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Analysis of total hemispherical reflectance of pharmaceutical packaging containing cefuroxime

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Background

One of the many requirements for the packaging of pharmaceutical preparations is to provide active pharmaceutical ingredients (API) with the most effective protection against harmful external factors, including radiation. Insufficient isolation of the drug from the environment can significantly reduce its pharmaceutical properties and lead to ineffective pharmacotherapy. In the case of cefuroxime, which is a representative of cephalosporin antibiotics, radiation leads to photoisomerization reactions and photolysis of the β-lactam ring, which is a key structural element for the antimicrobial activity. Therefore, a quick and effective assessment of the photoprotective properties of pharmaceutical packaging is of great importance in the drug manufacturing process. Light radiation falling on an object can be reflected, scattered and/or absorbed. By analyzing the amount of scattered or reflected light radiation from the pharmaceutical package, we are also able to determine how much radiation penetrates into the packaging.

The aim of the study was to evaluate the total directional hemispherical reflectance (THR) for outer packaging (cardboard boxes) and those in direct contact with the drug (blister package) for tablets containing cefuroxime.

Methods

Three types of measurement areas were analyzed within the packaging of four unexpired pharmaceuticals containing cefuroxime:

- white areas within the cardboard outer package,
- colored areas within the cardboard outer package
- a non-transparent blister made of aluminum and PVC.

The THR was measured using SOC-410 Directional Hemispherical Reflectometer (USA) within a wide wavelength range from 335 nm to 2500 nm at an angle of 20°. The SOC 410 apparatus measures the integrated surface reflectance for seven wavelength bands i.e. 335 – 380 nm, 400 – 540 nm, 480 – 600 nm, 590 – 720 nm, 700 – 1100 nm, 1000 – 1700 nm, 1700 – 2500 nm. The integrating sphere captures the reflected radiation from the tested object (in our study pharmaceutical package) integrating those reflections in all directions. Each of the selected areas within the analyzed package was measured three times.

Figure 1. On the left - directional Hemispherical Reflectometer. On the right - exemplary outer cardboard package of cefuroxime drug with measurement areas within white and colored areas.

To compare the obtained data between the analyzed areas, Statistica 13 software was used.

Keywords hemispherical directional reflectance; pharmaceutical packaging; radiation; photoprotective properties; drug stability;

Results

For the blister of each tested pharmaceutical product, the reflectance values changed the least between different wavelength ranges. Mean THR values varied significantly between blisters, white areas of the outer packaging, and colored areas of the outer packaging in each analyzed pharmaceutical ($p<0.001$).

Blisters of all tested products showed the best photoprotection within the wavelength range from 335 nm to 380 nm, i.e. within UV radiation as well as within the infrared ranges of 1000-1700 nm, and 1700-2500 nm compared to white and colored areas of outer packaging ($p<0.001$ each). In turn, the white outer package had the best photoprotection of the tablets within the radiation ranges of 400-540 nm, 480-600 nm, 590-720 nm and700-1100 nm ($p<0.001$ each), which covered visible light and near-infrared.

Table 1. Mean total directional reflectance of one of the tested packages of a preparation containing cefuroxime. Comparison of the analyzed measurement areas.

Wavelength ranges (nm)	335-380	400-540	480-600	590-720	700-1100	1000-1700	1700-2500
Measurement area	Total reflectance (a.u.), M ± SD						
WHITE	0,391 ±0,021	0,811 ±0,045	0,805 ±0,045	0,841 ±0,045	0,886 ±0,043	0,813 ±0,042	0,590 ±0,025
COLORED	0,298 ±0,032	0,676 ±0,042	0,557 ±0,073	0,562 ±0,079	0,854 ±0,011	0,814 ±0,007	0,590 ±0,009
BLISTER	0,739 ±0,074	0,802 ±0,050	0,780 ±0,067	0,768 ±0,069	0,841 ±0,026	0,928 ±0,017	0,924 ±0,010
P	<0,001	<0,001	<0,001	<0,001	<0,001	<0,001	<0,001

Conclusions

Aluminum blisters and white cardboard packaging of pharmaceutical preparations protect the solid dosage forms against radiation to the greatest extent.

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