PHYSICAL PROPERTIES OF MATERIALS USED FOR INFUSION SETS FOR PHOTOSENSITIVE MEDICINES

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Abstract

Continuous infusion, as one of the most effective methods of delivering pharmaceuticals to patients, uses infusion pumps to which a syringe and infusion drains are connected. Photosensitive drugs that require UV-VIS protection are delivered to patients with special infusion sets that reduce harmful radiation. However, these drains have different transparencies, which can affect the success of therapy.

This study investigated the optical properties of two types of drains used for infusion therapy of photosensitive drugs. UV-VIS spectroscopy studies were carried out, allowing the determination of the absorbance values and absorption coefficient of the two types of drains. The spectrum of their transmittance was also analyzed. The chemical composition of the samples was tested using FTIR-ATR spectroscopy. Furthermore, the roughness and wettability parameters of the drains were determined, which affect not only the kinematics of drug flow in the drains but also the way in which light is transmitted. The results of the study can be used to propose a solution to eliminate the problem of loss of properties of the photosensitive drug in drains, in contact with light. By selecting the appropriate drain thickness, it is possible to reduce the transmission of radiation in the UV-VIS range through the drain.

Keywords: *infusion drains, photosensitive medicines, polyvinyl chloride, UV-VIS spectrophotometry, transmittance, absorbance*

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Introduction

Medicinal products, which have been around for years in the history of mankind, are designed to reduce the effects of disease. Nowadays, where medicine and the pharmaceutical industry are developing rapidly, we have a wide range of drugs to choose from, which can prevent many diseases and even death. Not only the composition and proportions of the drug are important but also the way in which it is delivered to patients. One of the most effective methods of administering pharmaceuticals to patients is continuous infusion, which, compared to traditional gravity infusion, ensures that the preferred concentration of the drug in the blood is maintained constant, for a specified period of time. A drug product at the level of the so-called therapeutic window between the minimum therapeutic concentration and the minimum toxic concentration gives the best response of the body to the administered substance [1]. Additionally, infusion pumps are equipped with various types of alarm systems that greatly facilitate the work of medical personnel.

Some infusion drugs require special precautions during both storage and injection into the body. Particularly sensitive are photosensitive drugs, which are a group of drugs that react negatively to electromagnetic radiation in the visible and ultraviolet light range. In contact with light, they lose their physical, chemical and pharmacological properties, which can contribute to the ineffectiveness of the treatment. Moreover, their degradation products may worsen patient's condition.

Only a few studies on photosensistive pharmaceuticals and their physical and chemical transformations are available [2]. The main source of information presented on the purpose, storage, and supply of this type of drugs is the *National Register of Medicinal Products* [3] providing characteristics and brochures of selected pharmaceuticals.

Examples of photosensitive drugs are as follows: *Micafungin Accord, Detimedac, Linezolid Polpharma*. These drugs have a broad spectrum of applications. They are used in the treatment of invasive candidiasis or hospital-acquired pneumonia in both adults and newborns. They have also found use in cancer departments for the treatment of metastatic malignant melanoma, advanced *Hodgkin's disease,* or advanced soft tissue sarcomas [3].

Photosensitive drugs must be stored in the original tightly sealed packaging. Orange glass vials or special films that protect drugs from light are the most commonly used. For drug delivery, it is recommended to use light-resistant PVC infusion sets or a traditional aluminium foil-wrapped set [3]. However, it is worth paying attention to the individual components of the infusion line, which differ in translucency, as it can affect the effectiveness of the drug and thus the success of therapy.

The infusion line provides a permanent connection between the infusion pump and the patient. The syringe, the amber colored infusion extender, and the clear extension tube (FIGs. 1-3), which connects to the cannula and thus to the patient's vein, are connected to the pump in sequence. The amber syringe and the amber extension tube are adapted to protect drugs from light (FIG. 1 and FIG. 2). After a detailed review of the availability of this type of equipment and an interview with medical personnel, it can be concluded that there are no extension drains adapted for the infusion of photosensitive drugs on the global market for medical devices. In the characteristics of photosensitive drugs, it is clearly marked that infusion sets that ensure reduction of radiation transmittance are to be used.

FIG. 1. Amber-colored syringe for infusion pumps (Polmil Company).

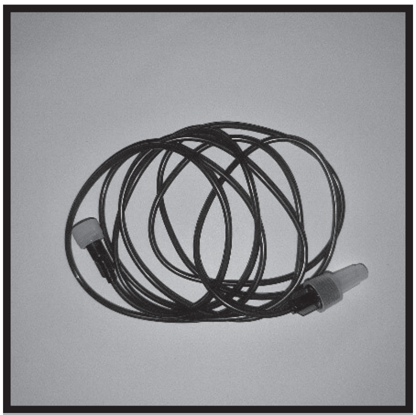

FIG. 2. Amber-colored infusion pump extension tube (Zarys Company).

FIG. 3. Three-way stopcock with extension tube (Zarys Company).

During treatment, time is of the essence, and medical personnel, when trying to protect the photosensitive drug by other means, waste that time. Photosensitive drugs are used on the wards where bedridden patients require immediate and reliable treatment. That is why it is so important to make the work of doctors and nurses as efficient as possible and to ensure that there is no doubt about the effectiveness of the pharmaceutical administered.

When the materials used for the production of basic devices for injecting drugs are analyzed, it should be noted that the basic materials are polypropylene, polyethylene, and polyvinyl chloride. Typically, the syringe body is made of polypropylene (PP), while the syringe plunger is made of polyethylene (PE) [4]. The rest of the infusion line is made of poly(vinyl chloride) (PVC) [4] mixed with various additives [5].

The main purpose of the study was to determine the optical properties of the amber-colored and transparent drains used for the continuous infusion of photosensitive drugs. Their transmittance and absorbance values were compared. In addition, the chemical composition of the drains was analyzed, and the topography and wettability of their surfaces were studied.

Materials and Methods

Drain materials

As mentioned above, two types of materials used for the production of infusion pump drains were used for comparative studies: amber, shown in FIG. 2 and transparent, shown in FIG. 3. These drains are manufactured by Zarys. They are available from the company and are widely used in healthcare facilities.

Detailed information on the amber and transparent drain composition data was provided by the company Zarys in TABLES 1 and 2, respectively. Based on these, the main component of the drains - PVC poly(vinyl chloride) - was determined. The rest of the components are various types of additives to match the properties of the drains for processing and utility purposes. A characteristic component of the drain adapted for the infusion of photosensitive drugs is *bis(2-ethylhexyl) phenyl phosphite*, which imparts an amber color and thus increases the absorbance value of visible light radiation.

TABLE 1. Percentage composition of the amber infusion pump extension tube.

Substance name	Percentage composition
PVC resin	64-70%
TOTM (trioctyl trimellitate)	25-28%
ESO (epoxidized soybean oil)	4-6%
Octadecanoic acid, zinc salt	2%
Ethene, homopolymer, oxidized	1%
Bis(2-ethylhexyl) phenyl phosphite	1%

TABLE 2. Percentage composition of the three-way stopcock with extension tube.

Substance name	Percentage composition
PVC (polyvinylchloride polymer)	63.2%
TOTM (trioctyl trimellitate)	33.5%
Epoxidized Soybean Oil	2.3%
Calcium-Zinc based heat-stabilizer	0.6%
Lubricant	0.2%
Other components	0.2%

FTIR-ATR Spectroscopy

A *Nicolet iS50 FTIR* spectrophotometer was used to study the chemical composition of the drains, together with a *GladiATR Illuminate ATR* measurement device. Special *OMNIC* software gave the possibility to read the mid-IR absorption spectra of the studied materials in the infrared range (4000-650 cm^{-1}).

Samples of each type of the drains (amber and transparent) were used in the study. The preparation of the samples required taking sections of drains approximately 7 mm in length and cutting them lengthwise (FIG. 4 and FIG. 5). The samples were studied at room temperature (25°C).

Infrared spectroscopy is a standard, fast, and economical measurement technique suitable for material characterization, e.g. polymer materials, and it provides the molecular fingerprint of the sample. It is expected that its sensitivity will enable the detection of small changes in the chemical composition of material samples related to the addition of a dye to absorb high-energy radiation in the UV-VIS range.

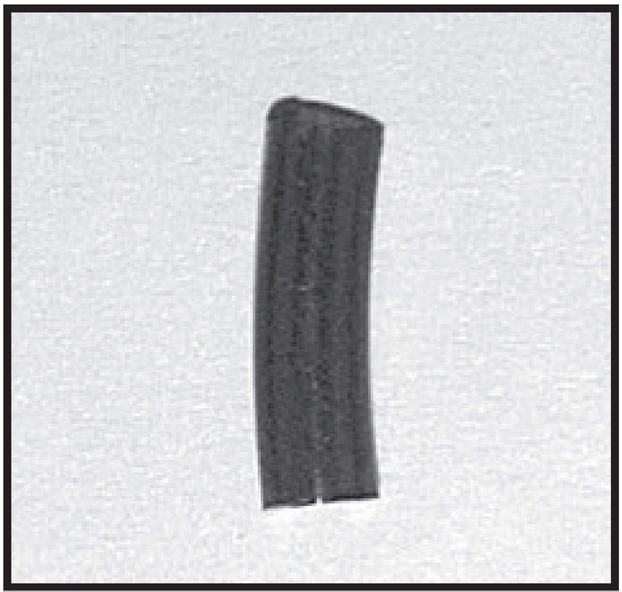

FIG. 4. Amber drain sample prepared for the FTIR-ATR spectrophotometric study.

FIG. 5. Transparent drain sample prepared for the FTIR-ATR spectrophotometric study.

UV-VIS absorption spectroscopy

UV-VIS spectroscopy is a powerful analytical technique for determining the optical properties (transmittance, reflectance, and absorbance) of gases, liquids, and solids. It can be applied to characterize different materials, i.e. polymers and many other research and manufacturing materials. In this research, UV-VIS operated in the optical range between 300 and 800 nm. The analysis of the optical properties of the tested samples was performed based on transmittance measurements. The test stand was equipped with a deuterium tungsten light source from Ocean Optics Inc. An *Ocean Optics HR ES2000+* fiber optic spectrometer was used as a detector for the study, along with special *Ocean Optics SpectraSuite* software for viewing spectra in the range of 300-800 nm. In order to properly measure the transmittance of the samples, a system of two collimators was used in the stand so that the beam of optical radiation passing through the tested sample was collimated.

Due to the need to use flat-parallel samples in the study, steps were taken to prepare the samples for the study. The drains of each type were cut into 6 sections of approximately 7 mm in length and cut lengthwise to flatten the sample. Then, each sample was placed between two microscope slides. To ensure the flatness of the samples, metal plates with the same thickness as the walls of the drains were placed between the slides. The samples prepared in this way were heated on both sides with a heating system consisting of ceramic-tourmaline plates and a power source. The heating temperature was set at 180°C. After 3 minutes of heating, the sample still placed between the slides was left to vitrify at room temperature (FIG. 6 and FIG. 7).

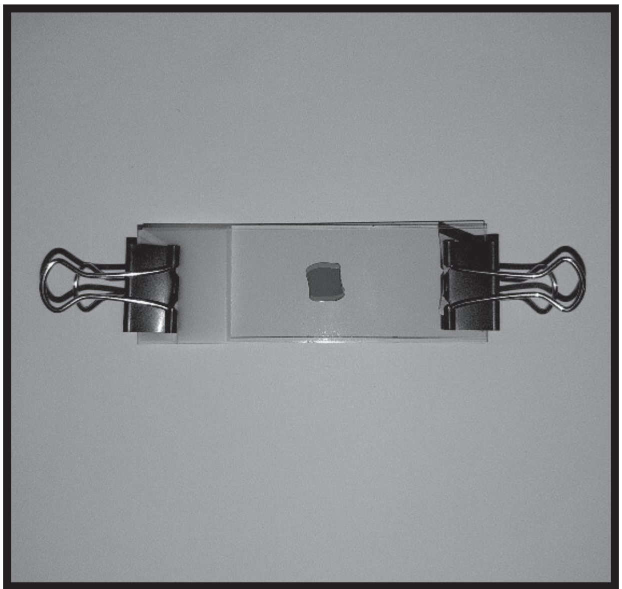

FIG. 6. Amber drain sample prepared for UV-VIS absorption spectroscopy study.

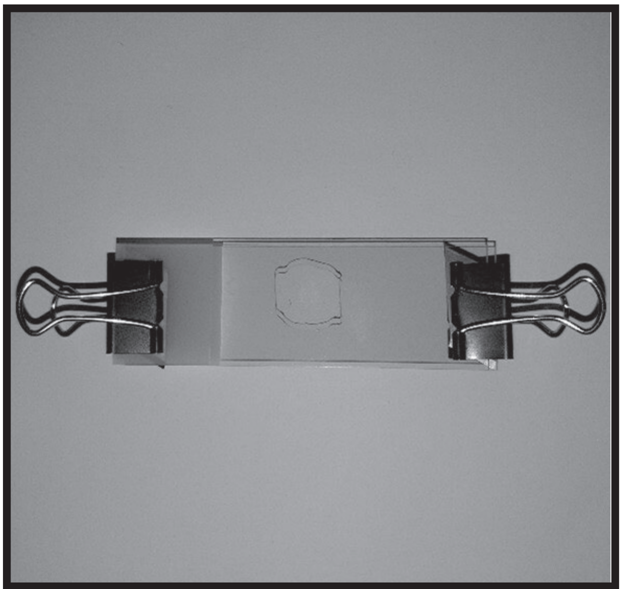

FIG. 7. Transparent drain sample prepared for UV-VIS absorption spectroscopy study.

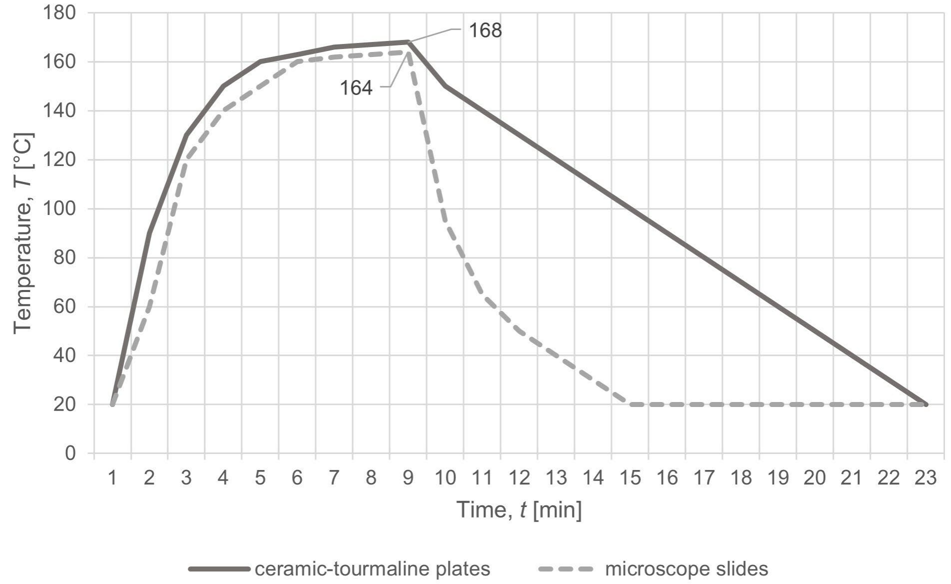

FIG. 8. Heating characteristics of the sample preparation system for UV-VIS spectrophotometric studies.

When selecting the heating temperature of the samples, the characteristic temperature ranges for PVC material were taken into consideration to prevent its degradation [6]:

- melting point T_m = 212°C,
- glass transition temperature T_g = 87°C,
- processing temperature T_p = 160-190°C.

It was necessary to take into consideration the difference between the set temperature of the system and the actual temperature of heating the sample. For this purpose, the characteristics of the sample heating system were determined as a function of time (FIG. 8). The heating temperature of the plates was set within the processing temperature T_p = 180°C. Using a *MY-64 multimeter of Xtreme* with a connected probe, the temperature values were measured as a function of time, both between the slides and the plates.

The temperature of the slides remains below that of the plates. A non-linear increase in temperature is observed (FIG. 8). On the other hand, when the heating system is turned off, the slides cool faster.

There is a difference in the maximum temperature value. For the measurement between the slides, it is 4°C lower than the measurement between the slides themselves. To reach the maximum temperature value between the microscope slides, it was necessary to wait about 9 min after turning on the heating system. After this time, the temperature oscillates around 164°C until the system is turned off. This temperature is the actual temperature of heating the samples and is within the range of processing temperatures.

Six samples of amber drain and one sample of transparent drain were analyzed. Each sample was sequentially placed between fiber optics. The collimated beam of radiation was directed first to the slides (as a reference measurement) and then to the sample placed between the slides. Spectral measurements must be accurate and precise representations of the target material, but there are many factors that affect the quality of spectral measurements. That is why it is so important to properly adjust the measuring system and set the appropriate parameters for recording the optical spectrum. In the measurements of the spectral transmittance of the samples, the measurements were recorded with averaging of 10 spectra. The integration time for each spectrum was 7 ms. The smoothing of the boxcar was 3. The measurements were carried out indoors with the lighting turned off.

To determine the spectral absorbance and absorption coefficients of the tested samples, the Beer-Lambert law and spectral transmittance measurements were used. Using UV-VIS spectroscopy in the spectral range of 300-800 nm, the transmittance spectra were recorded. These spectra were obtained by measuring the optical beam passing through the target samples I(λ) and referring it to the spectrum of the beam incident on the sample Io(λ) [7]. The transmittance is defined as T(λ):

$$T(\lambda) = \frac{I(\lambda)}{I_0(\lambda)} \qquad (1)$$

$I_0(\lambda)$ - intensity of radiation incident on the sample (reference beam),
I(λ) - intensity of the radiation that penetrated the sample after the absorbing layer passed through.

On the basis of transmittance measurements, the absorbance *A(λ)* of the samples was determined for peculiar spectral ranges characterized by minima in the transmittance spectrum. The absorbance A(λ) is the negative log-ratio of transmitted (sample in the beam) over incident (no sample in the beam) intensities:

$$A(\lambda) = -\log\left(\frac{I(\lambda)}{I_0(\lambda)}\right) = \log\left(\frac{1}{T(\lambda)}\right) \qquad (2)$$

An absorption spectrum A(λ) shows the wavelength at which a molecule can absorb light and thus provides information about electronic state energies.

In order to quantify the absorption process in the characteristic energies of radiation, the spectral absorption coefficients of the tested samples were determined. For this purpose, the Beer-Lambert law was used, which well imitates the absorption process in poorly absorbing samples (e.g. of small thickness). Taking into account the Beer-Lambert law, the transmittance of the samples is defined as follows:

$$T(\lambda) = \frac{I(\lambda)}{I_0(\lambda)} = e^{-\alpha(\lambda)l} \qquad (3)$$

l – sample thickness, mm,
α – absorption coefficient, mm^{-1}

Lambert-Beer's law shows that the intensity of a parallel beam of electromagnetic radiation decreases exponentially as the thickness of the absorbing solid increases [7]. Therefore, the absorbance A(λ) was given:

$$A(\lambda) = 0.4343 \cdot \alpha(\lambda) l \quad (4)$$

For spectrophotometric measurements, it is necessary to take into account the thickness of the absorbing layer l, which in the case of solids is the distance between the outer planar-parallel surfaces of the solid under study [8]. Thus, the absorption coefficient is determined as follows [8]:

$$\alpha(\lambda) = 2.302 \cdot \frac{A(\lambda)}{l} \quad (5)$$

Thickness measurement of samples

The thickness of the samples was tested to determine the effect of heating on the thickness of the samples. For the measurements, a micrometer screw was used with an accuracy of 0.01 mm. The thickness of two types of drains was measured before and after heating.

Surface topography studies

The study was carried out with a *Leica DCM8* optical profilometer. Using *Leica Scan* and *Leica Map Premium* software, a sample scan was obtained, profiles were extracted, and characteristic roughness parameters of the samples were determined.

Three samples of each type of the drain were prepared for the test. The roughness test requires a flat surface of the sample. For this reason, the drain samples were prepared in the same way as the samples used in UV-VIS spectrophotometric studies.

The measurement was carried out at three measuring points on both the outer and inner sides of the samples and a 20x magnification was used.

Surface wettability studies

Four samples were selected for the wettability study. Two amber drain samples and two transparent drain samples. The samples flattened by heating were placed between two microscope slides.

For all samples, the wetting angle was measured using the sessile drop method (FIG. 9). For these measurements, a *Surftens Universal* goniometer of *OEG GmbH* was used together with the software *Surftens 4.3.* The wetting angle *Θ* was measured on both the inner and outer sides of the sample, at three different measuring points.

Results and Discussions

FTIR-ATR Spectrophotometric studies

Based on the absorption spectra obtained (FIG. 10 and FIG. 11) there was a similarity between the studied composition of the drains and the information received by *Zarys* Company.

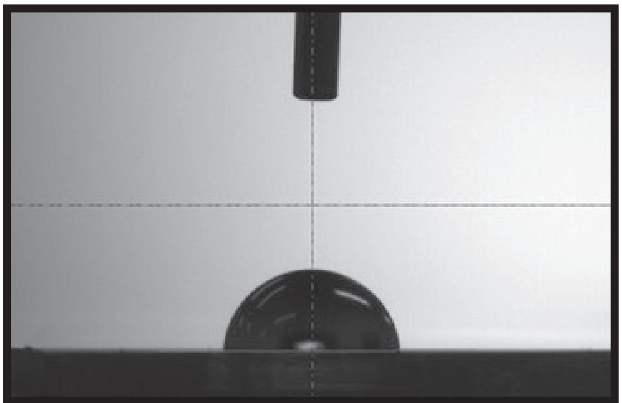

FIG. 9. Wettability study of drains by sessile drop method.

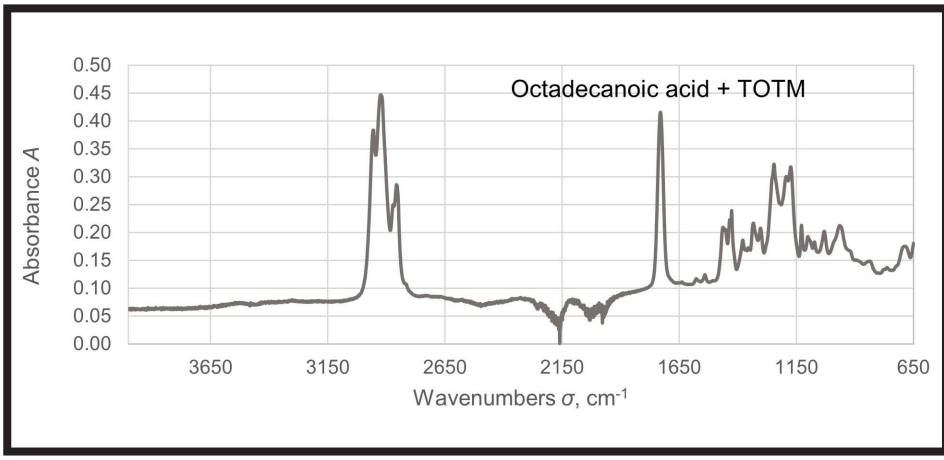

FIG. 10. FTIR-ATR absorption spectrum of the amber drain.

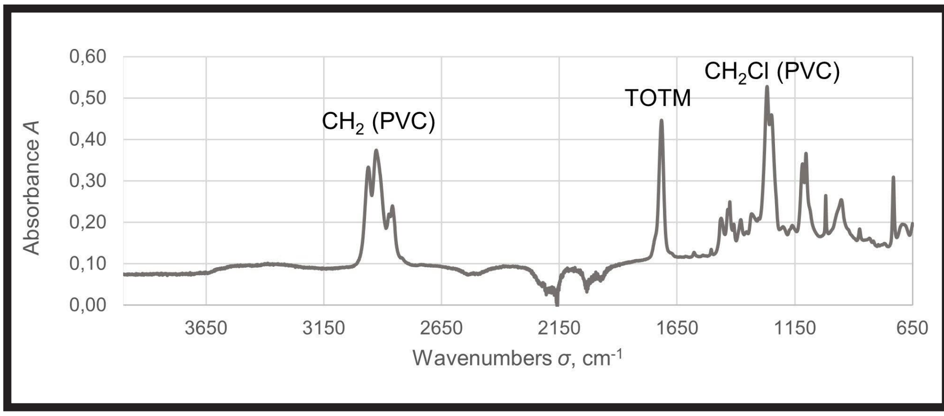

FIG. 11. FTIR-ATR absorption spectrum of the transparent drain.

The two types of drains studied overlap with the spectra of the PVC material [9]. In the vicinity of 2900 cm^{-1} and 1270 cm^{-1} there are signals characteristic of PVC bonds. Additionally, the presence of some plasticizers was detected. The signal near a wave number of about 1730 cm^{-1} is characteristic of the plasticizer TOTM (*trioctyl trimellitate*) for both the amber and transparent drain [9,10]. For the same wavelength number, *octadecanoic acid* was detected for the amber drain [11].

The amber *dye phenyl (bis-ethylhexyl) phosphite*, as reported by the manufacturer, is present at a concentration of 1%, which may result in a small signal in the absorption spectrum. Based on the similarity of the spectra of similar compounds [12,13] it can be assumed that the absorber signal is in the region of 1000 cm^{-1}. The presence of plasticizers in PVC material can be detected by vibrations in C-Cl bonds [9].

Thickness measurement of samples

After thermal flattening of the samples, a significant difference in their thickness can be observed which may be due to different pressure force of the office clips, fluctuation of the heating temperature or variation in the heating time of the samples (TABLE 3).

UV-VIS Spectrophotometric studies

Based on UV-VIS spectrophotometric studies, representative transmittance and absorbance spectra of the samples of two types of drains, with the same thickness, are presented (FIG. 12 and FIG. 13).

TABLE 3. Sample thickness l with standard uncertainty before and after heating.

Type of the drain	Thickness before heating l [mm]	Average thickness after heating l [mm]
Transparent drain	0.650(10)	0.373(44)
Amber drain	0.692(12)	0.348(70)

The amber color of the drain (component: *bis(2-ethylhexyl) phenyl phosphite*) causes the transmittance for both UV and VIS radiation to be limited. For radiation in the near UV range, it does not exceed 20%. For visible light, however, it increases from 450-800 nm with an inflection of the function around 550 nm but does not exceed the value of 80% for each wavelength. The lowest value of transmittance (about 0%) and thus the greatest drug safety occurs between 410-460 nm.

The lowest transmittance value (about 30%) of the transparent drain occurs at the wavelength representing ultraviolet radiation (315 nm). After that, the transmittance value increases and already at 450 nm it remains at almost 100%. From 600 nm onward, the transmittance gently decreases but remains above 96% all the time.

To compare the absorbance coefficient of the two types of drains at particular wavelengths λ, four characteristic points of the spectrum were chosen: 353.50 nm, 430.00 nm, 535.44 nm, 561.80 nm.

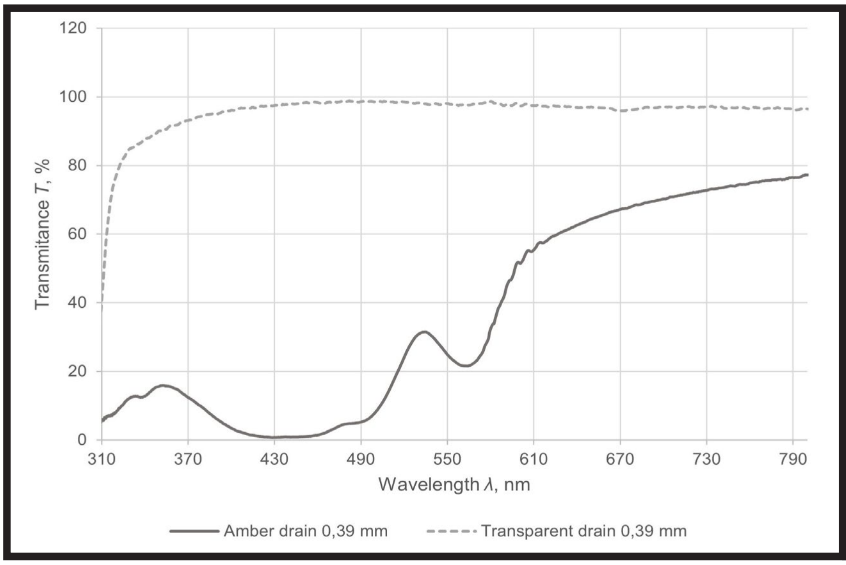

FIG. 12. Transmittance spectra of amber sample No. 4 and transparent sample No. 1.

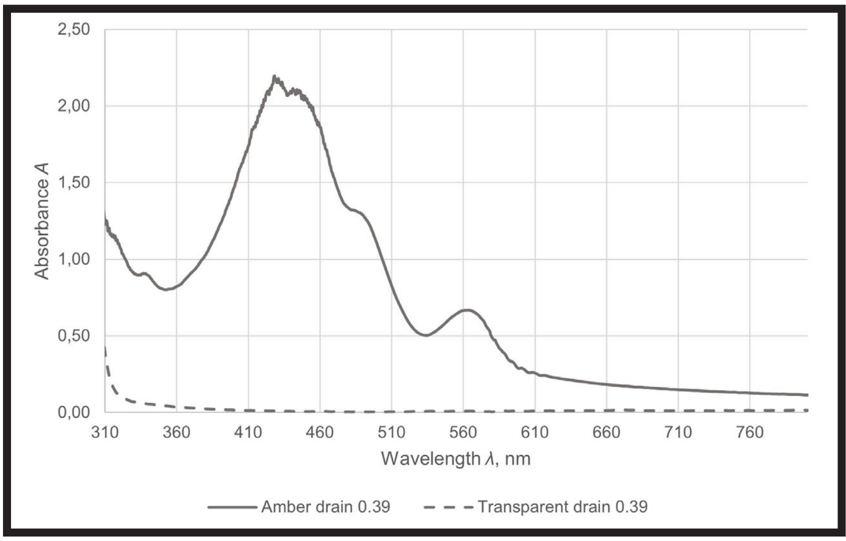

FIG. 13. Absorbance spectra of amber sample No. 4 and transparent sample No. 1.

TABLE 4. Absorbance values and absorption coefficient of amber samples.

	Amber drain				Transparent drain			
	A, a.u.		1/mm		A, a.u.		1/mm	
λ [nm]	Range	Mean	Range	Mean	Range	Mean	Range	Mean
353.5	0.48-0.80	0.71(13)	1.92-2.19	2.05(12)	0.04-0.35	0.18(17)	0.11-0.85	0.45(39)
430.01	1.36-2.19	1.95(33)	5.20-6.18	5.66(33)	0.01-0.08	0.028(35)	0.01-0.19	0.063(85)
535.44	0.32-0.51	0.455(81)	1.20-1.47	1.317(95)	0.01-0.09	0.030(40)	0.02-0.23	0.08(10)
561.8	0.42-0.67	0.60(11)	1.60-1.92	1.73(12)	0.01-0.10	0.033(45)	0.03-0.24	0.09(10)

The tables show the calculated average values of absorbance A and absorption coefficient α for the six amber samples and four transparent samples of the six tested. Transparent samples 3 and 5 were not included in the analysis of the results due to the appearance of measurement failure and the receipt of unreal results (TABLE 4).

The highest absorption coefficient of the amber drain was observed for a wavelength of 430.01 nm. For wavelengths of 535.44 nm and 561.8 nm, it occurs below 2 mm^{-1} while, for UV radiation (353.5 nm), the absorbance coefficient occurs at 2.05 mm^{-1}.

The transparent drain absorbs a small amount of radiation for each tested wavelengths. The highest absorption coefficient (0.11 mm^{-1}) occurred at the wavelength representing UV radiation (353.5 nm).

Surface topography studies

The average values of the S_a parameter are presented depending on the type of drain and the side of the test (FIG. 14). Analysis of the roughness parameter S_a indicates greater roughness of the transparent drain compared to the amber drain. The inner side of the two types of drains is characterized by a lower roughness, which is a more desirable situation due to the kinematics of drug flow in the drain.

The obtained surface topography results should be treated with uncertainty due to the way the samples were prepared. Placing the drains between microscope slides and heating them to high temperatures can introduce changes in their surface.

Surface wettability studies

Both amber and transparent drains show hydrophobic characteristics (FIG. 15).

Wettability tests of drains showed their variation depending on the type of drain and surface (internal, external). A lower value of the wetting angle was observed for the transparent drain, indicating its greater wettability compared to the amber drain.

Based on the results obtained, it is not possible to clearly say which side of the drain (external/internal) has greater wettability. For the transparent drain, we observed a larger wetting angle for the outer side. For the amber drain, on the other hand, we observed the opposite situation - a smaller wetting angle for the outer side, but the wide range of standard deviation should be kept under consideration.

The results of wetting angle measurements should be treated with some uncertainty. The preparation of the samples required deformation of the drains at high temperature, which may affect changes in the surface of the material and thus the obtained results.

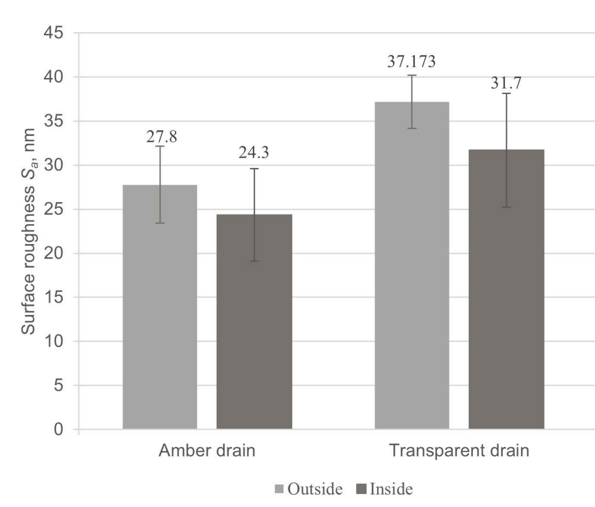

FIG. 14. The average values of the surface roughness (Sa) depending on the type of the drain and side of the tested surface.

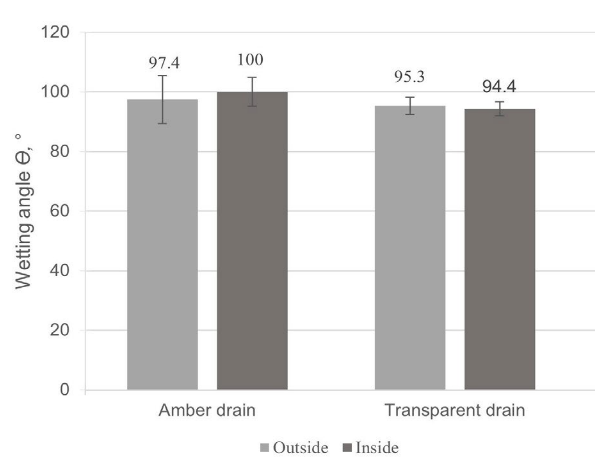

FIG. 15. The average value of the wetting angle to the type of drain and side of the test.

Conclusions

Both transparent and amber drains were made of PVC material. TOTM plasticizer was added to the transparent and amber drains, and octadecanoic acid was added only to the amber drain. According to manufacturer's information, the amber color of the drains was obtained by adding bis(2-ethylhexyl) phosphite. Its FTIR spectrum overlaps with the PVC spectrum, which can make it difficult to identify.

Transparent and amber drains have different optical properties. Transparent drain is characterized by high transmission in the entire UV-VIS range, which can cause negative radiation effects on photosensitive drugs. Amber drain is characterized by lower transmittance compared to transparent drains. The transmittance of the amber drain in the 400-500 nm range is close to zero and for higher wavelengths, it successively increases to about 80%.

Improved protection of the photosensitive drug from damaging radiation can be achieved by increasing the wall thickness of the drains. Doubling the thickness of the amber drain wall will result in a four-fold reduction of radiation transmittance in the entire UV-VIS range, which means almost complete elimination of harmful radiation. It is also possible to increase the thickness of the transparent drain, but this would be an impractical solution, so it is worth considering adding bis(2-ethylhexyl) phosphite (a component of the amber drain) in an amount that guarantees the protection of photosensitive drugs.

Both the amber and transparent drains show hydrophobic characteristics. It is impossible to clearly say which of the tested sides (outer/internal) of the drains shows a lower wettability, but the inner side is characterized by a lower roughness, which is significantly conducive to drug flow.

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