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Original article

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**(not exceeding 13 words, reflecting the goal, including min. 1–2 key words over the first 65 characters, study type at the end divided with a colon, e.g. “Randomised Control Trial”, “Analysis of Russian Pharmacovigilance Database” etc.)**

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**ABSTRACT** *The abstract should include as much of manuscript data as possible (150-300 words)*

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**Funding.** *For example:*

1. This study was conducted by the Scientific Centre for Expert Evaluation of Medicinal Products as part of the applied research funded under State Assignment No. \_\_\_ (R&D Registry No. \_\_\_).

2. The study was performed without external funding.

**Disclosure.** *For example:*

1. The authors have no conflict of interest.

2. Elena V. Ivanova has been a member of the Editorial Board of *Safety and Risk of Pharmacotherapy* since 2021. The other authors declare no conflict of interest.

3. The authors work for Bacteriophage JSC. However, when writing this paper, the authors were guided by considerations of the scientific value of the material obtained; the authors declare their impartiality in its assessment.

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Make sure you choose specific terminology (in BrE). Transliterarion from Russian into English is allowed only for proper names, devices and other objects that cannot be translated. Make sure you use the same terms all over the text. Active Voice is preferred over Passive Voice, i.e. “The study tested”, not “It was tested in this study”.

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The introduction should describe scientific relevance of the research topic (i.e. the degree of importance of this topic at this time and in this particular situation); establish the research problem; show the scope of this problem; describe initial hypotheses (if any); and identify the research gap through a review of previously published data (in Russia and internationally). When explaining the importance of their research, the authors should include significant points that prove the need to study the selected topic. When describing scientific relevance, the author(s) should answer the questions: why the study was performed, what pressing issue they were trying to solve, and why it was necessary to study this problem at the very given moment.

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The authors may use a separate paragraph to formulate the study objectives that need to be accomplished to achieve the aim.

**MATERIALS AND METHODS**

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This section should include object data and a detailed description of the materials and methods allowing to complete a study. Explain why you chose particular study objects, number of participants, and inclusion/ exclusion criteria.

For all animals, cell cultures, microbial strains etc. used in your study, give their source. Add manufacturer’s qualification and (if possible) catalog number of the reagents; manufacturer’s name; trade name, grade, and catalog number of all reference standards, as well as brand name and manufacturer of devices and equipment used for the experiments. Give the original names of the companies. If possible, give International non-proprietary name (INN) of the medicinal product instead of the trade name.

*Example 1:*

Urinalysis was performed on Day 45 and 90. In order to collect urine, the rats were placed in metabolic cages (Tecniplast, Italy) for 16–24 h, with a free access to drinking water. Urine output was evaluated, as well as glucose, protein, bilirubin, urobilinogen, ketones, рН, density, white blood cells, red blood cells, and mucus. Clinical urinalysis was performed with Aution Eleven 4020 analyser (Arkray, Japan) using dipsticks. Urine protein and creatinine was found with URIСКАН-BK biochemical analyser (Ailiton, Russia). The urine was microscopically analysed using supravital staining, counting cell elements on a cell counting plate magnified 100× and 400× on DM1000 light optical microscope (Leica, Germany).

Clinical studies should be approved by ethical committees (a numbered and dated document with the name of the committee). Human studies should comply with 2013 Declaration of Helsinki. Describe what kind of informed consent was obtained (e.g. for a study participation or publishing anonymised data). If applicable, add the number of dropouts.

*Example 2:*

1. 47 subjects were included in the study. The study was approved by an independent local ethical committee of [*name of the body*] (protocol statement No. \_, ethical committee of [*institution*] as of [*date*]). Each patient signed an informed voluntary consent for the examination and treatment results to be included in the study, performed in compliance with the protocol, ethical principles of World Medical Association’s Declaration of Helsinki, a trilateral GCP agreement (ICH GCP) and current Russian legislation [*document name*].

2. Inclusion criteria were: confirmed diagnosis with specific symptoms, patients older than 18 years, and a signed informed consent.

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- describe key results, regardless of whether they support or disprove your hypothesis, confirm or contradict other researches;

- summarise the results and compare them to other studies; give possible explanation to similarities and/or contradictions;

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- outline possible directions of further research.

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| *Text* | 0.25\* | – |
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**References**

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**Additional information.** The authors may provide a link to supplementary materials to the paper (figures, tables, and other files), including those placed in a repository (with their digital object identifiers (DOIs)).

**Authors’ contributions.** All the authors confirm that they meet the ICMJE criteria for authorship. The most significant contributions were as follows. *E.V. Ivanova* conceptualised the study, drafted the manuscript, formulated the conclusions, etc. *M.A. Petrova* worked with literature sources, etc. *M.N. Smirnova* carried out experiments, etc. *V.G. Sidorov* participated in formulating the conclusions and approved the final version of the manuscript for publication.

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The protocol of this observational clinical study was approved by the local ethics committee of the City Clinical Hospital No. X, Moscow Department of Healthcare (meeting minutes No. 29 of 21 October 2024).

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