NEIROMETRIX
Scientific Company

FOR STATE REGISTRATION OF A MEDICINAL PRODUCT, THE DEVELOPER OF THE MEDICINAL PRODUCT OR ANOTHER LEGAL ENTITY AUTHORIZED BY HIM (APPLICANT) SHALL SUBMIT TO THE AUTHORIZED STATE BODY OF THE RUSSIAN FEDERATION:

1. A copy of the license for the production of medicinal products issued to the manufacturer of the registered medicinal product for veterinary use for Russian manufacturers;
2. A copy of the license for the production of medicinal products issued to the manufacturer of the pharmaceutical substance that is part of the registered medicinal product for veterinary use for Russian manufacturers;
3. A copy of the document issued by the authorized body of the manufacturer's country for each production site of the registered medicinal product for veterinary use and confirming the compliance of the manufacturer of the medicinal product with the requirements of the rules of good manufacturing practice, and its translation into Russian, certified in accordance with the established procedure, as well as a copy of the conclusion on compliance manufacturer of medicinal products to the requirements of the rules of good manufacturing practice issued by the authorized federal executive body for each production site of the registered medicinal product for veterinary use, or a copy of the decision to inspect the manufacturer of medicinal products adopted by the authorized federal executive body for each production site of the registered medicinal product for veterinary use. These documents are submitted if the production of a medicinal product is carried out outside the Russian Federation;
4. A copy of the document issued by the authorized body of the country of the manufacturer of the pharmaceutical substance and confirming the compliance of the manufacturer of the pharmaceutical substance, which is part of the registered medicinal product for veterinary use, with the requirements of the rules of good manufacturing practice, and its translation into Russian, certified in accordance with the established procedure, if if the production of a pharmaceutical substance is carried out outside the Russian Federation;
5. Draft regulatory document for a medicinal product for veterinary use;
   - A document containing the following information on the pharmaceutical substance or pharmaceutical substances that are part of the medicinal product for veterinary use:
6. The name of the pharmaceutical substance, its structure, general properties (during the state registration of immunobiological medicinal products for veterinary use, information about the strain is provided, including its name, information on the origin, its properties, characteristics and place of deposit);

7. Name and address of the manufacturer;
8. Production technology with a description of the stages of production and control methods at all stages of production;
9. Information on impurities (not provided during state registration of immunobiological medicinal products for veterinary use);
10. Specification for a pharmaceutical substance (not submitted during the state registration of immunobiological medicinal products for veterinary use);
11. Description of quality control methods;
12. The results of the analysis of a series of pharmaceutical substances (not submitted during the state registration of immunobiological medicinal products for veterinary use);
13. List of reference materials or substances used in quality control;
14. Description of the characteristics and properties of packaging materials and closures;
15. Data on stability (not submitted during state registration of immunobiological medicinal products for veterinary use);
16. Shelf life, storage conditions;
17. A report on the results of a preclinical study of a medicinal product for veterinary use, including a description of methods for determining the residual amounts of an active substance (active substances) reaching (reaching) the systemic circulation in animal products after the use of such a medicinal product, as well as documentary confirmation (validation) specified methods;
18. Report on the results of a clinical study of a medicinal product for veterinary use in each species of animals specified in the instructions for veterinary use;
19. Draft instructions for the use of the medicinal product;
20. Projects of layouts of primary packaging and secondary (consumer) packaging of a medicinal product;
21. Description and composition of the medicinal product for veterinary use;
22. Description of the pharmaceutical development;
23. Description of the production process and its control;
24. Description of the control of critical stages of production and intermediate products, signed in accordance with the procedure established in accordance with part 1 of Article 17 of the Law;
25. Pharmaceutical compatibility;
26. Microbiological characteristics;
27. Material balance for the production of a batch of a finished product;

28. Description of the characteristics and properties of packaging materials and closures;
29. Documentary confirmation (validation) of processes and (or) their evaluation;
30. Requirements for the quality of excipients (certificate, specification for excipients and their justification);
31. Analytical methods used in the implementation of quality control of excipients;
32. Documentary confirmation (validation) of analytical methods used in the quality control of excipients;
33. Information on the use of excipients of human and animal origin;
34. Requirements for the quality of a medicinal product for veterinary use (certificate, specification for a medicinal product and their justification);
35. Analytical methods used in the implementation of quality control of a medicinal product for veterinary use;
36. Documentary confirmation (validation) of analytical methods used in quality control of a medicinal product for veterinary use;
37. A document confirming the quality of a medicinal product of three industrial series (analysis protocol or certificate of analysis), one series of which must coincide with the series of a sample of a medicinal product submitted for registration;
38. Characteristics of impurities;
39. List of standard samples used in the implementation of quality control of a medicinal product for veterinary use;
40. Data on the stability of a medicinal product for veterinary use;
41. A copy of the document containing information on the presence or absence of facts of registration of the medicinal product for veterinary use outside the Russian Federation;
42. Written consent provided for in part 6 of this Article in the case of registration of a reproduced medicinal product;
43. A copy of the document in Russian, certified in accordance with the established procedure and confirming the validity of the application for state registration of a medicinal product for veterinary use (power of attorney);
44. Copies of documents confirming payment of state duties (2 copies):
    - for conducting an examination of the quality of a medicinal product and an examination of the ratio of the expected benefit to the possible risk of using a medicinal product during its state registration;
    - for issuing a registration certificate of a medicinal product.
45. Information on the state registration of genetically engineered modified organisms intended for release into the environment (at the state registration of medicines for veterinary use obtained with the use of genetically engineered modified organisms or containing such organisms).