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Republic of Latvia
Cabinet
Regulation No. 319
Adopted 15 May 2007

Regulations Regarding the Manufacture and Control of Veterinary Medicinal Products, the Procedure for the Issuance of a Good Manufacturing Practice Certificate to a Manufacturer of Veterinary Medicinal Products and Regarding the Requirements for the Qualification and Professional Experience of the Official Responsible for the Manufacture of Veterinary Medicinal Products

[14 July 2009]

Issued pursuant to
Section 5, Clauses 3 and 13 and
Section 52 of the Pharmaceutical Law

I. General Provisions

1. This Regulation prescribes the procedure for the manufacture and control of veterinary medicinal products, the procedure for the issuance of a good manufacturing practice certificate to a manufacturer of veterinary medicinal products and regarding the requirements for the qualification and professional experience of the official responsible for the manufacture of veterinary medicinal products.

[14 July 2009]

2. The following terms are used in this Regulation:

2.1. validation - a documented programme, the implementation of which allows to affirm with great certainty that a certain process, method or system used in the manufacture or control of medicinal products, will work independently, ensuring the results which comply with the previously specified criteria;

2.2. qualification - an operation by which it is confirmed and documented that any device used for the manufacture

of veterinary medicinal products is appropriately installed, operates correctly and ensures the expected results. Qualification is a part of validation, but the performance of separate stages of qualification does not mean the validation of the process;

2.3. active substance - a substance or a mixture of substances intended for use in the manufacture of veterinary medicinal products and which in such case becomes an active ingredient of the particular medicinal product; and

2.4. manufacture of an active substance - complete or partial manufacture or bringing in (import) of an active substance and various types of weighing, packaging and presentation activities until incorporation of the relevant substance in the composition of veterinary medicinal products, including repackaging and re-labelling, such as carried out by a starting material distributor.

3. This Regulation shall apply to:

3.1. veterinary medicinal products intended to be placed on the market in a European Union Member State or in the states of the European Free Trade Association (EFTA), which have signed the Agreement on the European Economic Area (hereinafter - Member State), if the medicinal product has been prepared industrially or the preparation thereof is related to industrial medicinal product manufacture processes;

3.2. pre-mixes for medicated feedingstuffs (veterinary medicinal products intended for the preparation of medicated feedingstuffs);

3.3. homeopathic veterinary medicinal products;

3.4. active substances used as starting materials in the manufacture of veterinary medicinal products; and

3.5. substances that may be used as veterinary medicinal products and that have anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties.

4. A manufacturer of veterinary medicinal products or a manufacturer of medicinal products, which concurrently also manufactures veterinary medicinal products (hereinafter - manufacturer of veterinary medicinal products), shall have received a special permit (licence) for the manufacture of veterinary medicinal products issued by the Food and Veterinary Service (hereinafter - Service) or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - a special permit (licence) for the manufacture of veterinary medicinal products with the field of activity "manufacture of veterinary medicinal products" issued by the State Agency of Medicines (hereinafter - Agency). A special permit (licence) shall also be required for the manufacture of veterinary medicinal products intended for export (bringing out of veterinary medicinal products from the European Economic Area states).

[11 January 2011]

5. The special permit (licence) referred to in Paragraph 4 of this Regulation shall be necessary for both complete and partial manufacture activities, as well as for various dividing up, packaging and presentation activities of the finished product.

[11 January 2011]

5.^{1} A manufacturer of veterinary medicinal products shall be issued a good manufacturing practice certificate of veterinary medicinal products by the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - by the Agency.

[11 January 2011]

6. A manufacturer of veterinary medicinal products has the following duties:

6.1. to employ staff, which performs the manufacture and control of veterinary medicinal products in accordance with the requirements of this Regulation;

6.2. to dispose of the veterinary medicinal products, to which a marketing authorisation of veterinary medicinal products has been issued in accordance with the requirements specified in the regulatory enactments regarding registration, use and distribution of veterinary medicinal products;

6.3. to give prior notice without delay (not later than within five working days) to the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency in written or electronic form, if the responsible official referred to in Section 52 of the Pharmaceutical Law (hereinafter - qualified person) is changed;

6.4. to ensure the officials of the Service and - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency with a possibility to access the premises of manufacture and control of veterinary medicinal products at any time;

6.5. to comply with the principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in this Regulation, taking into account the principles and guidelines specified in the European Commission Guide to Good Manufacturing Practice for Medicinal Products referred to in Section 51.[1] of the Pharmaceutical Law (hereinafter - Guide of the European Commission), and to use only such active substances as starting materials, which have been manufactured in accordance with the Guide of the European Commission (Guide of the European Commission has been published in Volume 4 of the collection of documents of the Rules Governing Medicinal Products in the European Union);

6.6. to register the supplied veterinary medicinal products (also the samples supplied by the manufacturer of veterinary medicinal products) in accordance with the legal acts of the country of destination. The following information shall be indicated regarding each transaction involving veterinary medicinal products (also the supply of samples of veterinary medicinal products):

6.6.1. the date of supply;

6.6.2. the name of the veterinary medicinal product;

6.6.3. the quantity of the supplied medicinal product;

6.6.4. the given name, surname or the name and address of the recipient;

6.6.5. batch number;

6.7. to store the information referred to in Sub-paragraph 6.6 of this Regulation for at least three years and to present it to the officials of the Service upon request. Information relating to narcotic and psychotropic substances shall be stored for 10 years;

6.8. to promote the fulfilment of the duties of the qualified person, transferring the necessary equipment at the disposal thereof in order to ensure the meeting of the following requirements:

6.8.1. each batch of veterinary medicinal products shall be manufactured and controlled in accordance with the requirements of this Regulation and in accordance with the conditions included in the registration documentation of veterinary medicinal products;

6.8.2. the finished product of each manufactured batch of veterinary medicinal products shall be certified, making detailed entries in the registration journal or in another document provided for this purpose and confirming with a signature that the batch of medicinal products has been manufactured and controlled in accordance with the requirements referred to in Sub-paragraph 6.8.1 of this Regulation. The manufacturer shall store the registration journal or the relevant document for at least five years after making of the last entry and present, upon request, to officials of the Service and - in the case referred to in Section 51.[2] of the Pharmaceutical Law - the Agency.

[20 November 2008; 14 July 2009; 11 January 2011]

II. Requirements for the Qualification and Professional Experience of a Qualified Person

7. A manufacturer of veterinary medicinal products, constantly and continuously, shall have at least one qualified person at the disposal thereof whose qualification and professional experience conforms to the requirements referred to in Paragraph 8 of this Regulation.

8. The qualified person shall conform to the following requirements:

8.1. he or she is in possession of a diploma, certificate or other evidence of qualification in relation to the acquisition of the study programme of an institution of higher education (university), or acquisition of such study programme which, in accordance with the procedures specified in regulatory enactments, is recognised as equivalent to the university study programme in Latvia and which extends over a period of at least four years of theoretical and practical studies in one of the following scientific disciplines:

8.1.1. pharmacy;

8.1.2. medicine;

8.1.3. veterinary medicine;

8.1.4. chemistry;

8.1.5. pharmaceutical chemistry and technology;

8.1.6. biology;

8.2. theoretical knowledge and practical skills in the following subjects (courses) have been acquired in the study programmes referred to in Sub-paragraph 8.1 of this Regulation:

8.2.1. physics;

8.2.2. general chemistry;

8.2.3. inorganic chemistry;

8.2.4. organic chemistry;

8.2.5. analytical chemistry;

8.2.6. pharmaceutical chemistry (including analysis of medicinal products);

8.2.7. general and medical biochemistry;

8.2.8. physiology;

8.2.9. microbiology;

8.2.10. pharmacology;

8.2.11. pharmaceutical technology;

8.2.12. toxicology;

8.2.13. pharmacognosy (the study of the composition of the active substances of plant and animal origin and the effects of the active substances);

8.3. the minimum duration of his or her studies at an institution of higher education (university) may be three and a half years, if they are followed by theoretical and practical training of at least one year, in which a training period of at least six months in a general-type pharmacy is intended, and an examination according to the study programme of the institution of higher education (university) has been passed at the end of the training;

8.4. he or she has acquired practical experience over at least two years, in one or more undertakings, which have a special permit (licence) in the activities of qualitative analysis of medicinal products and quantitative analysis of active substances, as well as tests and inspections necessary to ensure the quality of veterinary medicinal products are performed at the undertaking. The duration of practical experience may be reduced by one year, if the duration of the university study programme had been five years, and by a year and a half, if the duration of the study programme of the institution of higher education (university) had been six years and more.

[11 January 2011]

9. If two study programmes or two courses recognised as equivalent co-exist in two institutions of higher education (universities) in Latvia and the duration of one course is four years and of the other - three years, the diploma, certificate or other evidence of qualification issued for the acquisition of a three-year study programme shall be considered to fulfil the conditions referred to in Sub-paragraph 8.1 of this Regulation as regards the duration of the studies.

10. If education of the qualified person does not conform to the criteria referred to in Sub-paragraph 8.1 of this Regulation, an applicant for the relevant position shall additionally submit documents regarding the acquisition of theoretical and practical knowledge. The amount of the studies in the subjects (courses) referred to in Sub-paragraph 8.2 of this Regulation shall be such as to enable the relevant person to perform the activities referred to in Sub-paragraph 6.8 of this Regulation.

III. Principles and Guidelines of Good Manufacturing Practice for Veterinary Medicinal Products

11. A manufacturer of veterinary medicinal products shall interpret the principles and guidelines of good manufacturing practice for veterinary medicinal products referred to in this Chapter according to the Guide of the European Commission.

12. A manufacturer of veterinary medicinal products shall:

12.1. ensure the manufacturing of veterinary medicinal products in accordance with the requirements of this Chapter and the conditions of the special permit (licence);

12.2. establish and maintain a system for quality assurance of veterinary medicinal products (hereinafter - quality

assurance system). The system shall include all the organisational measures in order to guarantee that the medicinal products manufactured conform to the intended quality of use. The system shall comply with the following requirements:

12.2.1. manufacturing and control activities are specified in detail and comply with the conditions of good manufacturing practice;

12.2.2. management duties are specified in detail;

12.2.3. all the necessary inspections of intermediary products and all inspections and validations of the process are performed;

12.2.4. the finished products are processed and inspected in accordance with a specific procedure;

12.2.5. the medicinal products are stored, distributed and disposed of in such a way as to maintain the quality of the medicinal products throughout the time period of storage; and

12.2.6. the efficiency and applicability of the quality assurance system is assessed regularly in accordance with a developed self-inspection system or a quality control procedure.

[11 January 2011]

13. A manufacturer of veterinary medicinal products shall register all activities related to the manufacture of veterinary medicinal products in accordance with the information provided in an application for the registration of veterinary medicinal products. The manufacturer of veterinary medicinal products shall review the methods of manufacture and submit an application to the Service on the changes required in the registration documentation if changes in the methods of manufacture are intended.

[11 January 2011]

14. A manufacturer of veterinary medicinal products shall ensure the implementation of the following requirements:

14.1. in each site of manufacture and control such employees are employed whose qualification and practical experience ensures the conformity of veterinary medicinal products with the intended quality of use;

14.2. the duties of the managing and supervisory personnel are specified in the job description. The principal personnel, which are responsible for the application and functioning of good manufacturing practice, are a qualified person, the head of the manufacturing unit and the head of the quality control unit. Subordination shall be determined in the structure chart of the undertaking. The structure chart of the undertaking and job descriptions shall be approved in accordance with the internal procedure specified by the manufacturer of veterinary medicinal products;

14.3. the personnel referred to in Sub-paragraph 14.2 of this Regulation shall be given certain authority for the performance of their duties;

14.4. the personnel is ensured initial and regular training, during which the personnel acquires theory of the principles of quality assurance and good manufacturing practice for veterinary medicinal products and the application thereof; and

14.5. hygiene programmes appropriate for the activities to be performed have been developed and are complied with. The requirements for the health, personal hygiene and clothing of the personnel shall be determined in hygiene programmes.

15. The premises and installations shall comply with the following requirements:

15.1. the premises and manufacturing installations are designed, constructed, stationed, adapted and maintained in order in accordance with the activities referred to in the application for a special permit (licence);

15.2. the premises and manufacturing installations are stationed, designed and used so that the veterinary medicinal products to be manufactured or starting materials thereof would not be damaged or contaminated. Efficient cleaning, exploitation and maintenance shall be ensured in order to avoid the contamination of veterinary medicinal products and starting materials, cross contamination (contamination of starting materials or medicinal products with another starting material or medicinal product) and any undesirable effects on the product quality; and

15.3. the premises and installations intended to be used in the stages of manufacture of veterinary medicinal products, which are critical for the quality assurance of veterinary medicinal products, have been appropriately qualified and validated.

[11 January 2011]

16. A manufacturer of veterinary medicinal products shall establish and maintain a documentation system conforming to the following requirements:

16.1. the documentation includes:

16.1.1. specifications;

16.1.2. manufacturing formulas;

16.1.3. processing and packaging instructions;

16.1.4. descriptions of procedures and notes on specific manufacturing operations;

16.1.5. instructions on precautionary measures;

16.2. the documentation is regularly updated;

16.3. descriptions of procedures, as well as specific documents, which reflect the course of the manufacturing process and quality process of a batch (hereinafter - batch records), are accessible. The referred to documentation shall ensure traceability of the manufacturing history of each batch of medicinal products, changes performed during the development of medicinal products, distribution of medicinal products and other significant circumstances affecting the quality of the finished product (hereinafter - batch documentation);

16.4. batch documentation is stored for at least a year after the expiry of the term of validity of the relevant batch of medicinal products or for five years after the issuance of the certification documents of veterinary medicinal products referred to in Sub-paragraph 6.8.2 of this Regulation, giving preference to the longest of the referred to terms;

16.5. if electronic, photographic or another data processing system is used for the batch documentation, the manufacturer of veterinary medicinal products shall at first validate the system in order to ensure the preservation of data until the end of the storage term thereof. Data stored in the relevant system shall be easily accessible and comprehensible, and they shall be submitted to the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency. Data stored in electronic form shall be provided with a protection system so that, upon duplicating them or preparing back-up copies, transferring to other information storage systems or preserving notes of inspections, data losses or damaging would be prevented.

[14 July 2009; 11 January 2011]

17. The manufacturing process of veterinary medicinal products shall comply with the following requirements:

17.1. manufacturing activities are performed in accordance with the developed instructions and procedures and according to the requirements of good manufacturing practice;

17.2. the necessary resources are available for the provision of control of the manufacturing process, deviations in the manufacturing process and product defects are documented, investigated and eliminated;

17.3. technical and organisational measures are taken to avoid cross contamination and mix-ups of veterinary medicinal products and starting materials; and

17.4. each new manufacturing process or significant changes to the manufacturing process are being validated. The critical stages of the manufacturing process shall be regularly re-validated.

18. The quality control of veterinary medicinal products shall conform to the following requirements:

18.1. a manufacturer of veterinary medicinal products establishes a unit for quality control and ensures operation thereof. The unit shall be managed by the responsible official who has appropriate qualification specified in the job description and who is not related to the manufacture;

18.2. the quality control unit has at the disposal thereof one or more quality control laboratories, which inspect and test starting materials, packaging materials, intermediate products and finished products. The quality of veterinary medicinal products may also be controlled by laboratories, with which a contract according to Paragraph 19 of this Regulation has been entered into;

18.3. the quality control unit, during the final evaluation of the finished product before placing on the market or distribution of veterinary medicinal products, in addition to the analytical results evaluates other essential information, for example, the description of the manufacturing conditions, the results of the inspections performed during the manufacturing process, the documentation of manufacturing, the conformity of the finished product and the packaging thereof with the specifications;

18.4. samples of each batch of the finished product are stored for at least a year after the expiry of the term of validity of the relevant batch of medicinal products;

18.5. samples of starting materials, other than solvents, gases or water, used in the manufacturing of veterinary medicinal products are stored for at least two years after the release of the finished product. The storage period may

be reduced if the stability period of the substance indicated in the specification is shorter;

18.6. inform (in hard copy format or electronically) the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency regarding the site where samples of the manufactured veterinary medicinal products and starting materials thereof are stored and ensure a possibility to visit the relevant storage site; and

18.7. if veterinary medicinal products are manufactured for an individual order, in small quantity or storage of veterinary medicinal products and starting materials is difficult because of the properties thereof, other conditions may be specified for the sampling or storage of veterinary medicinal products and starting materials after agreement with the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency.

[14 July 2009; 11 January 2011]

19. If any manufacturing activity or activity linked thereto or quality control is carried out by another person (hereinafter - contract acceptor), a manufacturer of veterinary medicinal products and the contract acceptor shall enter into a contract regarding the performance of certain work. The contract shall clearly define the duties and responsibility of each party, indicating, in particular, the duty of the contract acceptor to observe the principles and guidelines of good manufacturing practice, as well as the manner in which the qualified person responsible for certifying each batch fulfils his or her duties.

20. A contract acceptor:

20.1. without a written consent of a manufacturer of veterinary medicinal products, shall not enter into a sub-contract with a third person regarding the performance of such works, regarding which a contract has been entered into with the manufacturer of veterinary medicinal products;

20.2. on contractual basis shall perform the manufacturing or part of manufacturing activities of veterinary medicinal products if he or she has received a special permit (licence); and

20.3. shall observe the principles of good manufacturing practice and abide to the control of the Service and - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency.

[11 January 2011]

21. A manufacturer of veterinary medicinal products, prior to entering into a contract with a laboratory regarding quality control of veterinary medicinal products, shall ensure that the officials of the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency perform an inspection in the laboratory and provide a statement on the conformity of the laboratory to the requirements of good manufacturing practice.

[11 January 2011]

22. A manufacturer of veterinary medicinal products shall introduce a system for registration and examination of complaints, concurrently ensuring the operation of the system for immediate withdrawal of veterinary medicinal products from circulation in the distribution network, which can be performed at any time. Each complaint regarding quality defects of veterinary medicinal products shall be registered and investigated. The manufacturer of veterinary medicinal products shall, within 24 hours after establishment of the fact, inform the Service regarding any defect or complaint, which may be the basis for recall of veterinary medicinal products from the market or restrictions on distribution, as well as shall indicate the receiving states. Distribution of veterinary medicinal products shall be restricted or medicinal products shall be recalled from the market in accordance with the regulatory enactments regarding labelling, distribution and control of veterinary medicinal products.

[20 November 2008; 11 January 2011]

23. A manufacturer of veterinary medicinal products shall ensure repeated self-inspection with a previously specified regularity in order to supervise the introduction and implementation of good manufacturing practice and to propose the necessary improvement measures. Information regarding each performance of self-inspection and any further corrective actions shall be documented and stored for at least five years.

IV. Procedure for the Issuance of a Good Manufacturing Practice Certificate and Control Thereof

24. After a special permit (licence) for the manufacturing of veterinary medicinal products has been issued, the Service shall supervise the conformity of the manufacturing and control of veterinary medicinal products with the requirements of this Regulation:

24.1. at least once every three years shall perform repeated checks (inspection) of good manufacturing practice. The Service shall agree with the manufacturer of veterinary medicinal products on the time of inspection and, not later

than 10 working days before the inspection, notify about it in writing;

24.2. if necessary, perform unannounced inspections. In such case samples shall be tested in a laboratory, which has the right to control medicinal products.

[11 January 2011]

24.^{1} In the case referred to in Section 51.^{2} of the Pharmaceutical Law the Agency shall supervise the conformity of the manufacturing and quality control of veterinary medicinal products with the requirements of this Regulation:

24.^{1} 1. at least once every three years shall perform repeated checks (inspection) of good manufacturing practice. The Agency shall agree with the manufacturer on the time of inspection and, not later than 10 working days before the inspection, notify about it in writing;

24.^{1} 2. if necessary, perform unannounced inspections. In such case samples shall be tested in a laboratory of the Agency, which has the right to control medicinal products.

[11 January 2011]

25. The Service is entitled to perform unannounced inspections in the premises of manufacturers of active substances and owners (holders) of the marketing authorisation of veterinary medicinal products in the following cases:

25.1. the Service has justified suspicions that the principles and guidelines of good manufacturing practice of active substances are not being observed;

25.2. a request of another Member State, the European Commission or the European Medicines Agency to perform such inspection has been received; or

25.3. a request of a manufacturer of active substances registered in the Republic of Latvia to perform such inspection has been received.

[14 July 2009; 11 January 2011]

26. The inspections referred to in Paragraphs 24, 24.^{1} and 25 of this Regulation, according to the competence, shall be performed by competent officials authorised by the Service or the Agency, who have been trained to perform the control of the conformity with the requirements of good manufacturing practice and who have the following rights:

26.1. to inspect manufacturers and laboratories, which perform control of veterinary medicinal products upon assignment of the holder (owner) of the licence. Expenditure related to the inspection shall be covered by the person to be inspected in accordance with the regulatory enactments regarding payment for the State supervision and control activities performed by the Service and paid services provided by it or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the price list of public paid services of the Agency;

26.2. to take samples, also in order to perform an independent analysis of veterinary medicinal products in a laboratory, which has the right to perform control of veterinary medicinal products. Expenditure related to the testing of veterinary medicinal products shall be covered by the person to be inspected in accordance with the regulatory enactments regarding payment for the State supervision and control activities performed by the Service and paid services provided by it or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the price list of public paid services of the Agency; and

26.3. to examine documents related to the object to be inspected, observing the restrictions of authorisation as regards the description of manufacturing methods.

[11 January 2011]

27. The Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency shall inspect in addition whether the manufacturing processes used by manufacturers of immunological veterinary medicinal products have been validated and ensure homogeneity of batches.

[11 January 2011]

28. The Service or the Agency shall, within 10 working days after each inspection referred to in Paragraphs 24, 24.^{1}, 25 and 27 of this Regulation, prepare a control report of good manufacturing practice (Annex 1). It shall be indicated in the report whether the manufacturer of veterinary medicinal products complies with the principles and guidelines of good manufacturing practice. The manufacturer of veterinary medicinal products or the holder (owner) of the marketing authorisation of veterinary medicinal products inspected shall be sent one copy of the report, and the second copy, where appropriate, shall be sent to the institution, which requested the inspection.

[11 January 2011]

29. The Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency, on the basis of the report referred to in Paragraph 28 of this Regulation, shall, within a month after completion of the inspection, take a relevant decision:

29.1. on the issuance of the conformity certificate of good manufacturing practice, if conformity with the principles and guidelines of good manufacturing practice has been established during the inspection;

29.2. on the temporary suspension of the issuance of the conformity certificate of good manufacturing practice, indicating the reasons and time period during which the necessary measures should be carried out. When determining the period of time, it shall be taken into account that the time period for the issuance of the certificate of good manufacturing practice may not exceed 90 days after carrying out the inspection referred to in Paragraphs 24, 25 and 27 of this Regulation; or

29.3. on refusal to issue the conformity certificate of good manufacturing practice. The decision on refusal to issue the conformity certificate of good manufacturing practice shall be notified to the manufacturer of veterinary medicinal products in writing within five working days.

[11 January 2011]

30. The Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency shall take a decision on refusal to issue the certificate of good manufacturing practice if it has been established according to the report that:

30.1. the manufacturing of veterinary medicinal products does not comply with the principles and guidelines of good manufacturing practice specified in this Regulation;

30.2. there is no qualified person at the undertaking manufacturing veterinary medicinal products; or

30.3. the duties of a qualified person are carried out by a person whose qualification or professional experience does not comply with the requirements of this Regulation.

[11 January 2011]

31. The Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency:

31.1. shall issue the conformity certificate of good manufacturing practice to a manufacturer of veterinary medicinal products (Annex 2) after the manufacturer of veterinary medicinal products has paid for the issuance of the certificate in accordance with the regulatory enactments regarding payment for the State supervision and control activities performed by the Service and paid services provided by it or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the price list of public paid services provided by the Agency;

31.2. if the decision referred to in Sub-paragraph 29.3 of this Regulation has been taken, in accordance with the regulatory enactments regarding the procedure for the issuance, suspension and cancellation of special permits (licences) for pharmaceutical or veterinary pharmaceutical activities, shall take a decision, according to the competence, on the suspension of operation of the special permit (licence) for the manufacturing of veterinary medicinal products until elimination of the deficiencies referred to in the control report of good manufacturing practice;

31.3. shall enter information regarding the certificate referred to in Sub-paragraph 31.1 of this Regulation or the refusal to issue a certificate referred to in Sub-paragraph 29.3 of this Regulation into the database of the European Union, which is managed by the European Medicines Agency upon assignment of Member States; and

31.4. [14 July 2009].

[14 July 2009; 11 January 2011]

32. A manufacturer of veterinary medicinal products shall, upon a request, provide the officials authorised by the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency with the information regarding control performed for the veterinary medicinal products or components thereof and intermediate products of the manufacturing process according to the registration conditions of veterinary medicinal products.

[11 January 2011]

33. The authorised officials of the Service and the Agency, upon inspecting the manufacturers of veterinary medicinal products, shall take into account the compilation of the European Commission regarding the inspection and information exchange procedures of the Community. In order to interpret the principles and guidelines of good manufacturing practice of veterinary medicinal products and starting materials, the Guide of the European Commission shall be taken into account.

[11 January 2011]

V. Supervision and Control

34. The supervision of the requirements for the manufacturing and control of veterinary medicinal products specified in this Regulation shall be ensured by the Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency.

[11 January 2011]

35. The Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency shall check whether the qualification of a qualified person meets the requirements set out in this Regulation, as well as is entitled to propose that a manufacturer of veterinary medicinal products carries out a temporary suspension or dismissal from office of the qualified person if he or she fails to perform the duties referred to in Sub-paragraph 6.8 of this Regulation.

[11 January 2011]

36. The Service or - in the case referred to in Section 51.^{2} of the Pharmaceutical Law - the Agency, upon a request, shall provide the competent authorities of other Member States with the information regarding control reports of good manufacturing practice, prepared in accordance with Paragraph 28 of this Regulation.

[11 January 2011]

37. *[11 January 2011]*

38. *[11 January 2011]*

39. Upon a request of another Member State, the European Commission or the European Medicines Agency, the Service shall authorise officials for the performance of the inspections referred to in Paragraphs 24, 25 and 27 of this Regulation at a manufacturer of veterinary medicinal products located in the third countries.

[11 January 2011]

40. The State Agency of Medicines, the Health Inspectorate and the Food and Veterinary Service shall ensure, according to their competence, prompt information exchange for the promotion of the enforcement of the requirements of this Regulation, as well as shall provide law enforcement institutions and the Ministry of Health with information regarding the circumstances that are the evidence of the deviation of veterinary medicinal products to illegal circulation.

[20 November 2008]

VI. Closing Provision

41. Cabinet Regulation No. 445 of 12 August 2003, *Regulations Regarding the Manufacture and Control of Veterinary Medicinal Products* (*Latvijas Vēstnesis*, 2003, No. 114; 2006, No.68), is repealed.

Informative Reference to European Union Directives

This Regulation contains legal norms arising from:

1) Commission Directive 91/412/EEC of 23 July 1993 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products;

2) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products; and

3) Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products.

Prime Minister A. Kalvītis

Minister for Agriculture M. Roze

Annex 1
Cabinet Regulation No. 319
15 May 2007

[11 January 2011]

Control Report of Good Manufacturing Practice

(European Commission Standard Form)

1.	**Report No.**		
2.	**Name of product(s) and pharmaceutical form(s)**	Essential for inspections requested by the European Medicines Agency (EMA). Only necessary for product specific inspections	
3.	**Inspected site(s)**	Name and full address of the inspected site, including exact location/designation of the production facilities inspected. *EudraGMP* reference number. Site location identifier (Data Universal Numbering System (DUNS) number/Global Positioning System (GPS) coordinates)	
4.	**Manufacturing activities carried out**	Manufacture of finished products	
		sterile	
		non-sterile	
		biologicals	
		Sterilisation of excipient, active substance or medicinal product	
		Primary packaging	
		Secondary packaging	
		Quality control testing	
		Importing	
		Batch certification	
		Storage and distribution	
		Manufacture of active substances	
		Other _____	
5.	**Inspection date(s)**	Date(s), month, year	
6.	**Inspector(s) and expert(s)**	Given name, surname of the inspector(-s)	
		Given name, surname of the expert (assessor) (if applicable)	
		Name of the competent control authority	
7.	**References**	Reference number of the marketing authorisation of veterinary medicinal products and (or) reference number of the special permit (licence) for the manufacturing of veterinary medicinal products. Reference number(s) of the European Medicines Agency (if the inspection is requested by the EMA)	
8.	**Introduction**	Short description of the company and the activities of the company.	
		For inspections in non-European Economic Area countries, it should be stated whether the competent authority of the country, where the inspection took place, was informed of the inspection and whether the relevant competent authority took part in the inspection	
		Date of previous inspection	
		Inspector(s) involved in previous inspection (given name, surname)	
		Major changes since the previous inspection	
9.	**Brief report of the inspection activities undertaken:**		
9.1.	**scope of inspection**	Short description of the inspection (product related, process related inspection and (or) general good manufacturing practice inspection (reference to specific dosage forms where appropriate)). The reason for the inspection should be specified (e.g. new application for registration of veterinary medicinal products, routine inspection, investigation of product defect)	
9.2.	**inspected area(s)**	Each inspected area should be specified.	
10.	**Activities not inspected**	Where necessary attention should be drawn to areas or activities not subject to inspection on this occasion	
11.	**Personnel met during the inspection**	The key personnel met should be specified (given name, surname, position). The list shall be attached to the annex to report	
12.	**Inspector(s) observations and**	Relevant headings of chapters according to the Guide of the European	

	deficiencies established	Commission for good manufacturing practice of medicinal products and investigational medicinal products published in Volume 4 of the Rules Governing Medicinal Products in the European Union. This section could be used to explain classification. The content of this section may be reduced where a site master file acceptable to the control persons has been submitted to the competent authority
13.	**Heading to be used** (new headings may be introduced when relevant)	Overview of inspection findings from last inspection and the corrective action taken
		Quality Management
		Personnel
		Premises and Equipment
		Documentation
		Production
		Quality Control
		Contract Manufacture and Analysis (Quality Control)
		Complaints and Product Recall
		Self-inspection
14.	**Distribution and shipment (dispatch)**	
15.	**Questions raised relating to the assessment of an application for registration of veterinary medicinal products**	E.g. inspections before registration of veterinary medicinal products
16.	**Other specific issues identified**	E.g. substantial future changes announced by manufacturer
17.	**Site master file**	Assessment of site master file if any. Data of site master file
18.	**Miscellaneous** (samples taken)	
19.	**Annexes attached**	List of annexes attached
20.	**Deficiencies* (critical, major and others)**	All deficiencies should be listed and the relevant reference to the part "Guide on Good Manufacturing Practice of Medicinal Products and Investigational Medicinal Products" of Volume 6 of the Good Manufacturing Practice Guide of the European Union should be mentioned. All deficiencies found should be listed even if corrective action has taken place straight away. If the deficiencies are related to the assessment of the application for registration of veterinary medicinal products, it should be clearly stated. The manufacturer should be asked to inform the competent authority about the proposed time schedule for corrections and on progress.
21.	**Inspectors' comments on the manufacturer's response to the inspection findings**	Including whether the responses are acceptable
22.	**Inspectors' comments on the questions/issues raised in the assessment report**	
23.	**Recommendations for further actions (if any)**	To the institution requesting the inspection or to the competent control authority of the state where the company inspected is located.
24.	**Summary and conclusions**	The inspector(s) should state whether, within the scope of the inspection, the company operates in compliance with the provisions of good manufacturing practice of the European Union (they have been specified in Cabinet Regulation No. 319 of the Republic of Latvia of 15 May 2007, *Regulations Regarding the Manufacture and Control of Veterinary Medicinal Products, the Procedure for the Issuance of a Good Manufacturing Practice Certificate to a Manufacturer of Veterinary Medicinal Products and Regarding the Requirements for the Qualification and Professional Experience of the Official Responsible for the Manufacture of Veterinary Medicinal Products*) and whether the manufacturer or importer of the product to be inspected may be issued the certificate of good manufacturing practice (this would apply to situations where there is a degree of non-compliance but where a corrective action plan has been agreed and the inspector has a reason to believe that it will be implemented and where there is no immediate threat to public health)

25.	**Inspection was performed by:**	
25.1.	**given name, surname**	The inspection report should be signed and dated by all inspectors and assessors having participated in the inspection
25.2.	**signature**	
25.3.	**organisation**	
26.	**Date**	
27.	**Distribution of report**	For inspections requested by the European Medicines Agency the inspection report should be forwarded to the Agency

* Deficiencies:

1) critical deficiencies - deficiencies which have produced, or lead to a significant risk of producing either veterinary medicinal products which are harmful to the human or animal, or veterinary medicinal products which could result in a harmful residue in a food producing animal;

2) major deficiencies (non-critical deficiencies) are deficiencies which conform to at least one of the following conditions:

a) such veterinary medicinal products have been produced or such veterinary medicinal products may be produced, which do not comply with the information indicated in the marketing authorisation of veterinary medicinal products; or

b) there are such major deviations from the requirements of good manufacturing practice, which may affect the quality of the veterinary medicinal products to be produced; or

c) there are such major deviations from the terms of the special permit (licence) for the manufacturing of veterinary medicinal products, which may affect the quality of the veterinary medicinal products to be produced; or

d) procedures referred to in the special permit (licence) for the manufacturing of veterinary medicinal products are not performed for release of batches or (within European Union) the qualified person fails to fulfil his or her duties; or

e) a combination of several other deficiencies, none of which on their own may be major, but which may together represent a major deficiency. It should be explained and reported as such;

3) other deficiencies - deficiencies, which cannot be classified as either critical or major, but which indicate a departure from the principles of good manufacturing practice, as well as other deficiencies either because they are judged as minor, or because there is insufficient information to classify them as a major or critical.

Annex 2
Cabinet Regulation No. 319
15 May 2007

[11 January 2011]

Good Manufacturing Practice Certificate

(European Commission Standard Form)

LATVIJAS REPUBLIKA	***REPUBLIC OF LATVIA***
_____ (kompetentās iestādes nosaukums, adrese, reģistrācijas numurs, tālruņa numurs, faksa numurs, e-pasta adrese)	_____ (*competent authority, address, registration number, phone, fax number, e-mail*)

Sertifikāts Nr. _ _ _/_ _ _/_ _ _
Certificate No

RAŽOTĀJA LABAS RAŽOŠANAS PRAKSES ATBILSTĪBAS SERTIFIKĀTS[1]
CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER[1]

1.daļa
Part 1

Izsniegts pēc oficiālas pārbaudes (inspicēšanas) saskaņā ar Direktīvas 2001/82/EK 80.panta 5.punktu*

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC*
vai/or
izsniegts saskaņā ar Savstarpējās atzīšanas līgumu starp Eiropas Savienības (EEZ) valstīm un (Savstarpējās atzīšanas līguma partnervalsts)*
***Issued under the provisions of the Mutual Recognition Agreement between the European Community and** [MRA Partner]**
Latvijas kompetentā iestāde apliecina:
Competent Authority of Latvia confirms the following:

Ražotājs/*Manufacturer* _____

_____ ,

ražošanas vietas adrese/*Manufacturing site address* _____

_____

_____ ,

ir oficiāli pārbaudīts nacionālajā uzraudzības un kontroles programmā par atbilstību speciālajai atļaujai (licencei) veterināro zāļu ražošanai Nr..... saskaņā ar Direktīvas 2001/82/EK 44.pantu, kas pārņemts Latvijas Republikas Ministru kabineta 2007.gada 15.maija noteikumos Nr.319 "Noteikumi par veterināro zāļu ražošanu un kontroli, kārtību, kādā veterināro zāļu ražotājam izsniedz labas ražošanas prakses sertifikātu, un par veterināro zāļu ražošanu atbildīgās amatpersonas kvalifikācijas un profesionālās pieredzes prasībām",
has been inspected under the national inspection programme in connection with manufacturing authorisation No. ..... in accordance with Article 44 of Directive 2001/82/EC transposed in the following national legislation:
Cabinet Regulation No. 319 of 15 May 2007 "Regulations Regarding the Manufacture and Control of Veterinary Medicinal Products, the Procedure for the Issuance of a Good Manufacturing Practice Certificate to a Manufacturer of Veterinary Medicinal Products and Regarding the Requirements for the Qualification and Professional Experience of the Official Responsible for the Manufacture of Veterinary Medicinal Products"
vai/*or*
ražotājs, kas atrodas ārpus Eiropas Ekonomikas zonas, ir oficiāli pārbaudīts un atbilst veterināro zāļu reģistrācijas apliecībā norādītajam saskaņā ar Eiropas Parlamenta un Padomes 2004.gada 31.marta Regulas (EK) Nr.726/2004 33.panta 2.punktu (44.panta 3.punktu)* vai Direktīvas 2001/82/EK 80.panta 4.punktu, kas pārņemts Latvijas Republikas Ministru kabineta 2007.gada 15.maija noteikumos Nr.319 "Noteikumi par veterināro zāļu ražošanu un kontroli, kārtību, kādā veterināro zāļu ražotājam izsniedz labas ražošanas prakses sertifikātu, un par veterināro zāļu ražošanu atbildīgās amatpersonas kvalifikācijas un profesionālās pieredzes prasībām",
has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Article 8(2)/33(2)/19 (3)/44(3) of Regulation (EC) 726/2004* or Article 80(4) of Directive 2001/82/EC transposed in the following national legislation:*
Cabinet Regulation No. 319 of 15 May 2007 "Regulations Regarding the Manufacture and Control of Veterinary Medicinal Products, the Procedure for the Issuance of a Good Manufacturing Practice Certificate to a Manufacturer of Veterinary Medicinal Products and Regarding the Requirements for the Qualification and Professional Experience of the Official Responsible for the Manufacture of Veterinary Medicinal Products"
un (vai)*/*and (or)**
ir aktīvo vielu ražotājs, kurš ir oficiāli pārbaudīts saskaņā ar Direktīvas 2001/82/EK 80.panta 1.punktu, kas pārņemts Latvijas Republikas Ministru kabineta 2007.gada 15.maija noteikumos Nr.319 "Noteikumi par veterināro zāļu ražošanu un kontroli, kārtību, kādā veterināro zāļu ražošanas uzņēmumam izsniedz labas ražošanas prakses sertifikātu, un par veterināro zāļu ražošanu atbildīgās amatpersonas kvalifikācijas un profesionālās pieredzes prasībām",
is an active substance manufacturer that has been inspected in accordance with Article 80(1) of Directive 2001/82/EC transposed in the following national legislation:
Cabinet Regulation No 319 of 15 May 2007 "Regulations Regarding the Manufacture and Control of Veterinary Medicinal Products, the Procedure for the Issuance of a Good Manufacturing Practice Certificate to a Manufacturer of Veterinary Medicinal Products and Regarding the Requirements for the Qualification and Professional Experience of the Official Responsible for the Manufacture of Veterinary Medicinal Products"
vai/*or*

cits (norādīt)*/*other (please specify)** _____

_____

_____

Ražotāja oficiālajās pārbaudēs, no kurām pēdējā tika veikta ...../...../..... (datums), konstatēts, ka ražotājs atbilst labas ražošanas prakses prasībām[1], kas noteiktas Savstarpējās atzīšanas līgumā starp Eiropas Savienības (EEZ) valstīm un (Savstarpējās atzīšanas līguma partnervalsts)/labas ražošanas prakses principiem un pamatnostādnēm, kas noteiktas Direktīvā 91/412/EEK[2]/aktīvo vielu labas ražošanas prakses principiem[2], kuri norādīti

Direktīvas 2001/82/EK 51.pantā.
From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ...../...../..... [date], it is considered that it complies with the Good Manufacturing Practice requirements[1] referred to in the Agreement of Mutual Recognition between the European Union and [MRA partner]/The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC[2]/The principles of GMP for active substances[2] referred to in Article51 of Directive 2001/82/EC.

Šis sertifikāts atspoguļo ražošanas vietas statusu minētās oficiālās pārbaudes (inspekcijas) laikā, un tas nevar atspoguļot atbilstības statusu, ja pēc oficiālās pārbaudes un šā sertifikāta izsniegšanas ir pagājuši vairāk nekā trīs gadi.
Sertifikāta autentiskumu var apliecināt izsniedzējiestāde.
This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection and issuing of this certificate.
The authenticity of this certificate may be verified with the issuing authority.

Notes.

[1] Sertifikāta nepieciešamība ir noteikta Direktīvas 2001/82/EK 80.panta 5.punktā. Sertifikāts nepieciešams arī ievešanai Eiropas Savienības dalībvalstīs no trešajām valstīm.
The certificate referred to in Paragraph 80(5) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into Member States.

[2] Šīs prasības atbilst Pasaules veselības organizācijas (PVO) labas ražošanas prakses ieteikumiem.
These requirements comply with GMP recommendations of the WHO.

2.daļa
Part 2

Veterinārās zāles ***Veterinary medicinal products***

1. RAŽOŠANAS DARBĪBAS* ***MANUFACTURING OPERATIONS**** - licencētās ražošanas darbības ietver pilnīgu un daļēju ražošanu (tai skaitā dažādus sadalīšanas, iepakošanas un noformēšanas procesus), sērijas izlaidi un sertifikāciju, noteiktu zāļu formu uzglabāšanu un izplatīšanu - *authorized manufacturing operations include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary* - kvalitātes kontroles (testēšanas) un (vai) sērijas izlaides un sertifikācijas darbības bez ražošanas darbībām norāda attiecīgajiem produktiem - *quality control(testing) and/or release and batch certification activities without manufacturing operations should be specified under the relevant items* - ja ražotājs ir iesaistīts tādu veterināro zāļu ražošanā, kurām ir īpaši nosacījumi, piemēram, radiofarmaceitiskie preparāti, veterinārās zāles, kas satur penicilīnu, sulfonamīdus, citotoksīnus, cefalosporīnu, vielas ar hormonālu iedarbību vai citas potenciāli bīstamas aktīvās vielas, to norāda pie atbilstošā zāļu veida un formas - *if the company is engaged in manufacturing of products with special requirements e.g. radiopharmaceuticals, veterinary medicinal products containing penicillin, sulphonamides, cytotoxics, cephalosporins, substances with hormonal activity or other potentially hazardous active substances this should be stated under the relevant product type and dosage form*	
1.1.	Sterilie produkti *Sterile products*
1.1.1.	aseptiski iegūti (zāļu formu saraksts) *aseptically prepared (list of dosage forms)*
1.1.1.1.	šķidrumi liela tilpuma iepakojumā *large volume liquids*
1.1.1.2.	liofilizāti *lyophilisates*
1.1.1.3.	mīkstās zāļu formas *semi-solids*
1.1.1.4.	šķidrumi maza tilpuma iepakojumā *small volume liquids*
1.1.1.5.	cietās zāļu formas un implanti *solids and implants*
1.1.1.6.	citi aseptiski iegūtie produkti (brīvs uzskaitījums)

	other aseptically prepared products (free text)
1.1.2.	sterilizēti galaprodukti (zāļu formu saraksts) *terminally sterilized (list of dosage forms)*
1.1.2.1.	šķidrumi liela tilpuma iepakojumā *large volume liquids*
1.1.2.2.	mīkstās zāļu formas *semi-solids*
1.1.2.3.	šķidrumi maza tilpuma iepakojumā *small volume liquids*
1.1.2.4.	cietās zāļu formas un implanti *solids and implants*
1.1.2.5.	citi sterilizēti produkti (brīvs uzskaitījums) *other terminally sterilized products (free text)*
1.1.3.	tikai sērijas sertifikācija *batch certification only*
1.2.	Nesterilās zāļu formas (zāļu formu saraksts) *non-sterile products (list of dosage forms)*
1.2.1.	cietās kapsulas *capsules, hard shell*
1.2.2.	mīkstās kapsulas *capsules, soft shell*
1.2.3.	košļājamās zāļu formas *chewing gums*
1.2.4.	impregnētās matrices *impregnated matrices*
1.2.5.	šķidrumi ārīgai lietošanai *liquids for external use*
1.2.6.	šķidrumi iekšķīgai lietošanai *liquids for internal use*
1.2.7.	medicīniskās gāzes *medicinal gases*
1.2.8.	citas cietās zāļu formas *other solid dosage forms*
1.2.9.	aerosolu preparāti (zem spiediena) *pressurised preparations*
1.2.10.	radionuklīdu ģeneratori *radionuclide generators*
1.2.11.	mīkstās zāļu formas *semi-solids*
1.2.12.	supozitoriji s*uppositories*
1.2.13.	tabletes *tablets*
1.2.14.	transdermālie plāksteri *transdermal patches*
1.2.15.	intraruminālās ierīces *intraruminal devices*
1.2.16.	veterinārie premiksi *veterinary premixes*
1.2.17.	citas nesterilās zāļu formas (brīvs uzskaitījums) *other non-sterile medicinal products (free text)*
1.2.18.	tikai sērijas sertifikācija *batch certification only*
1.3.	Bioloģiskas izcelsmes zāles *Biological medicinal products*
1.3.1.	no asinīm iegūtas zāles *blood products*
1.3.2.	imunoloģiskie preparāti *immunological products*
1.3.3.	biotehnoloģijas preparāti *biotechnology products*

1.3.4.	no cilvēka vai dzīvnieku materiāliem izdalīti preparāti *human or animal extracted products*
1.3.5.	citas bioloģiskas izcelsmes zāles (brīvs uzskaitījums) *other biological medicinal products (free text)*
1.3.6.	tikai sērijas sertifikācija *batch certification only*
1.3.6.1.	no asinīm iegūtas zāles *blood products*
1.3.6.2.	imunoloģiskie preparāti *immunological products*
1.3.6.3.	biotehnoloģijas preparāti *biotechnology products*
1.3.6.4.	no cilvēka vai dzīvnieku materiāliem izdalīti preparāti *human or animal extracted products*
1.3.6.5.	citas bioloģiskas izcelsmes zāles (brīvs uzskaitījums) *other biological medicinal products (free text)*
1.4.	Citi produkti vai ražošanas darbības (citas līdzīgas ražošanas darbības vai zāļu veidi, kas nav iepriekš minēti, piemēram, aktīvo vielu sterilizācija, bioloģiski aktīvu izejvielu ražošana, medicīniskās gāzes, augu izcelsmes zāles vai homeopātiskās zāles, pilna vai daļēja ražošana) *Other products or manufacturing activity (any other relevant manufacturing activity/ product type that is not covered above e.g. sterilization of active substances, manufacture of biological active starting materials, medicinal gases, herbal or homoeopathic products, bulk or partial manufacturing etc.)*
1.4.1.	ražošana *manufacturing of*
1.4.1.1.	augu izcelsmes zāles *herbal products*
1.4.1.2.	homeopātiskās zāles *homeopathic products*
1.4.1.3.	bioloģiski aktīvās izejvielas b*iological active starting material*
1.4.1.4.	citi (brīvs uzskaitījums) *other (free text)*
1.4.2.	aktīvo vielu, palīgvielu, galaproduktu sterilizācija *sterilisation of active substances, excipients, finished products*
1.4.2.1.	filtrēšana *filtration*
1.4.2.2.	sterilizācija ar karstu sausu gaisu *dry heat*
1.4.2.3.	sterilizācija ar ūdens tvaiku *moist heat*
1.4.2.4.	ķīmiski *chemical*
1.4.2.5.	apstarošana ar gamma stariem *gamma irradiation*
1.4.2.6.	apstarošana ar elektronu kūli *electron beam*
1.4.3.	citi (brīvs uzskaitījums) *other (free text)*
1.5.	Tikai iepakošana *Packaging only*
1.5.1.	primārā iepakošana (saraksts, kurā norādīts zāļu veids vai zāļu forma) *primary packing (list of product types/dosage forms)*
1.5.1.1.	cietās kapsulas *capsules, hard shell*
1.5.1.2.	mīkstās kapsulas *capsules, soft shell*
1.5.1.3.	košļājamās zāļu formas *chewing gums*
1.5.1.4.	impregnētās matrices *impregnated matrices*
1.5.1.5.	šķidrumi ārīgai lietošanai *liquids for external use*

1.5.1.6.	šķidrumi iekšķīgai lietošanai *liquids for internal use*
1.5.1.7.	medicīniskās gāzes *medicinal gases*
1.5.1.8.	citas cietās zāļu formas *other solid dosage forms*
1.5.1.9.	aerosolu preparāti (zem spiediena) *pressurised preparations*
1.5.1.10.	radionuklīdu ģeneratori *radionuclide generators*
1.5.1.11.	mīkstās zāļu formas *semi-solids*
1.5.1.12.	supozitoriji *suppositories*
1.5.1.13.	tabletes *tablets*
1.5.1.14.	transdermālie plāksteri *transdermal patches*
1.5.1.15.	intraruminālās ierīces *intraruminal devices*
1.5.1.16.	veterinārie premiksi *veterinary premixes*
1.5.1.17.	citas nesterilās zāļu formas (brīvs uzskaitījums) *other non-sterile medicinal products (free text)*
1.5.2.	sekundārā iepakošana *secondary packing*
1.6.	Kvalitātes kontroles testēšana *Quality control testing*
1.6.1.	mikrobioloģiskā: sterilitāte *microbiological: sterility*
1.6.2.	mikrobioloģiskā: nesterilo zāļu formu tīrība *microbiological: non-sterility*
1.6.3.	ķīmiskā vai fizikālā *chemical/physical*
1.6.4.	bioloģiskā *biological*

2. VETERINĀRO ZĀĻU IEVEŠANA (IMPORTS)*
IMPORTATION OF VETERINARY MEDICINAL PRODUCTS*
- ievešana (imports) bez ražošanas darbībām
- *importation activities without manufacturing activity*
- ievešana (imports), kas ietver uzglabāšanu un izplatīšanu
- *importation activities including storage and distribution unless informed to the contrary*

2.1.	levesto (importēto) zāļu kvalitātes kontroles testēšana *Quality control testing of imported medicinal products*
2.1.1.	mikrobioloģiskā: sterilitāte *microbiological: sterility*
2.1.2.	mikrobioloģiskā: nesterilo zāļu formu tīrība *microbiological: non-sterility*
2.1.3.	ķīmiskā vai fizikālā *chemical/physical*
2.1.4.	bioloģiskā *biological*
2.2.	levesto (importēto) zāļu sērijas sertifikācija *Batch certification of imported medicinal products*
2.2.1.	sterilās zāļu formas *sterile products*
2.2.1.1.	aseptiski iegūtas zāļu formas *aseptically prepared*
2.2.1.2.	sterilizēti galaprodukti *terminally sterilized*

2.2.2.	nesterilās zāļu formas *non-sterile products*
2.2.3.	bioloģiskas izcelsmes veterinārās zāles *biological veterinary medicinal products*
2.2.3.1.	no asinīm iegūtas zāles *blood products*
2.2.3.2.	imunoloģiskie preparāti *immunological products*
2.2.3.3.	biotehnoloģijas preparāti *biotechnology products*
2.2.3.4.	no cilvēka vai dzīvnieku materiāliem izdalīti preparāti *human or animal extracted products*
2.2.3.5.	citas bioloģiskas izcelsmes veterinārās zāles (brīvs uzskaitījums) *other biological veterinary medicinal products (free text)*
2.2.4.	citas ievešanas (importa) darbības (citas līdzīgas ievešanas (importa) darbības, kas nav iepriekš minētas, piemēram, radiofarmaceitisko preparātu, medicīnisko gāzu, augu izcelsmes zāļu vai homeopātisko zāļu ievešana (imports)) *other importation activities (any other relevant importation activity that is not covered above e.g. importation of radiopharmaceuticals, medicinal gases; herbal or homoeopathic products etc.)*
2.2.4.1.	radiofarmaceitiskie preparāti vai radionuklīdu ģeneratori *radiopharmaceuticals/radionuclide generators*
2.2.4.2.	medicīniskās gāzes *medicinal gases*
2.2.4.3.	augu izcelsmes zāles *herbal products*
2.2.4.4.	homeopātiskās zāles *homoeopathic products*
2.2.4.5.	bioloģiski aktīvie izejmateriāli *biological active starting materials*
2.2.4.6.	cits (brīvs uzskaitījums) *other (free text)*

Aktīvo vielu ražošana. Pārbaudīto (inspicēto) vielu nosaukumi*
*Manufacturing of active substances. Names of substances subject to inspection**

Jebkuri ierobežojumi vai paskaidrojumi saistībā ar šā sertifikāta jomu*
*Any restrictions or clarifying remarks related to the scope of this certificate**

……/……/…… (datums/*date*)	Latvijas kompetentās iestādes pilnvarotās amatpersonas vārds, uzvārds un paraksts** *Name, surname and signature of the authorized person of the Competent Authority of Latvia*** (vārds, uzvārds, amats, kompetentā iestāde, tālruņa un faksa numurs/ *name, surname, title, national authority, phone and fax number*)

Z.v.
Seal

Notes.

1. * Izdzēst neatbilstošo.
Delete the items which do not apply.

2. ** Paraksts, datums un kontaktinformācija ir uz katras sertifikāta lapas.
Signature, date and contact details should appear on each page of the certificate.
