ($p < 0.001$) for 480–600 nm, 590–720 nm, 700–1100 nm, and 1700–2500 nm. The blisters of the unexpired Zinnat preparation exhibited greater photoprotective properties than the expired in the 335–380 nm range while the unexpired and expired blisters of Ceroxim did not differ.

CONCLUSIONS: Based on the reflectance value, blisters and white cardboard packages protect cefuroxime against radiation to a greater extent than coloured packages.

KEYWORDS

hemispheric directional reflectance, direct packaging, outer packaging, antibiotics, cefuroxime

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STRESZCZENIE

WPROWADZENIE: Niewłaściwe zabezpieczenie substancji czynnej może doprowadzić do utraty jej pierwotnych właściwości. Do oceny własności fotoprotekcyjnych opakowań leków można zastosować wiele metod, w tym hemisferyczną reflektancję kierunkową. Celem badania była ocena wartości reflektancji dla opakowania zewnętrznego (pudełko kartonowe) i opakowania bezpośredniego (blister) zawierającego cefuroksym.
MATERIAŁ I METODY: Za pomocą reflektometru 410-Solar zbadano opakowania dwóch preparatów (Ceroxim i Zinnat), zarówno przeterminowanych, jak i nieprzeterminowanych. Analizie poddano trzy rodzaje obszarów pomiarowych: „biały" (biały karton zewnętrzny), „kolorowy" (obszary kolorystyczne kartonu zewnętrznego) oraz „blister" (opakowanie bezpośrednie wykonane z aluminium i PCV).
WYNIKI: Największą wartość reflektancji stwierdzono w zakresie 700–1100 nm zarówno dla preparatów przeterminowanych, jak i nieprzeterminowanych. W zakresie 335–380 nm ilość odbitego promieniowania dla nieprzeterminowanych opakowań Ceroxim vs Zinnat wynosiła odpowiednio: 30% vs 12% dla obszarów kolorowych, 39% vs 24% dla obszarów białych i 74% vs 70% dla blistrów. W przypadku preparatu Ceroxim, reflektancja nieprzeterminowanych obszarów kolorowych była znacząco wyższa niż przeterminowanych ($p < 0,001$) we wszystkich zakresach spektralnych, z wyjątkiem 1700–2500 nm. Natomiast reflektancja przeterminowanych obszarów białych preparatu Ceroxim była wyższa niż nieprzeterminowanych ($p < 0,001$) dla 480–600 nm, 590–720 nm, 700–1100 nm i 1700–2500 nm. Blistry nieprzeterminowane preparatu Zinnat wykazywały mocniejsze właściwości fotoprotekcyjne niż przeterminowane w zakresie 335–380 nm. Nie stwierdzono różnic pomiędzy przeterminowanymi i nieprzeterminowanymi blistrami preparatu Ceroxim.
WNIOSKI: Wartość reflektancji wskazuje, że blistry i opakowania z białego kartonu w większym stopniu chronią cefuroksym przed promieniowaniem niż opakowania kolorowe.

SŁOWA KLUCZOWE

hemisferyczna reflektancja kierunkowa, opakowania bezpośrednie, opakowania zewnętrzne, antybiotyki, cefuroksym

INTRODUCTION

Drug packaging is essential to ensure the stability of the pharmaceutical preparation during storage; it protects the drug from sunlight, humidity and temperature [1]. Consequently, proper drug packaging helps to provide effective and safe pharmacotherapy for the patient [2]. The packaging of pharmaceutical products must meet the standards necessary to confirm that it will provide optimal conditions for the storage of medicines, including limiting the impact of factors that may reduce the shelf life of the medicine. This applies to both the pre-opening and post-opening periods, within a timeframe that is within the manufacturer's guaranteed shelf life.
The term "stability" refers to maintaining the ability of the medicine to exert the desired pharmacological effect on the body and to maintain the declared content of the active substance in the preparation during the drug's shelf life. A drug content not less than 90% of the declared amount during storage under conditions recommended by the manufacturer's recommendations is the criterion for a medicine to be considered stable in terms of the content of the medicinal substance [3]. In the case of antibiotics, given the growing global problem of bacterial resistance, it is particularly important that the antimicrobial drugs provided to the patient are characterized by the best possible properties to fight infections [4,5,6]. Cephalosporins are currently among the most relevant groups of antibiotics due to their broad spectrum of antimicrobial activity and relatively low toxicity. The mechanism of action of cephalosporins is typical of β-lactam antibiotics and involves the inhibition of murine synthesis. This group of antibiotics also exhibits greater resistance to the bacterial enzymes that degrade the β-lactam ring than penicillins [6]. Various analytical methods may be used to analyse the photoprotective properties of the packaging. One of these techniques is hemispheric directional reflectance, which is defined as the ratio of light reflected from a surface in a given direction to light incident on the surface from above, from theta (θi) direction. By measuring and summing the amounts of reflected and scattered light, it is possible to determine how much of the incident light has been absorbed by the surface [7].
The study aimed to assess the value of hemispheric directional reflectance from the outer packaging (cardboard box) and direct packaging (blister) for cefuroxime in various spectral bands. Using hemispheric directional reflectance, the photoprotective properties of any given object may be evaluated.

MATERIAL AND METHODS

Two different cefuroxime preparations (i.e. Ceroxim and Zinnat) were analysed in the study. Each studied preparation included both unexpired and expired tablets (Ceroxim – expiration date May 2015, Zinnat – expiration date August 2016). The expired packages were analysed to assess whether long-term storage of the drugs negatively affects the packaging of the pharmaceutical preparation, reducing its protective ability against radiation. These packages were stored

in ambient conditions according to the manufacturer's recommendations.

The outer packaging of each product was a cardboard box and the immediate packaging was a non-transparent blister made of aluminium and PVC. All the packaging protected tablets containing cefuroxime in the form of cefuroxime axetil at a dose of 500 mg. Cefuroxime axetil is hydrolyzed by esterases to the active form of an antibiotic, i.e. cefuroxime. We measured three areas of each preparation, i.e. the white area of the outer cardboard, the coloured area of the outer cardboard and the blister. Within the coloured areas, we analysed red and blue spaces.

To evaluate the value of total hemispherical reflectance (THR), a hemispherical reflectometer 410-Solar (Surface Optics Corporation, San Diego, CA, USA) was used. The basic element of the measuring head of the apparatus is the integrating sphere in which the reflectance measurement takes place. Light in the sphere falls on the sample at an angle of 20°, covering wavelengths from 335 nm to 2500 nm (ultraviolet light, visible light and near-infrared) in seven different spectral ranges, i.e. 335–380 nm, 400–540 nm, 480–600 nm, 590–720 nm, 700–1100 nm, 1000–1700 nm and 1700–2500 nm. The measurement head also contains detectors that measure the voltage of reflected and/or scattered light (depending on the setting of the beam blocker element) incident on the detectors. The voltage of the light reaching the detector is directly proportional to the reflectance of the sample surface.

THR testing was conducted on the surface of the packages, i.e. the blister packs and the cardboard outer packs. In the case of the blister, four measuring areas were selected on the aluminium foil side of the surface, while in the case of the outer packaging, eight measuring areas were selected on the surface of the box (four areas of white cardboard and four areas of coloured cardboard). The test was performed by applying the aperture of the reflectometer's integrating sphere as precisely as possible to the surface and then pressing the trigger to activate the measuring instrument. Analysis was preceded by calibration of the apparatus using two calibration coupons: mirror and specular. The calibration process was carried out in accordance with the guidelines appearing on the reflectometer screen, i.e. first a specular coupon was placed in the aperture, then a mirror one and the last measurement in the series was taken on a space. Three calibration series were repeated each time. Similarly, the reflectance measurement was repeated three times for each of the selected measuring areas. The reflectance values were displayed on the instrument's LED screen and stored on a memory card.

The obtained data were analysed utilizing Statistica 13 software (StatSoft; Statistica, Tulsa, OK, USA) using non-parametric tests: Mann-Whitney U (when two samples were compared) and Kruskal-Wallis (when more than two samples were compared). When significant differences were observed in the Kruskal-Wallis test, post-hoc pairwise comparisons between the measurement areas (i.e. white vs coloured, white vs blister and coloured vs blister) were performed employing the Mann-Whitney U test. The criterion for the occurrence of statistically significant differences between the reflectance values of the compared test areas was $p < 0.05$.

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RESULTS

Graphs presenting the distribution of the mean total reflectance values for various spectral ranges in the white, coloured and blister measurement areas of both the Ceroxim and Zinnat preparations are shown in Figures 1 and 2. For the Ceroxim preparations, the curve for the blister, both expired and unexpired, has a very similar shape with a similar magnitude of mean THR value in each measurement point, regardless of the validity period. In turn, the curves for the white and coloured areas differ in course between the unexpired and expired preparations (Figure 1). There were statistical differences in the THR values between all the measurement areas in both the expired and unexpired Ceroxim preparations ($p < 0.001$). In the posthoc analysis for the expired Ceroxim, in the spectral bands of 335–380 nm, 1000–1700 nm, and 1700–2500 nm, i.e. in UV light and infrared, significant differences in THR between the white vs blister, white vs coloured and coloured vs blister comparisons were found ($p < 0.001$ each). In the 400–540 nm range, the significance was observed for white vs coloured ($p < 0.001$) and coloured vs blister ($p = 0.037$). In the bands of 480–600 nm, 590–720 nm and 700–1100 nm, differences between the pairs of white vs coloured and white vs blister were seen ($p < 0.001$ each). On the other hand, in the post-hoc analysis for the unexpired Ceroxim preparation, significant differences in THR between all the comparisons were found only for the 335–380 nm band ($p < 0.001$ each). Differences in the THR values between white vs coloured and coloured vs blister were observed within the ranges of 400–540 nm, 480–600 nm and 590–720 nm ($p < 0.001$ each). In the infrared ranges, i.e. 1000–1700 nm and 1700–2500 nm, THR differed between white vs blister and coloured vs blister ($p < 0.001$ each). In turn, in the 700–1100 nm band THR differed significantly between the white areas and both the coloured areas and blister packs ($p = 0.019$ and $p < 0.001$, respectively).

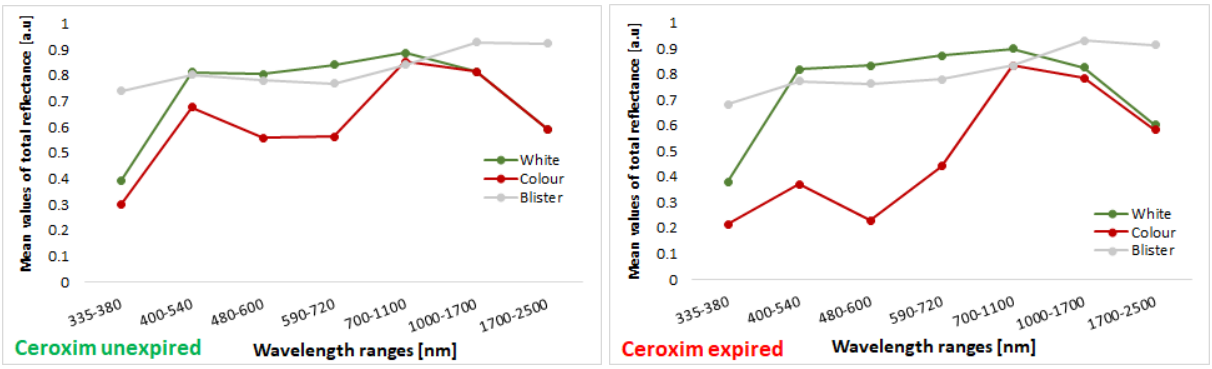

Fig. 1. Distribution of mean total reflectance values for all analysed spectral ranges in different measurement areas of Ceroxim preparation.

For the Zinnat preparations, the curve for the coloured areas, both expired and unexpired, has a very similar shape. The average THR values were of a similar magnitude regardless of the validity period. In turn, the curves for the white areas and blister packs show differences in the course of the graph between the unexpired and expired preparations (Figure 2). There were statistical differences in the THR values between all the measurement areas in both the expired and unexpired Zinnat preparations ($p < 0.001$ each). In the post-hoc analysis for the expired Zinnat preparation, in the spectral bands of 335–380 nm, 400–540 nm, 480–600 nm and 590–720 nm, i.e. in UV and visible light, significant differences in THR between white vs blister, white vs coloured and coloured vs blister comparisons were found ($p < 0.001$ each). In turn, for 700–1100 nm the following significances were observed: white vs blister ($p < 0.001$) and coloured vs blister ($p = 0.004$). Similarly, in the 1700–2500 nm range differences in the same pairs of tested areas were demonstrated (white vs blister $p = 0.004$ and coloured vs blister $p < 0.001$). In the spectral band of 1000–1700 nm, only the white areas differed from the blister pack ($p = 0.006$). On the other hand, in the post-hoc analysis for the unexpired Zinnat preparation, significant differences in THR between all the comparisons were found in the spectral bands of 335–380 nm and 400–540 nm ($p < 0.001$ each). In the 480–600 nm and 700–1100 nm ranges, white vs coloured and coloured vs blister of the unexpired Zinnat were significant ($p < 0.001$ and 0.008 in 480––600 nm, respectively and $p < 0.001$ and 0.004 in 700–1100 nm, respectively). In 590–700 nm, white vs coloured and white vs blister of the unexpired Zinnat were significant ($p < 0.001$ each). In 1700–2500 nm, we observed statistical differences in THR when white vs blister and coloured vs blister were compared ($p = 0.007$ and $p < 0.001$, respectively).

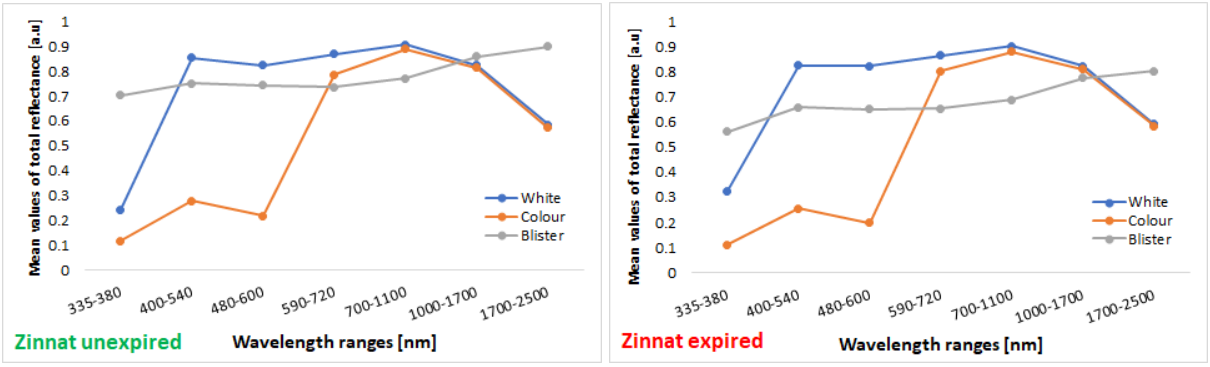

Fig. 2. Distribution of mean total reflectance values for all analysed spectral ranges in different measurement areas of Zinnat preparation.

The coloured areas of the Ceroxim package were painted blue and these surfaces reflected a great amount of light beam in the wavelength ranges comprising UV light and visible light (i.e. 335––380 nm, 400–540 nm, and 480–600 nm ranges). In turn, the red areas of the Zinnat unexpired preparation had greater photoprotection properties in subsequent spectral ranges, i.e. infrared.

Figure 3 presents a comparison of the average values of THR measured within the white and coloured areas of the Ceroxim packages as well as within the blister (expired vs unexpired) in the seven spectral ranges. For the white areas of the outer package of the Ceroxim preparation, we observed that in the wavelength range of 335–380 nm, the values of THR were the lowest, while the highest average values of

THR were seen in the range of 590–700 nm and 700––1100 nm, both in the unexpired and expired preparations. Significant differences in the reflectance values between the expired and unexpired preparations were found for 480–600 nm, 590––700 nm, 700–1100 nm and 1700–2500 nm ($p < 0.001$ each). Surprisingly, in those spectral ranges, the expired preparation showed better reflectance than the unexpired one. In the case of the coloured areas of the outer package of the Ceroxim preparation, significant differences between the expired and unexpired preparations were found in all the wavelength ranges except 1700–2500 nm ($p < 0.001$ each). For these measurements, the unexpired preparations showed higher THR values as expected. As for the blister, no significant differences were observed between the expired and unexpired preparations in all the spectral ranges.

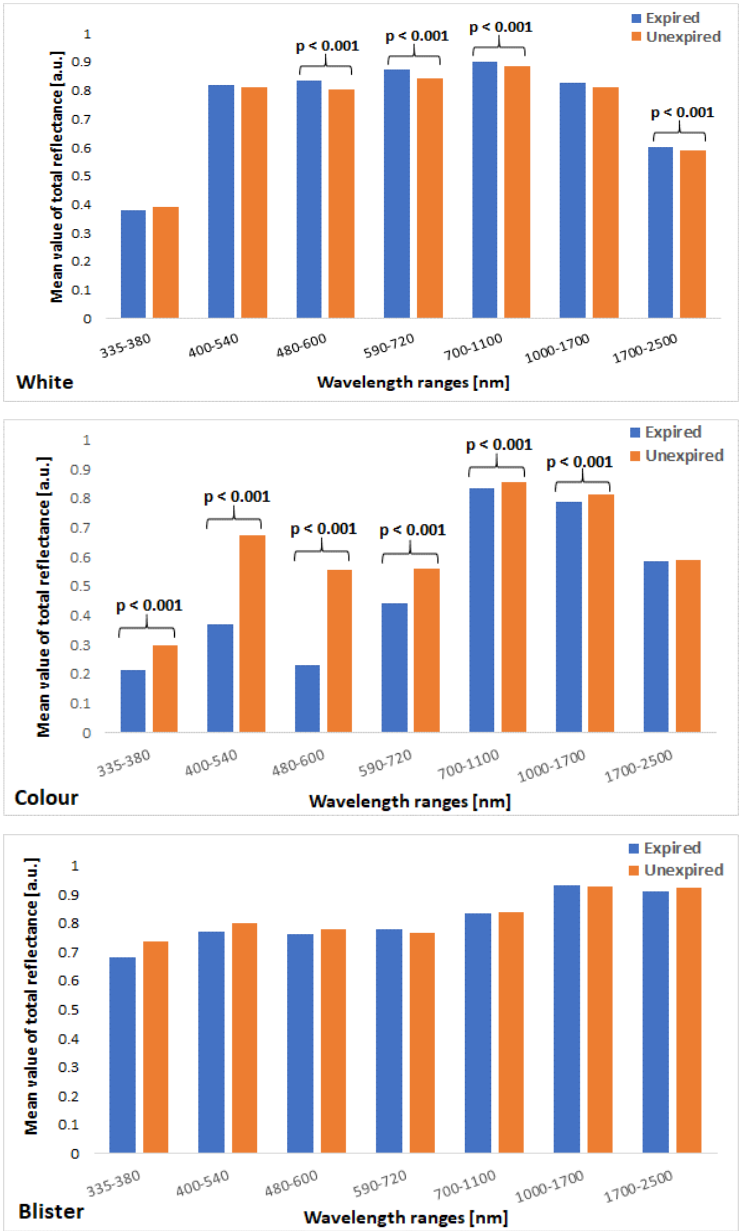

Fig. 3. Comparison of average values of total directional reflectance (THR) measured within white and coloured areas and blister of Ceroxim packages (expired vs unexpired) in seven spectral ranges of 335–380 nm, 400–540 nm, 480–600 nm, 590–720 nm, 700–1100 nm, 1000–1700 nm, 1700–2500 nm.

Figure 4 displays a comparison of the average values of THR measured within the white and coloured areas of the Zinnat packages as well as within the blister (expired vs unexpired) in the seven spectral ranges. Similar to the Ceroxim preparation, the white areas of the outer package of the Zinnat preparation were the lowest in the wavelength range of 335–380 nm THR values, while the highest average values of THR were

demonstrated in the range of 700–1100 nm, both in the unexpired and expired preparations. The white areas of the expired preparation had a higher reflectance value within the spectral bands of 335––380 nm and 1700–2500 nm than the unexpired preparation ($p < 0.001$). In addition, significant differences in the reflectance values between the expired and unexpired preparations were found for 400–540 nm and 480–600 nm ($p < 0.001$ each). Regarding the coloured areas of the outer package of the Zinnat preparation, significant differences in the reflectance values between the tested preparations were recorded in 400–540 nm, 480–600 nm, 590––700 nm, 700–1100 nm and 1700–2500 nm ($p < 0.001$ each). For the 335–380 nm and 1700––2500 nm measurements, the expired preparations exhibited higher THR values, thus a greater amount of light was reflected from the coloured areas than in the unexpired preparation. As for the Zinnat blister, a significant difference in THR was observed between the expired and unexpired preparations in the 335––380 nm band.

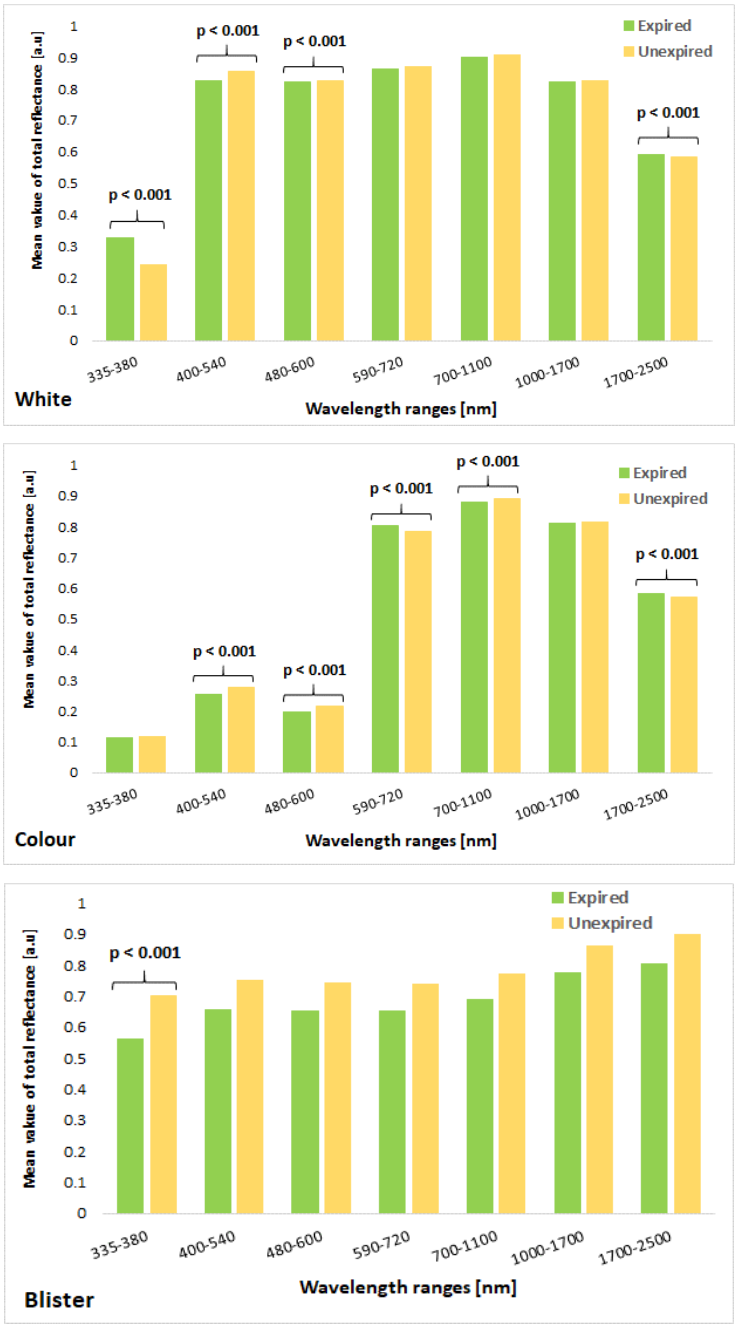

Fig. 4. Comparison of average values of total directional reflectance (THR) measured within white and coloured areas and blister of Zinnat packages (expired vs unexpired) in seven spectral ranges of 335–380 nm, 400–540 nm, 480–600 nm, 590–720 nm, 700–1100 nm, 1000–1700 nm, 1700–2500 nm.

DISCUSSION

The purpose of the study was to evaluate the total hemispherical reflectance of different types of pharmaceutical packs containing cefuroxime. The outer cardboard packaging in the white and coloured areas and packaging in direct contact with the drug, i.e. blister packs, were analysed. In all the investigated packages, statistical differences in the mean value of total reflectance between the white and coloured areas of the same formulation were found; the results were higher for the white areas. A study by Błoński et al. [7] showed a similar relationship, according to which bright surfaces reflect light to a greater extent than more intensely coloured surfaces.

The hemispherical directional reflectance method allows one to determine the amount of radiation absorbed or reflected by the packaging of a pharmaceutical preparation in a given spectral range. Therefore, the methodology enables optimization of this packaging. In the case of the examined cefuroxime packaging, the highest reflectance value was found in the spectral range of 700–1100 nm for both the unexpired and expired preparations. For example, in the unexpired Zinnat preparation, it ranged from 77% for the blister, through 89% for the coloured areas, to 91% for the white areas. Therefore, 23%, 11% and 9% of light, respectively, may penetrate the packaging and interact with the medicinal preparation itself. In turn, in the 335–380 nm band, the amount of reflected radiation for the unexpired Ceroxim vs Zinnat packages was as follows: 30% vs 12% from the coloured areas, 39% vs 24% from the white areas and 74% vs 70% from the blister, respectively. Therefore, it seems that protection against this particular wavelength should be taken into account so that pharmaceutical packaging protects especially against radiation in this spectral range.

We observed differences in the amount of reflected light from different colours of the analysed unexpired preparations. In the Ceroxim preparation, the blue surface exhibited better reflection of light in the wavelength ranges comprising UV light and visible light (i.e. 335–380 nm, 400–540 nm, and 480–600 nm ranges) over other spectral bands. In turn, the red areas of the Zinnat unexpired preparation had greater photoprotection properties in infrared. Kundu et al. [8] also observed varying reflectance values for different colours in the same wavelength of incident light. The results collected for both types of outer packaging areas demonstrate the important role that cardboard boxes play in protecting the drug from radiation exposure. Their role is therefore not limited to providing basic information to the patient and facilitating the logistics involved in transporting and storing the preparation. Data obtained using the hemispheric directional reflectance method suggest that the coloured graphic elements on the surface of the packaging may result in a decrease in the photoprotective properties of these areas due to increased light transmission to the interior of the preparation. This in turn affects the properties of the drug. At the same time, it is impossible to introduce all-white packaging, hence coloured graphic elements should be limited to the necessary minimum.

The blister packs of pharmaceutical preparations have a complex structure with multiple layers and are most commonly made of polyvinyl chloride (PVC) [9]. The blisters of the unexpired Zinnat preparation at all the wavelengths showed greater photoprotective properties than the expired blisters but the difference was significant only in UV light (335–380 nm). In the case of the Ceroxim preparation, no differences were found between the unexpired and expired blisters. Therefore, it can be concluded that the blister packs provide very similar and high protection against radiation. The results for the blisters are therefore consistent with previous data indicating the high photoprotective properties exhibited by aluminium surfaces [10].

The present study is one of the very few research studies analysing the photoprotection of pharmaceutical packages using a THR parameter. The work has some limitations, mainly owing to the small number of packages used. In our study, under the term “coloured areas” different colours were taken into account: for Ceroxim it was blue and for Zinnat it was red. In some preparations, the packaging design may contain stripes/areas of different colours and the measuring equipment such as a reflectometer may include all the mentioned colours, each of which has the highest reflectivity in a different wavelength range. Nevertheless, the obtained results provide information on the photoprotective properties of the packaging of various cefuroxime preparations. Based on the total directional reflectance data, it is possible to compare the selected packaging/packaging areas and determine which of them provides the best protection against light in a given wavelength range. The higher the reflectance value of the investigated packaging surface, the more light is reflected. The rest of the radiation is transmitted/absorbed and can adversely affect the drug, impairing its pharmacokinetic and pharmacodynamic properties [11,12]. In the case of cefuroxime, the action of radiation leads to photoisomerization reactions and photolysis of the β-lactam ring, which is a key structural element for the antimicrobial activity of cephalosporin antibiotics [13]. Therefore, in order to preserve the drug’s efficacy, it is necessary to store it under light-limited conditions.

The usage of hemispherical directional reflectance in package analysis may provide new data that has not been provided by previously used procedures. In the future, the information obtained by means of this technique may assist in the selection of appropriate packaging parameters, such as surface texture or package thickness, and specific materials for the preparation of blisters and cardboard outer packages.

CONCLUSIONS

The reflectance value indicates that the blisters and white cardboard packaging of preparations protect the drug against radiation to the greatest extent. In the case of blisters, the reflectance values differed the least between the different wavelength ranges. There were significant differences in the total directional reflectance for the coloured areas of the outer packaging between the unexpired and expired packages. The reflectance of the blister packs did not however change during the long-term shelf life, thus there were no differences between the expired and unexpired blisters in all the wavelength ranges. In order to ensure the best possible radiation protection, a pharmaceutical preparation packaged in a blister pack should additionally be placed in a white cardboard box, with the smallest possible area covered by coloured graphics.

Author's contribution

Study design – T. Górka, M. Meisner, B. Sarecka-Hujar
Data collection – T. Górka, M. Meisner
Data interpretation – T. Górka, M. Meisner, B. Sarecka-Hujar
Statistical analysis – B. Sarecka-Hujar
Manuscript preparation – M. Meisner, B. Sarecka-Hujar
Literature research – T. Górka, M. Meisner, B. Sarecka-Hujar

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