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Ultraviolet disinfection of activated carbon from microbiological contamination

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ABSTRACT

Purpose: This article aims to investigate the effectiveness of the use of ultraviolet radiation or a combination of ultraviolet radiation and ozonation in the inactivation of microorganisms in activated carbon "Silcarbon".

Design/methodology/approach: Several experimental studies where ultraviolet light, a combination of UV radiation, and ozonation were used have been performed to disinfect "Silcarbon" from microbiological contaminants.

Findings: Experimental results have shown that with pulsed xenon lamps and low-pressure mercury ozone lamps, satisfactory results can be obtained in which the total amount of yeast and mould fungi range from 50 CFU/g to 75 CFU/g.

Research limitations/implications: It is advisable to continue the study of powder materials, including drugs, on the content of microbiological contaminants to assess their compliance with regulatory requirements.

Practical implications: The application of the proposed approach to the inactivation of microorganisms allows one to obtain a safe sorbent on the content of microbiological indicators and can be successfully used in any other field to disinfection powder materials using different modes of UV irradiation.

Originality/value: The originality of the article's results proposes a method of disinfection of the sorbent "Silcarbon" from moulds and yeasts for therapeutic purposes in medicine.

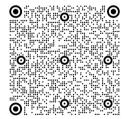
Keywords: UV irradiation, Activated carbon, Microbiological purity

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BIOMEDICAL AND DENTAL MATERIALS AND ENGINEERING



1. Introduction

Pharmaceutical practice divides medicines into sterile and non-sterile. Moreover, non-sterile medicinal products must meet certain criteria for microbiological purity, which determine their suitability for use [1,2]. The microbiological quality of the product is one of the main requirements, ensuring the safety of the patient [3].

Analysis of works [4-8] showed that in some cases, drugs and medical preparations [9] do not meet the requirements of the current legislation on microbiological purity [2]. So in work [4], 1285 samples of non-sterile preparations were analysed. In about 2% of preparations, fungi and aerobic bacteria were found, the number of which exceeds the permissible limits or the presence of which is generally prohibited [1,2]. Also, the assessment of non-sterile drugs used in a hospital was carried out in 2016 [5]. Three hundred ninety-two preparations were analysed. Immediately after preparation, they met the requirements of the pharmacopoeia [2], but after storage, the number of microbes in some batches exceeded the defined limits until the date of expiration of the period of use. Based on the results obtained, the authors of [5] recommend monthly microbiological control of random samples of drugs to establish their safety for use.

In work [6], microbial contamination of 10 non-sterile medicinal preparations delivered to outpatients was investigated. It was shown that 50% of the tested products were heavily contaminated with Klebsiella, Bacillus, and Candida. Such contamination of pharmaceuticals by microorganisms, no matter how harmful they are, can cause changes in the physicochemical characteristics of drugs. Evaluation of orthodox ophthalmological preparations was carried out in work [7] on possible microbial contamination that can cause eye infections. It was found that all samples were contaminated with bacteria, most of them with a fungus. Moreover, bacteria are noted to be resistant to common antibiotics.

A large discrepancy is represented by pre-used nonsterile drugs collected in random consumers and research for possible bacterial contamination [8]. Of the 85 formulations tested, 41 bacterial contaminants were identified in 31.

Medicines used for weight loss, cosmetic procedures, which should not potentially be life-threatening, are also dangerous [9]. The discrepancy between counterfeit and unauthorised drugs for microbiological contamination was 23% in Canada and 6% in Austria, posing a potential threat to consumers' health.

The work [10] developed a comprehensive and specific risk assessment for selecting drugs with a high level of safety for patients through the online pharmaceutical market.

According to the work authors, over the past 20 years, there has been no standardised methodology for effectively detecting the safety of pharmaceutical products. What gives us reason to think about the quality of what we consume and which unpredictable consequences it may cause.

Not only sterile drugs do not meet the requirements of regulatory documents for microbiological indicators [3], but also chewable tablets [11] and ordinary tea [12] can negatively affect the human body. So in work [11], the analysis of chewable gel tablets was carried out depending on the storage conditions and shelf life used in the pharmaceutical or food industry. The appearance of mould in 60% of the products after 14 days was noted when packed in bags. More resistant to mildew (over 180 days) were tablets packed in sealed boxes containing essential oil or ethanol extract of nutmeg. In work [12], 18 samples of green and herbal tea of widespread trademarks were studied. In addition to toxic heavy metals, microbial contamination with a high content of aerobic microbes (TAMC), fungi, and moulds (TYMS) was found in 6 samples. It is known that mycotoxins are formed under the action of fungi, which can cause an adverse effect on the human body [13]. Like melamine in food [14], Mycotoxins can cause toxicosis, gastroenteritis, and other dangerous diseases [15].

The analysis showed that the discrepancy of medicinal products in terms of microbiological indicators is not an isolated case. The greatest attention should be paid to drugs used to detoxify toxic substances [16]. Since the detoxification process involves the neutralisation of the poison and its accelerated elimination from the body, the microbiological purity of the treatment should be undeniable so as not to cause more harm to the patient.

In pharmaceutical practice, sorbents are used for poisoning, among which the most common and well-known is activated carbon. If the sorbent does not meet the requirements of regulatory documents for microbiological purity [2], the therapeutic effect of such a sorbent can have an adverse impact on the human body. According to [2], the total number of aerobic bacteria in activated carbon is no more than 1×10^3 CFU/g, the total amount of mould and yeast is no more than 1×10^2 CFU/g.

In Europe and most countries in pharmacology, raw materials of the Silcarbon trademark are used to produce activated carbon. The analysis of several batches of raw materials for the production of activated carbon at the incoming control showed that the content of microbiological contaminants does not meet the requirements of regulatory documents [2]. The analysis results are presented in Table 1.

One of the directions of inactivation of microbiological effects when using drugs is the use of various antibacterial materials for biomedical use [17], nanoparticles [18], and

hydrogel [19]. Thus, hybrid hydrogels [17] demonstrated 100% efficiency in destroying *Escherichia coli*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* with a bacterial concentration from 10⁵ CF/ml to 10⁷ CFU/ml. However, the effect of antibacterial materials is not always economically beneficial, and the consequences of their exposure can pose a threat to the environment [20]. Nanoparticles are increasingly used to fight bacterial infections [18]. The use directions are different: antibacterial implant coatings, medicinal materials to prevent infections, drug delivery systems, bacteria detection systems, and antibacterial vaccines to fight infections. The problem is that the antibacterial mechanisms of nanoparticles are insufficiently studied and require rather large expenditures for their development and implementation [20].

Table 1.

The number of aerobic, mould, and yeast fungi in activated carbon "Silcarbon"

Microbiological purity	Requirements, CFU/g	Number of microorganisms, CFU/g
TAMC (number of aerobic microorganisms)	$1x10^{3}$	corresponds to (500)
TYMC (total number of yeast and mould fungi)	1x10 ²	does not match (2575)

There are other approaches and methods for the inactivation of microorganisms [3,21]. So in work [3], the assessment of the use of various sterilisation methods of gamma radiation, ultraviolet irradiation, chlorination, and treatment with low-pressure argon plasma on the stability of matrices containing drugs was carried out. All methods used have been shown to reduce bioburden, and only plasmatreated matrices were not sterile.

The use of currently existing methods of powdered materials disinfection [22] allows you to fully achieve positive results in the destruction of vegetative and spore-forming forms of microorganisms on the treated object. It should be noted that disinfection methods using strong chemical oxidants (ozone and chlorine) and radiation methods, when exposed to this object, can lead to irreversible changes in physical and chemical characteristics [3]: the quality of the product is lost, and the biological value deteriorates. Therefore, when researching any disinfection method, its technical features and possible consequences of use should be considered. In particular, it was found that during the heat treatment of activated carbon organoleptic

properties deteriorate [23], the activity of the action of activated carbon slows down.

An effective way to solve this problem is to use ultraviolet radiation with a wavelength of 254 nm [24-26], which has a strong bactericidal effect and ensures the inactivation of microorganisms. So in work [27] investigated the effect of ultraviolet radiation in the wavelength range 185-256 nm on the surface deactivation of various microorganisms: Escherichia coli. Saccharomyces cerevisiae, Trichoderma harzianum, Micrococcus luteus, and Bacillus subtilis. Depending on the biological characteristics, microorganisms have different sensitivity to disinfecting agents and ultraviolet radiation. It has been shown that ultraviolet disinfection combined with ozonation can be successfully used on porous surfaces, where ozone can penetrate places invisible to light. Thus, the ultraviolet method is easy to operate and can be used for air disinfection [25], surfaces [27], and pre-sowing seed stimulation [28].

Bactericidal disinfection of microorganisms occurs due to photochemical reactions [32], and the effectiveness is determined by the wavelength of ultraviolet radiation (wavelength range 200-400 nm) or photon energy. Almost all solids very strongly absorb UV radiation, and only their thin surface layer is treated, and the bulk of the substance is not exposed. A thin surface layer is processed under ultraviolet irradiation of powder materials [16]. Under such UV irradiation, the bulk is not affected, and therefore, the biochemical properties of the product do not change. In comparison with methods of chemical radiological disinfection, UV radiation, when doses are exceeded, does not change the biochemical properties and does not impair the biological value of the product [33]. However, the opacity of solid media for UV radiation when processing bulk materials requires the effective mixing of particles so that the surface of each particle is accessible for UV radiation [16].

Considering the above advantages of physical methods using optical radiation for the disinfection of materials with a particle size of several microns, the proposed UV radiation technology for the treatment of activated carbon. UV treatment methods and possible technical solutions are below.

The work aims to study the possibility of microbiological purification of activated carbon from microbiological contamination by ultraviolet radiation.

2. Materials and methods

In this work, studies were carried out on activated carbon "Silcarbon", made in Germany with a particle size from 1 micron to 0.2 mm. Figure 1 shows a sample study.



Fig. 1. Activated carbon "Silcarbon"

For UV irradiation, the lamps presented in Table 2 and Table 3 were used.

Table 2.
Characteristics of ozone-free quartz lamps, power 80 W.

Characteristics of ozone-free quartz famps, power 80 w						
Type of lamp used	P, W	U, V	UV exposure at a distance of 1 m			
ZW80D19W	80	120	240-270 W/cm ²			

Table 3. Characteristics of ozone quartz lamps, power 20 W

Type of lamp used	P, W	U, V	UV exposure at a distance of 1 m
ZW20D15Y	20	40-53	62-67 W/cm ²

To address the inactivation of microorganisms in activated carbon, a number of studies use UV radiation and different types of lamps of ozone and non-ozone action (Tab. 2 and Tab. 3):

- I. UV irradiation of activated carbon on the surface using low-pressure discharge lamps with maximum radiation at a wavelength of 254 nm;
- II. UV irradiation of activated carbon in a cylindrical chamber under the action of free fall, using lowpressure discharge lamps with maximum radiation at a wavelength of 254 nm;
- III. UV irradiation of activated carbon in a closed chamber, with the use of low-pressure discharge lamps with maximum radiation at wavelengths of 185 nm and 254 nm;
- IV. UV irradiation of activated carbon in a cylindrical chamber under the action of free fall, using pulsed lamps with radiation in the range of 100-300 nm.

3. Results and discussion

3.1. Experiment I

Activate carbon powder with initial characteristics on the content of yeast $(CFU/g - 7.2x10^3)$ and mould fungi (CFU/g

 $-1.1x10^3$), was irradiated with doses of UV-C 300-350 J/m² and 1000-1100 J/m², with using an ozone-free lamp, the parameters of which are presented in Table 2.

The results of the analysis after irradiation of the powder with a dose of 300-350 J/m² for yeast CFU/g – 2600, for mould CFU/g – 800. When irradiated with a dose of 1000-1100 J/m² for yeast, respectively, CFU/g – 2200, and for mould CFU/g – 700. The total amount of fungi at a dose of 300-350 J/m² is 3400 CFU/g, and at a dose of 1000-1100 J/m² – 2900, that is, in the first case, they are exceeded 34 times, and in the second – 29 times. The results of the experiment are presented in Figure 2.

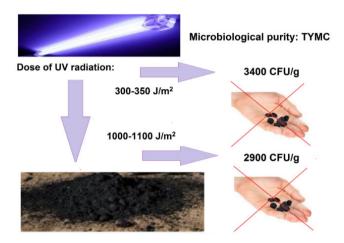


Fig. 2. The results of checking the conformity of activated carbon (Experiment I)

The obtained results of inactivation for microorganisms on the surface of activated carbon are unsatisfactory. We have assumed that microbiological contaminants are not only on the surface, and these doses are insufficient for inactivation. It was decided to look for a more efficient way to use UV radiation.

3.2. Experiment II

For solving the issue of inactivation of microorganisms, was used a technical approach proposed in [6]. Inactivation of microorganisms under the influence of powerful UV lamps (Tab. 2) occurs in a cylindrical chamber height of 2 m. A sieve is placed above the disinfection chamber, onto which activated carbon is uniformly fed. Activated charcoal is dissolved and passes through the irradiation chamber under the action of gravity.

The particles of activated charcoal, when falling in the decontamination chamber, are irradiated from all sides with powerful low-pressure lamps. The irradiation occurs in the

container when packaging. This approach reduces the probability of repeated infection of activated charcoal.

Checking three batches of activated carbon, the number of yeast fungi did not exceed 2100 CFU/g during irradiation, which was 500-600 W/cm². Increasing the radiation dose to 2000-2100 W/cm², a slightly better result was obtained: the amount was 1200 CFU/g. With appropriate irradiation doses, mould mushrooms obtained: 850 CFU/g and 450 CFU/g. The results of experimental studies are presented in Figure 3.

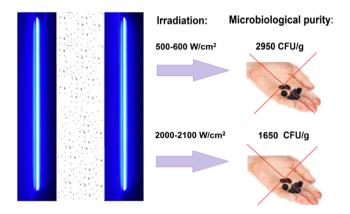


Fig. 3. The results of checking the conformity of activated carbon (Experiment II)

The results of the content of microorganisms do not satisfy the requirements of normative documentation [1]. It was assumed that by irradiating only the surface layer, it is impossible to achieve the inactivation of microorganisms. They are debris not only on the surface but also in the thickness of the layer of particles due to the peculiarities of the surface of activated carbon.

3.3. Experiment III

The effectiveness of bactericidal disinfection of activated coal depends on the following factors: radiation doses, ambient parameters (temperature, humidity), size, surface and amount of agglomerated particles.

Based on the indicated factors, further research was conducted under the action of a combination of UV radiation and ozonation using raw materials with the following parameters: the number of yeast fungi – 8500 CFU/g, and the number of mould fungi is 1100 CFU/g. To obtain a combined action of ultraviolet irradiation and ozonation the UV lamps, presented in Table 3, were used.

A feature of ozone is the ease of its decay with the formation of atomic oxygen – one of the most powerful

oxidising agents. Atomic oxygen destroys bacteria, spores, and viruses inside the particles of activated carbon.

The results of the analysis after irradiating the powder with a dose of $1200\text{-}1250~\text{J/m}^2$ for yeast CFU/g - 45, for mould CFU/g - 30. The total amount of fungi at a dose of $1200\text{-}1250~\text{J/m}^2$ is 75 CFU/g, which satisfies the requirements [1]. The results of the experiment are presented in Figure 4.

Dose of UV radiation: Microbiological purity: 1200-1250 J/m² 75 CFU/g





Fig. 4. The results of checking the conformity of activated carbon (Experiment III)

Thus, the desired results were achieved when exposed to a combination of UV radiation and ozone. However, as is known, ozone, even in low concentrations, causes the oxidative properties of activated carbon, which can affect the effectiveness of exposure to the human body.

In this regard, it was decided to conduct an experiment using xenon flash tubes, which have a continuous emission spectrum and are characterised by a high radiation density.

3.4. Experiment IV

The most effective UV disinfection today are low-pressure mercury discharge lamps [10], but they have low power per unit arc length (1-2 W/cm), which does not allow creating lamps of high unit power with small overall dimensions. For such conditions, it is advisable to use pulsed UV lamps, which can provide the necessary dose of UV irradiation for less than 1 sec.

To implement the technical solution using pulsed UV lamps in the irradiation chamber (Experiment II), low-pressure mercury lamps were replaced with pulsed UV lamps. The results of the experiment are presented in Figure 5.

The number of yeast fungi after irradiation with a flux density of 10000-10500 W/cm² was 30 CFU/g, and for mould fungi – 20 CFU/g, which meets the requirements [1].

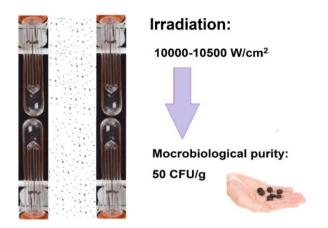


Fig. 5. The results of checking the conformity of activated carbon (Experiment IV)

3.5. Discussion

Following the requirements of regulatory documents, the compliance of medicines is ensured by the principles of Good Manufacturing Practice (GMP) [29]. Violation of the production process, storage conditions, including transportation, is the leading cause of microbiological contamination. Thus, the implementation of the study [11,12] warns of the need for corrective measures, including quality control, audit, the need to implement effective methods of disinfection. Microbiological contamination of pharmaceuticals creates problems for the manufacturing process, especially from a medical and economic point of view [8]. Therefore, the search for modern approaches to disinfecting drugs from microbiological contamination is an unsolved problem that scientists have been working on for decades. The endlessness of research in this direction is due to the emergence of new viruses and bacteria, which are registered all over the world [30,31].

The use of currently existing methods of disinfection of powdered materials [22] allows to fully achieve positive results in the content of microbiological contaminants. An environmentally friendly method of disinfection activated carbon using UV radiation is proposed, which has advantages over previously used methods [3]. Bactericidal disinfection of microorganisms occurs due to photochemical reactions [32], and the effectiveness is determined by the wavelength of ultraviolet radiation (wavelength range 200-400 nm) or photon energy. Almost all solids very strongly absorb UV radiation, and only their thin surface layer is treated, and the bulk of the substance is not exposed. A thin surface layer is processed under ultraviolet irradiation of powder materials [16]. Under such UV irradiation, the bulk is not affected, and therefore, the biochemical properties of

the product do not change. In comparison with methods of chemical radiological disinfection, UV radiation, when doses are exceeded, does not change the biochemical properties and does not impair the biological value of the product [33]. However, the opacity of solid media for UV radiation when processing bulk materials requires the effective mixing of particles so that the surface of each particle is accessible for UV radiation [16].

The obtained results of UV irradiation of activated carbon showed a significant reduction in the overall degree of inactivation by yeast and mould fungi (TYMC) in experiments 1 and 2. When using the combined method, with the use of low-pressure mercury ozone lamps, satisfactory results can be obtained in which the total amount of yeast and mould fungi range from 50 CFU/g to 75 CFU/g. The effectiveness of bactericidal disinfection of activated carbon depends on the following factors: radiation dose, surface characteristics, environmental parameters (temperature, humidity).

It is recommended to use the ultraviolet method not only in the inactivation of bacteria in medicine but also in the irradiation of powder materials (milk powder, biomass) and surfaces of various products in the food industry, both in the process of production and storage.

4. Conclusions

- The problem of ensuring the duration of storage of activated carbon and other pharmaceutical preparations without creating appropriate storage conditions has been one of the essential tasks of the pharmaceutical industry, where the use of known methods of disinfection (sterilisation) is limited due to the loss of the necessary properties of the preparation.
- It is necessary to carry out disinfection during the production process to obtain a sanitary and hygienic safe product in terms of microbiological indicators. It is also important to carry out periodic monitoring during storage and, if necessary, to inactivate microorganisms using ultraviolet disinfection methods.
- Optimal results of inactivation of yeasts and moulds in activated carbon can be obtained using pulsed ultraviolet lamps in a free-fall chamber with irradiation doses of 10000 J/m², and the irradiation time does not exceed 1 sec.
- Optimal results of inactivation of yeasts and moulds in activated carbon can be obtained using the combined action of ozone and ultraviolet radiation in a closed UV exposure chamber, with a total radiation dose exceeding 1200 J/m².

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