Inventions of this type are subject to the general requirements of sufficiency of disclosure, i.e., the description of the invention must disclose the invention with sufficient clarity and detail to enable a person skilled in the art to use it. This also means that all essential features should be included, and description of the invention must not contain misleading statements.

The national rules for filing applications and granting patents also define specific requirements for applications where the invention relates to biological materials, or the invention is of a biotechnological/chemical nature.

**The requirements for the description of the respective methods are as follows (Rules 69.5.3):**

When describing a method for the preparation of a new group of compounds defined by a general structural formula, examples of the preparation of the group of compounds by this method must be given. If the group consists of radicals of different chemical nature, one example of each compound must be given, and if it is a homologous sequence, examples of representatives of the outer and middle member must be given. For the compounds forming the group, structural formulas confirmed by known modern methods and their physical and chemical properties must be provided. The description must also provide information on the use of the new compounds or on their biological activity.

When describing the method of preparation of a macromolecular compound of unknown structure, data identifying it must be provided. Data must be provided on the starting reagents from which the compound is obtained, as well as data confirming that its use can be realized.

When describing the method of obtaining or specific use of a mixture of unknown structure and composition with biologically active properties, in the examples, in addition to steps and conditions for the implementation of the method, the necessary data on the identification of the mixture must be provided, as well as data that confirm the possibility of realizing the mixture according to the specified purpose, specifying the characteristics that define such purpose.

**The requirements for the description of the respective compounds or groups of compounds are as follows (Rules 69.5.4):**

If the invention is a new individual compound with a defined structure, the description must include its structural formula, confirmed by known modern methods, its physical and chemical constants, and describe the method by which this new compound was obtained for the first time. In addition, data on its use should be indicated, and for biologically active substances quantitative indicators of biological activity and toxicity and, where necessary, specific action and other data should be also included.

If the invention is a drug for the treatment of certain human and/or animal diseases, the description must include the data proving that the drug is intended to treat that disease.

If a new individual compound is obtained using a microorganism strain or plant and animal cell culture, data on the biosynthesis process in which this strain was involved, characteristics of the strain and, if necessary, knowledge of its deposition must be provided.

If the invention is a group of individual compounds of unknown structure defined by a common structural formula, the description must prove that the group can be obtained

according to the specified general scheme of preparation, examples of the preparation of specific compounds must also be provided, and if the group contains compounds with different chemical nature radicals, at least one example of such a compound. For the obtained compounds, their structural formulas confirmed by known modern methods, their physical and chemical constants, data proving their applicability and confirmation of that applicability using at least one compound of this group must be provided.

If the new compounds are biologically active substances, quantitative data on their activity and toxicity and, where appropriate, their specific action and other indicators must be provided.

If the invention is an intermediate compound, the description must also show the possibility of obtaining a known final product from it or the possibility of obtaining a new final product with a specific purpose or biologically active properties.

If the invention is a composition (mixture, solution, etc.), the examples provided in the description must indicate the ingredients included in the composition, their characteristics and their quantitative composition. The method of obtaining the composition must be described, and if its ingredient is a new substance, the method of obtaining it must also be described. In the presented examples, the amount of each ingredient must be indicated in such a unit value that is within the limits specified in the interval of the claims of the invention (maintaining the quantitative ratio of all ingredients in the claims of the invention in percent (by mass or volume), and the sum of all the ingredients indicated in the example must be equal to 100%).

**The requirements for the description of the microorganism strain, plant and animal cell culture are as follows (Rules 69.5.5):**

If the invention is a strain of a microorganism, the description must include nomenclatural data and the origin of the strain, quantitative and qualitative data on the composition of feeding media (seeded and enzymatic) and cultivation conditions (temperature, pH, relative oxygen mass transfer, lighting, etc.), as well as fermentation time, biosynthetic characteristics, end products, strain productivity and its testing methods; methods for isolation and purification of end products (producers of new products such as antibiotics, enzymes, monoclonal antibodies, etc.) should also be disclosed.

If the invention is a consortium of microorganisms, plant and animal cells, the following data must be specified in the description: the method of determination the composition of the components, the method of isolation (selection), the characteristics according to which the selection is carried out, the stability of the consortium during long-term cultivation and its resistance to contamination by other microorganisms.

If the invention relates to biological material that cannot be described in such a way that it can be used by a person skilled in the art, and this material is not available to the public, it must be deposited in a depository institution.