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DEVELOPMENT OF SOFTWARE FOR CALCULATING THE BIOLOGICAL ACTIVITY OF MYCOBACTERIAL ALLERGENS

Bilushko V. V., Zavgorodniy A. I.

National Scientific Center 'Institute of Experimental and Clinical Veterinary Medicine', Kharkov, Ukraine, e-mail: bw.pochta@gmail.com

Bilushko E. V.

National Technical University 'Kharkiv Polytechnic Institute', Kharkov, Ukraine, e-mail: belushko@gmail.com

Summary. The paper contains the results of the development and production testing of the software tool calculation for biological activity of mycobacterial allergens for veterinary use. Purpose — to develop the software for calculating of the biological activity of mycobacterial allergens, and conduct it's testing of industrial development in the catch during the control of commercial series of tuberculin purified (PPD) for mammals (n = 28).

Software design system was used on *cba* platform .NET Framework 4.5, the programming language C# 5.0, the development environment Microsoft Visual Studio 2013, as well as WPF technology. Clinical studies were performed under conditions of Sumy State Biofactory by the parallel calculation of tuberculin purified activity (PPD) for mammals in the standard solution (series number = 28) using the developed program cba and calculation method of biological activity according to the current TC U 24.4-00497087-107:2011 'Tuberculin dry purified (PPD) for mammals (National standard)'.

As a result, the calculation of the biological activity of 28 experimental series of tuberculin for mammals according to the procedure specified in regulatory documents and with the help of the developed software *cba* demonstrated activity of the preparation at the level 53 746 U/cm^3 in standard solution.

The computer program *cba* for the determination of the biological activity of mycobacterial allergens provides accurate and timely calculation of the amount of unit content in the volume 1.0 cm^3 of the standard solution of purified tuberculin (PPD) for mammals.

Perspectives for future research will include conduction of the further testing of the software for allergen dry purified from atypical mycobacteria (AAM) and avian purified tuberculin (PPD) in the production environment, as well as in the development of targeted programs for different operating processes that require complex mathematical calculations in the manufacture process of different preparation dilutions, as the conditions of the producing and for research purpose.

Keywords: biological activity, software, units (U), mycobacterial allergens, tuberculin.

Introduction. Tuberculosis remains to be a dangerous anthroponotic disease requiring special attention in order to prevent more widespread. The main method of lifetime diagnostics of animals tuberculosis today is the skin allergic test performed using mycobacterial allergens (PPD tuberculin for mammals, avian PPD tuberculin, allergens derived from the atypical mycobacteriums (AAM)) (Kozlov, Bezgin and Shumilov, 2004; Kozlov, 2007).

One of the most important parameters of mycobacterial allergen quality, along with a specificity, sterility, environmental safety is their biological activity, which is measured in international units — 'U'. Provided excessive activity of allergen are manifestations of allergic reactions in healthy animals, and vice versa, if the biological activity of the drug is low — with TB animals do not react to tuberculin, which leads to the further spread of tuberculosis infection and, as a consequence, an increase in terms of improvement of disadvantaged households (Zavgorodniy et al., 2006). Therefore, it is very important to the accuracy of the calculation of this indicator in the production of commercial series mycobacterial allergens. Development of the target software for calculating the amount of U/cm^3 of the finished product allows standardization and speed up of the quality process control and support the elimination of possibility false estimation caused with 'human factor'.

The study aimed to develop the software for calculating the biological activity of mycobacterial allergens and conduct testing of developments in production conditions during the commission of control of commercial series tuberculin purified (PPD) for mammals (n = 28) on Sumy State Biofactory.

Materials and methods. The system *cba* was used developing software .NET Framework 4.5 platform, the C# 5.0 programming language, the Microsoft Visual Studio 2013 IDE, as well as WPF technology were used (Troelsen, 2013; Richter, 2013). Clinical studies were performed under conditions of Sumy State Biofactory by the parallel calculation of tuberculin purified activity (PPD) for mammals in the standard solution (series number 28) using the developed software *cba* and calculation method of biological activity according to the current TC U 24.4-00497087-107 'Tuberculin dry purifications (PPD) for mammals (National standard)' (2011).

The results of the work. As a result, the calculation of the biological activity of the experimental series of tuberculin for mammals (n = 28) according to the procedure specified in regulatory documents (TC U 24.4-00497087-107, 2011), and with the help of the developed software *cba* (Fig. 1, 2) demonstrated that the activity of the preparation was on the level of under using of the 53 746 U/cm^3 of standard solution.

Figures 1 and 2 demonstrate the performance of the calculation of the biological activity of examined preparation — tuberculin for mammals (28). In order to determine the activity of the test preparation in international units (U) must be made in cells # 1, 2, 4, 5, 7, 8, 10 and 11 (Fig. 1) the magnitude of the dimensions of papules guinea pigs (mm) of each individual formed in 24 hours after administration of the preparation in 4 dilutions — first dilution: 1 and cell 2 II (4, 5), III (7, 8) and IV (10, 11). The cells # 3, 6, 9 and

12 respectively defined by the average value of allergic reactions in laboratory animals in each of 4 dilution of the preparation. The system then calculates the index cba bioactivity, which is reflected in the corresponding panel (Fig. 2). The principle of software calculation corresponds to the method of calculation according to TC U 24.4-00497087-107:2011. In addition, the program has the ability to comparison of this indicator up to 3 series products at the same time reflecting the results in graphical form, as shown in Fig. 1. Thus, the developed software cba using allows to found that the activity of a series of tuberculin for mammals (n = 28) of Sumy State Biofactory is 53,746 U/cm^3 of standard solution. This figure is identical to the measure of biological activity specified in the certificate of quality on this series of tuberculin for mammals.
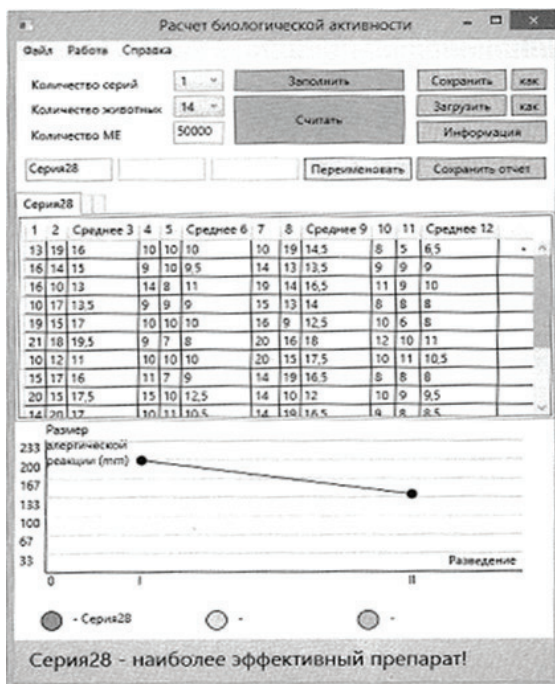
Conclusion. The cba software for determination of the biological activity of mycobacterial allergens provides accurate and timely calculation of the U/cm^3 of standard solution of purified tuberculin (PPD) for mammals.

Prospects for further research are to conduct further testing of this software for allergen dry purified from atypical mycobacteria (AAM) and avian tuberculin purified (PPD) in the standard solution in a production environment, as well as in the development of software for different operating processes that require complex mathematical calculations in the manufacture of various products, the preparation of the dilutions in the conditions of production, and for research purpose.
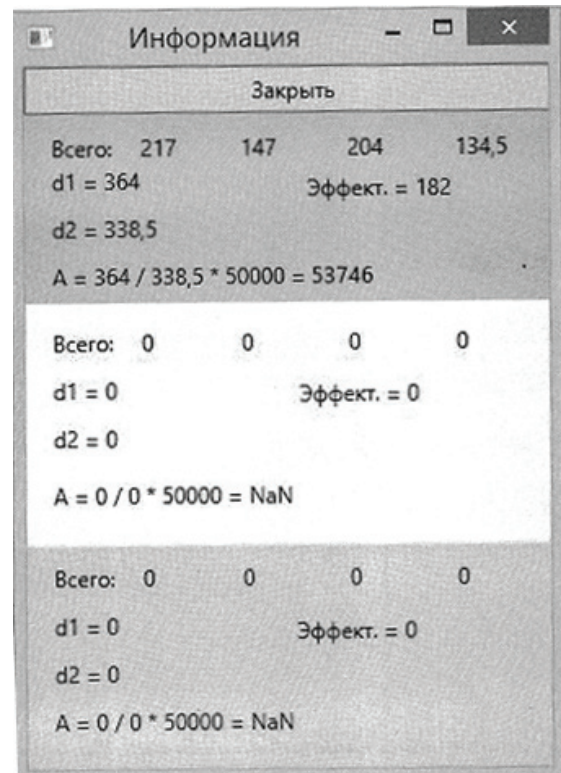

Figure 1. The calculation panel of the biological activity of tuberculin for mammals (screenshot in Russian)

Figure 2. The calculation panel results of the biological activity of tuberculin for mammals (screenshot in Russian)

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