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EXPRESS QUALITY CONTROL OF PRODUCTS AFTER AEROSOL CAMERAS OF THE FLUIDIZED BED BY RADIATION OF NANOPARTICLES

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INTRODUCTION

Nowadays, antibody (AB) and interferon (INF) preparations They are increasingly being used in medicine because of their more precise focus on the main causes of autoimmune, infectious, oncological and other significant diseases.

In the hierarchy of biosystems, the higher the level of organization of living matter, the more sensitive it can be to lower-energy effects.

Most biotechnological solid dosage forms (powders, pills, dragee) are produced using fluidized bed(FB) cameras, the basis of which are the laws of hydrodynamics and heat transfer in dispersed media. And of course, quality control of such drugs by classical methods can cause difficulties due to the low concentration of the active pharmaceutical ingredient (API). As a rule, in these cases, they resort to the use of complex methods of biopharmaceutical analysis – from IFA and PCR to biotesting, which in itself is quite long and energy-consuming and can take from 4 man-hours to analyze one sample.

As we found out, preparations made in the FB devices containing AB to INF-γ emit in the subterahertz and gigahertz range, several times exceeding the background values. Mandatory when studying the radio thermal properties of these drugs is their activation – heating up to 37^0C. Referring to the works of IRE RAS (Academician N.D. Devyatkov, prof. O.V.Betsky) according to the distinctive reactions of aqueous solutions to contact with the millimeter wavelength range of electromagnetic radiation, the fundamental point of this interaction is the modulation of shimmering dipoles on the surface of supramolecular complexes.

A few specific characteristics are determined for preparations containing biologically active nanoparticles that are capable of induced radio thermal radiation as an active substance (DV): 1) increased radio thermal emission in the subterahertz region – as an indicator of the formed complex with increased internal energy; 2) special terahertz spectra – as a reflection of a specific supramolecular organization. It is worth noting that dispersion will lead to degeneration of the spectra); 3) special biological activity relative to the unicellular model of S. Ambigua.

Activation with the main drug AB to INF-γ of a drug prepared using the "Placebo" technology is a substance prepared according to the same technological process as a drug containing antibodies to gamma interferon, except for the solvent used: with the absence of an antibody to gamma interferon, due to its own subterahertz radiation, is proof of the formation of water-lactose supramolecular complexes, and hence, biological activity.

Study of the possibility of non-contact exposure of water samples containing ultrahigh dilution (UHD) to sensor solutions by measuring their own radio thermal electromagnetic radiation (EMR):

a) Investigation of own radiothermal radiation of samples containing SVR (i.e. effector solutions).

b) Studies of the induction of intrinsic radiothermal EMR in sensor solutions.

In the Faraday chamber, in the absence of background radiation, placebo and lactose UHD solution in Petri dishes are located at a distance of 1 cm.The effector solution and the sensor solution are heated to a temperature of 37 ° C. Experiments to control their own EMR are carried out 2 times for reproducibility, provided that the MAX AVG mode is used, which is the result of hardware measurement of the EMR flux density for 300-fold repeatability.

c) Investigation of relaxation kinetics of effectors and sensors before and after contactless incubation.

The relaxation kinetics of the remotely activated sample is recorded according to the EMR flux density data after 1 hour, 10 minutes, 48 hours and 169 hours. All measurements of aqueous solutions are performed using the TES92 detector in the Faraday's camera.

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Thus, the main goal of our work is to develop an express method of quality control of biotechnological drugs, the active substance of which is AT to INF–γ, to study its physico-chemical properties and compare it with a placebo drug.

Methods. In the course of our work, the following substances were used: lactose monohydrate as an excipient filler; affine purified polyclonal rabbit AB to recombinant human INF as API; lactose powder intact as a control of results.

Equipment: Pilotlab fluidized bed apparatus, which was used to saturate lactose powder with solutions with pharmaceutical substances before granulation; TES-92 integrated flux density sensor (TES Electrical Electronic Corp., Taipei, Taiwan), which was used to determine the flux density of radiothermal radiation, having a frequency range from 50 MHz to 3.5GHz, measuring range the electric field strength is from 20 mV/m to 108 V/m, and the measuring range of the magnetic field strength is from 53 μA/m to 286.4 mA/ m.

RESULTS AND DISCUSSION

In our studies on the study of own radiothermal radiation of drug, which presents AB to INF-γ as an API, placebo of the drug and IL, there is a clear distribution of the device readings between the drugs, which makes it possible to distinguish them from each other.

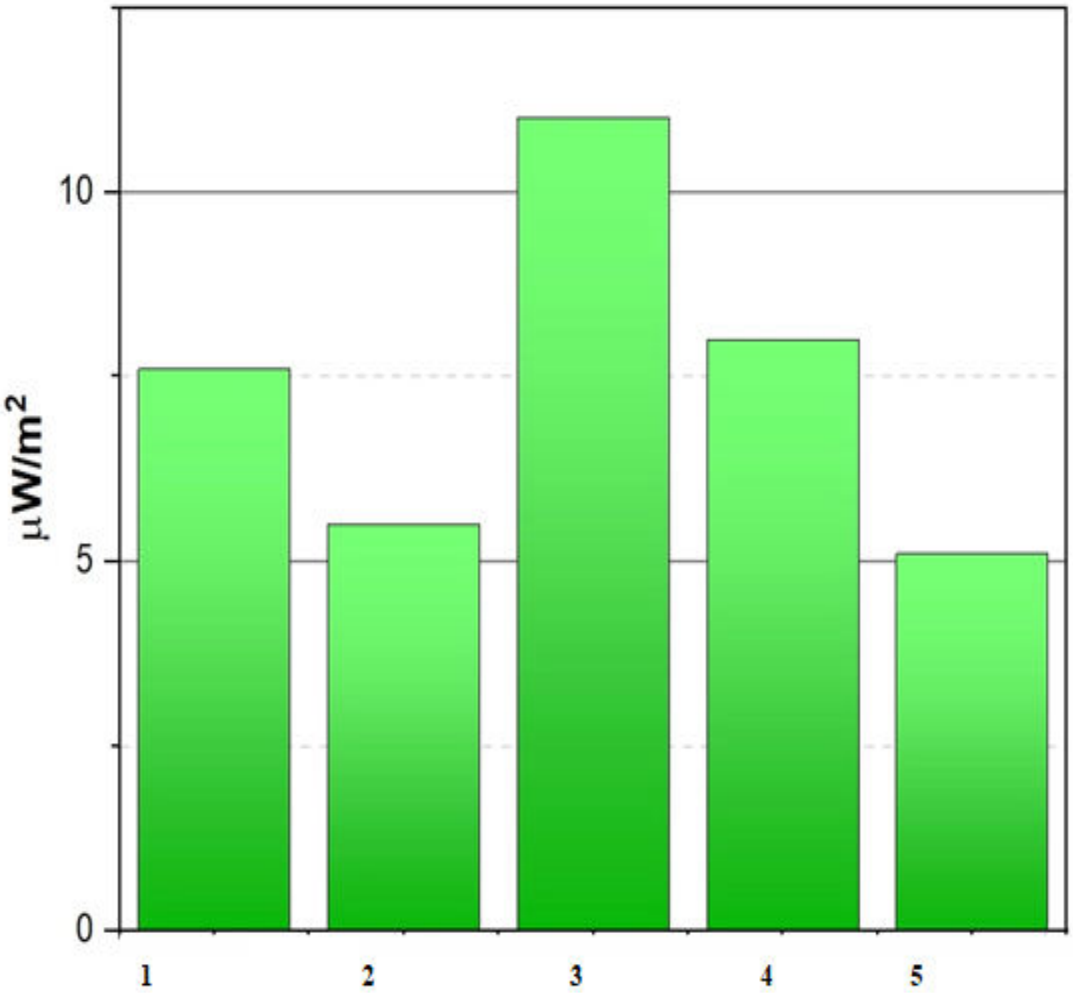

Fig. 1 Comparison of measurement results of activated sludge from 14.04 to March 2022, where 1 – 14.04.22; 2 – 21.04.22; 3 – 12.05.22; 4 – 12.11.22; 5 – March 2022 (average values of three samples).

In turn, the IL values during all measurements do not go beyond the background radiation of 1 μW/m2, regardless of whether it was activated or not. The difference in drug AB to INF-γ and its placebo drug was also traced. In the case of the drug, TES-92 detected on average 74,8 +/- 7 MW/m2 when heated to 370C. For his placebo drug, the readings of the device did not exceed the values in 6,42 +/- 4 μW/m2.

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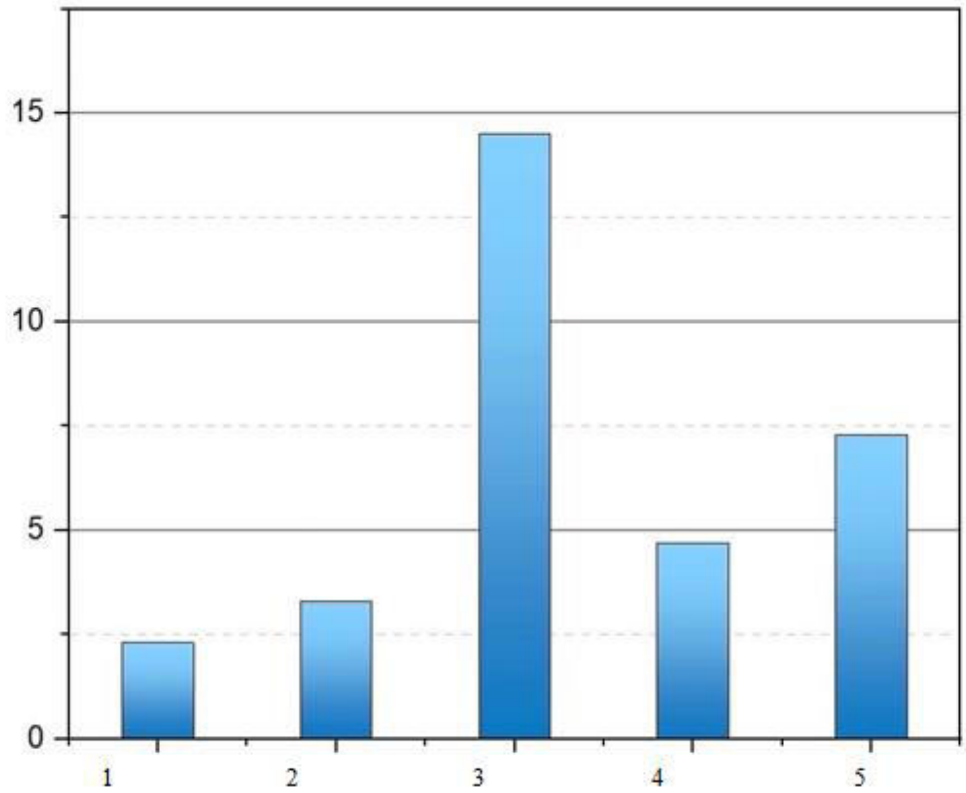

Fig. 2 Comparison of Placebo drug measurements from 14.04 to March 2022, where 1 – 14.04.22; 2 – 21.04.22; 3 – 12.05.22; 4 – 12.11.22; 5 – March 2022 (average values of three samples). Units of measurement along the ordinate axis - μW/m^2

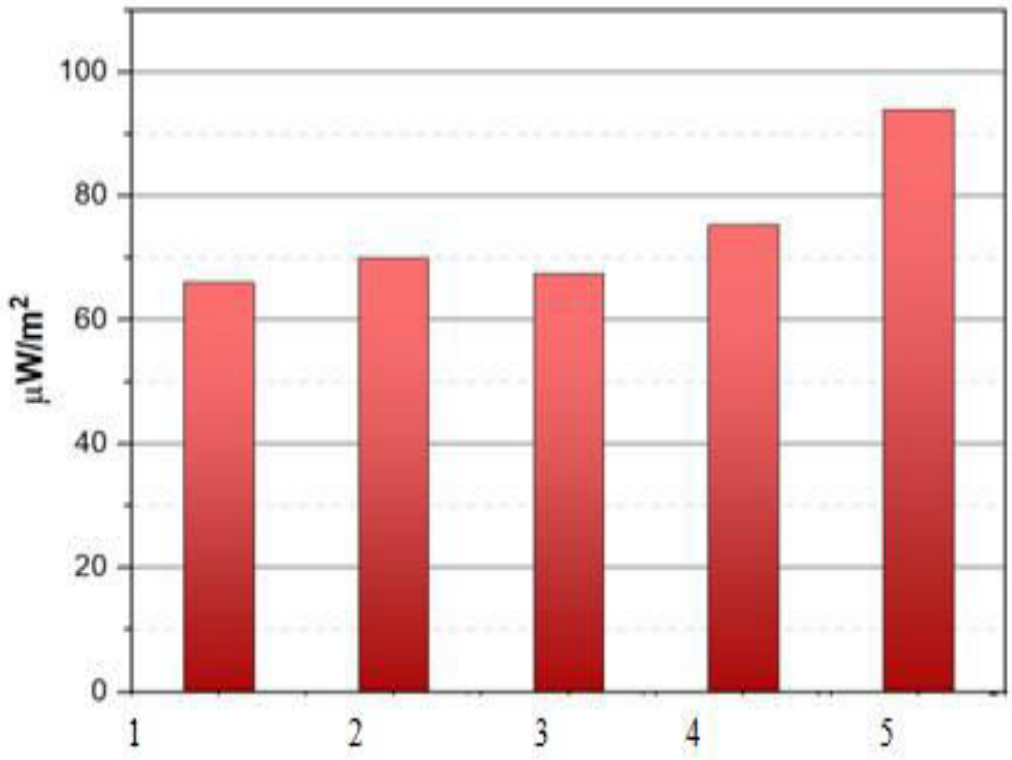

Fig. 3 Comparison of measurements for the drug AB to INF-γ from 14.04 to March 2022, where 1 – 14.04.22; 2 – 21.04.22; 3 – 12.05.22; 4 – 12.11.22; 5 – March 2022 (average values of three samples).

We also investigated the intrinsic radiation of 5% solutions of these substances. For solutions or placebo of the drug in the activated state, the indications did not exceed 2,5+/- 1,5 μW/m2, while the drug readings reached 27.5 μW/m2.

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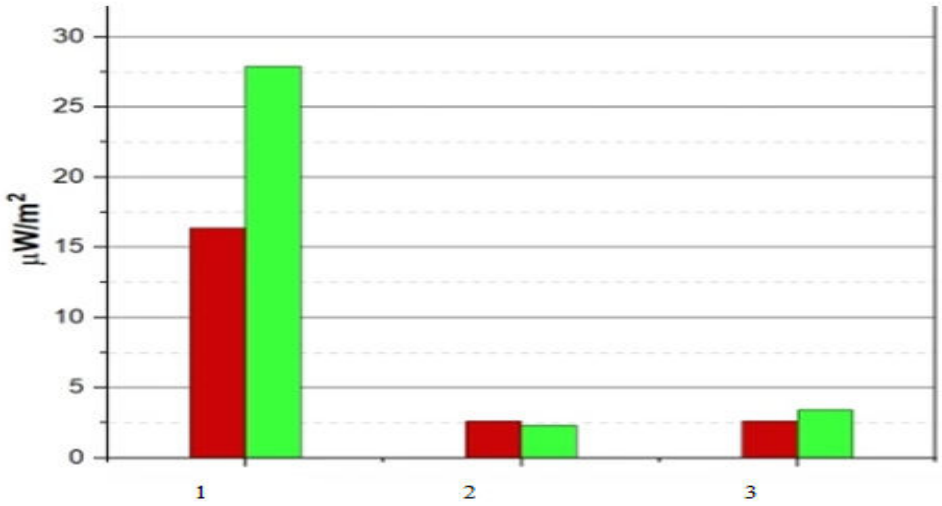

Fig. 4 Comparation of 5% Solution of the drug AB to INF - γ, IL and placebo without activations and heated up to 37^0C, where 1 – 5% sol. of the drug AB to INF - γ; 2 – 5% sol. IL; 3 – 5% sol. placebo.

In the case of activation of the drug with AB to INF - γ, its placebo drug and IL with different relaxation periods, the following data were obtained. In the maximum value for the drug Ab 27 μW/m^2, as well as for placebo at 60 minutes of heating to 37^0C, and in the case of IL, values below the background are observed in 1,5 +/- 1 μW/m^2.

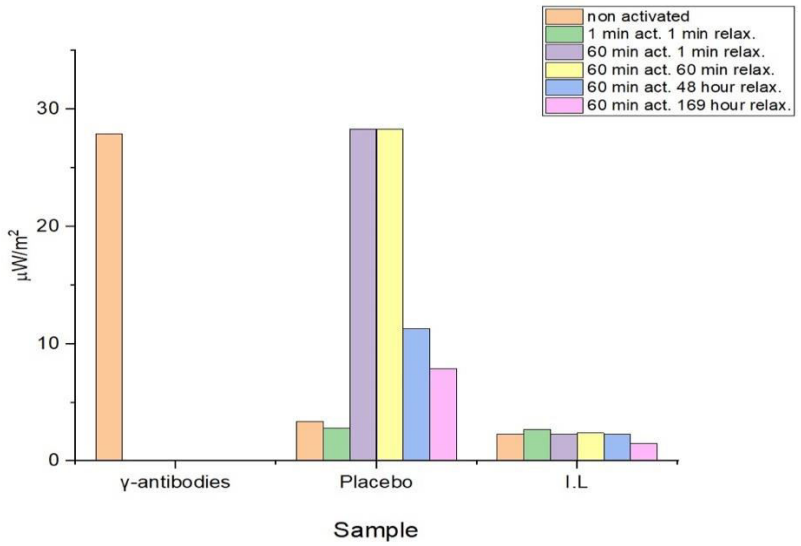

Fig.5 Graphical representation of the results obtained using various modes of activation by the effector solution (AB to INF - γ) of the sensor solution (placebo).A 5% solution of intact lactose was used as a control.

CONCLUSION

In this article, we propose a modern approach to quality control of biotechnological drugs, offering a new express method for products containing nanoparticles (AB, INF).

The proposed methodology is distinguished by its mobility, the speed of obtaining results, and the simplicity of interaction, which together allows it to be implemented at the stages of development or in the production process of biotechnological drugs.

Based on the data obtained using TES-92, we can observe the presence of distant effects of activation by drug with AB to INF- γ with a Placebo and relaxation through certain time points.

REFERENCE

Uspenskaya, E.V., Pleteneva T. V., Syroeshkin, A. V., Tarabrina I. V. (2020). Preparation, Characterization And Studies Of Physicochemical And Biological Properties Of Drugs Coating Lactose In Fluidized Beds. International Journal of Applied Pharmaceutics, 12(5). 272–278. https://doi.org/10.22159/ijap.2020v12i5.38281