Text consolidated by Valsts valodas centrs (State Language Centre) with amending regulations of:

17 January 2017 [shall come into force on 1 March 2017];

4 March 2021 [shall come into force on 9 March 2021];

14 December 2021 [shall come into force on 17 December 2021].

If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 344

Adopted 25 June 2013

**Procedures for Importing and Distributing Active Substances**

*Issued pursuant to*

*Section 5, Clause 23 of the Pharmaceutical Law*

**I. General Provisions**

1. The Regulation prescribes the requirements and procedures for importing and distributing active substances, as well as the procedures for registering importers, manufacturers and distributors of active substances.

2. This Regulation shall apply to the active substances which are used for the manufacture of medicinal products for human use or preparation thereof in a pharmacy.

3. This Regulation shall not apply to the active substances:

3.1. which are used for industrial manufacture of veterinary medicinal products or for preparation thereof in a pharmacy;

3.2. in imported finished medicinal products (dosage form).

4. For importing and distribution of narcotic and psychotropic substances and precursors, the requirements laid down in the Law on the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products, and also Precursors shall be complied with in addition to the requirements referred to in this Regulation.

[*4 March 2021*]

**II. Procedures for Importing Active Substances**

5. It shall be permitted to import active substances if:

5.1. the active substances have been manufactured according to the principles of good manufacturing practice and the guidelines in accordance with Commission Delegated Regulation (EU) No 1252/2014 of 28 May 2014 supplementing Directive 2001/83/EC of the European Parliament and of the Council with regard to the principles and guidelines of good manufacturing practice for active substances for medicinal products for human use (hereinafter – Regulation No 1252/2014), and the guidelines laid down in the European Commission Guidelines to good manufacturing practice referred to in Section 51.1 of the Pharmaceutical Law for active substances which has been published by the European Commission in Volume 4 of “The rules governing medicinal products in the European Union” (available on the website of the State Agency of Medicines), and they are distributed in accordance with the requirements referred to in this Regulation;

5.2. each consignment of active substance has been accompanied by written confirmation which has been issued by the competent authority of the manufacturing third country and which conforms to the uniform template approved by the European Commission (hereinafter – the written confirmation) (Annex 1).

[*17 January 2017*]

6. Upon importing active substances, the consignment shall be accompanied by the original or a copy of the written confirmation.

7. The written confirmation shall also be required for active substances which will be used for the manufacture of such medicinal products in the European Economic Area states which are intended to be exported to the third countries.

8. An importer of active substances shall inspect the conformity with the requirement referred to in Paragraph 6 of this Regulation. If the consignment of medicinal products has been accompanied by a copy of the written confirmation, the importer shall verify the authenticity of the copy and the validity of the confirmation by contacting the manufacturer of the relevant active substances or the relevant competent authority of the third country.

9. Upon importing active substances, the written confirmation shall not be required for the active substances which:

9.1. are used in research, development of dosage forms, and clinical trials;

9.2. are brought in for export to the third countries;

9.3. have been mixed with excipients during the manufacturing process and are not the finished product;

9.4. [17 January 2017].

10. The requirement referred to in Paragraph 6 of this Regulation shall not be applicable to the active substances that have been exported from a third country which has been evaluated by the European Commission and the legal provisions of which regarding good manufacturing practice of active substances and ensuring of the control, supervisory and execution activities thereof have been recognised by the European Commission as equivalent to the level of public health protection existing in the European Union (Annex 2).

11. As an exception Paragraph 6 of this Regulation need not be applied to ensuring availability of medicinal products, if any other competent authority of the European Union Member State has performed an inspection which confirms the compliance with the good manufacturing practice of active substances, and the State Agency of Medicines was aware of it or if the authorised persons of the State Agency of Medicines inspect the manufacturing plant of the active substances in the exporting country of the active substance and confirm its compliance with the good manufacturing practice, for a period of time which does not exceed the term of validity of the issued certificate of good manufacturing practice.

12. Upon performing regular controls of manufacturers of medicinal products and importers of active substances, the Health Inspectorate shall inspect whether the consignment of imported active substances has been accompanied by the written confirmation.

13. Upon performing supervision of manufacturers and importers of medicinal products in accordance with the laws and regulations regarding licensing of pharmaceutical activity and upon performing regular inspections in accordance with the laws and regulations regarding the procedures for manufacturing medicinal products, the State Agency of Medicines shall inspect whether the imported active substance used in manufacture has the written confirmation.

14. The State Agency of Medicines shall notify the European Commission regarding application of the exception referred to in Paragraph 11 of this Regulation.

**III. Procedures for Distributing Active Substances in Wholesale Dealing**

[*17 January 2017*]

15. A manufacturer, importer and distributor of active substances registered with the State Agency of Medicines shall be permitted to distribute active substances in wholesale dealing.

[*17 January 2017*]

15.1 It shall be permitted to procure active substances from the manufacturers, importers and distributors of active substances registered with the competent authority of the relevant European Union Member State.

[*17 January 2017*]

16. The compliance of distribution of an active substance with the requirements of good distribution practice shall be confirmed by a certificate of good distribution practice compliance issued by the State Agency of Medicines in relation to the active substances to be used in manufacture of medicinal products for human use (hereinafter – the certificate of good distribution practice of active substances) (Annex 3).

17. A manufacturer of active substances shall be permitted to distribute active substances which have been manufactured in accordance with Regulation No 1252/2014 and the guidelines laid down in the European Commission Guidelines to good manufacturing practice referred to in Section 51.1 of the Pharmaceutical Law for active substances, and a manufacturer, importer and distributor of active substances shall be permitted to distribute active substances according to the good distribution practice which is laid down in the Guidelines No 2015/C 95/01 of the European Commission of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (available on the website of the State Agency of Medicines) referred to in Section 22, Paragraph three of the Pharmaceutical Law.

[*17 January 2017*]

18. The State Agency of Medicines shall perform inspections on compliance of distribution of active substances with the good distribution practice and, if necessary, shall perform unannounced inspections, including in co-operation with the European Medicines Agency. The State Agency of Medicines shall agree with the manufacturer, importer or distributor of active substances on the time for the inspection to be commenced, and shall notify the manufacturer, importer or distributor of active substances thereof in writing (this condition shall not apply to unannounced inspections). Sample tests shall be performed at the laboratory of the State Agency of Medicines. If necessary, the State Agency of Medicines shall request to perform a sample testing at the official laboratory for control of medicinal products of a European Economic Area state.

19. The State Agency of Medicines shall perform inspections and follow-up inspections regarding the compliance of distribution of active substances implemented in the premises of manufacturers, importers or distributors of active substances in Latvia with the good distribution practice. If there are suspicions regarding non-compliance with the requirements of good distribution practice, the State Agency of Medicines is entitled to inspect the compliance of distribution of active substances with good distribution practice in the premises of a manufacturer or distributor of an active substance in the third countries.

20. The State Agency of Medicines is entitled to perform the inspections referred to in Paragraph 19 of this Regulation in the European Economic Area states and the third countries also upon request of the European Commission and the European Medicines Agency.

21. The authorised officials of the State Agency of Medicines shall draw up a control report after each compliance inspection of distribution of active substances with good distribution practice and shall notify the person inspected of whether he or she complies with the requirements of good distribution practice.

22. The State Agency of Medicines shall, within three working days after drawing up the control report, send it to the inspected person in the form of an electronic document to his or her electronic mail address or, upon request, in the form of a printed document, and shall ensure the possibility to provide comments.

[*4 March 2021*]

23. [4 March 2021]

24. The State Agency of Medicines, on the basis of the control report and the comments provided by the manufacturer, importer or distributor of active substances, shall take a decision to issue the certificate of good distribution practice of active substances if distribution of active substances conforms to the requirements of good distribution practice, or a decision to refuse to issue the certificate.

25. The State Agency of Medicines shall, within three working days after taking of the decision to issue the certificate of good distribution practice of active substances, include the information regarding the issued certificate in the European Union database on manufacturing and import authorisations and good manufacturing practice certificates managed by the European Medicines Agency (hereinafter – the EudraGMDP database).

26. If the result of the inspection referred to in Paragraph 29 of this Regulation or the inspection of the distributor of active substances shows that the person inspected does not comply with the requirements referred to in this Regulation regarding compliance with the requirements of good distribution practice, the State Agency of Medicines shall enter the relevant information in the EudraGMDP database referred to in Paragraph 25 of this Regulation.

27. The State Agency of Medicines shall issue the certificate of good distribution practice of active substances on the day when payment for the inspection and expert-examination of the documentation submitted for the issuance of the certificate has been made. The certificate shall be issued in the form of an electronic document by sending it to the electronic mail address of the submitter of the submission. The certificate shall be issued in the form of a printed document within three working days after receipt of the request for an additional fee according to the price list of paid services of the State Agency of Medicines.

[*17 January 2017*]

28. The Health Inspectorate shall perform the regular inspections, as well as extraordinary inspections of distribution of active substances without prior warning in relation to persons who carry out activities involving active substances in wholesale dealing (including at customs warehouses where active substances are stored).

[*17 January 2017*]

29. Inspections shall be performed by the officials of the State Agency of Medicines and Health Inspectorate, according to the competence, who are authorised:

29.1. to take samples for testing;

29.2. to examine all documents in relation to the object to be inspected.

29.1 A manufacturer, importer or distributor of active substances shall, without delay – during the inspections performed by officials of the State Agency of Medicines and Health Inspectorate – or within five working days upon request of the State Agency of Medicines and the Health Inspectorate, ensure that they have access to all documentation (all written procedures, instructions, contracts, records and data prepared in printed or electronic form) which is related to compliance of action of the distributor with the good distribution practice laid down in the Guidelines No 2015/C 95/01 of the European Commission of 19 March 2015 on principles of Good Distribution Practice of active substances for medicinal products for human use (available on the website of the State Agency of Medicines) referred to in Section 22, Paragraph three of the Pharmaceutical Law.

[*17 January 2017*]

29.2 The manufacturer, importer and distributor of active substances who are suspecting that the active substance distributed or imported by him or her is falsified, at the time of establishing the fact shall separate it physically or with the help of an equivalent electronic system and shall inform the State Agency of Medicines and the Health Inspectorate thereof without delay.

[*17 January 2017*]

29.3 The manufacturer, importer and distributor of active substances shall, without delay – during the inspections performed by officials of the State Agency of Medicines and Health Inspectorate – or within three working days upon request of the State Agency of Medicines and the Health Inspectorate, inform the original manufacturer of active substances.

[*17 January 2017*]

29.4 If a complaint regarding the quality of the active substance has been submitted, the manufacturer, importer and distributor shall examine the complaint together with the original manufacturer of the active substance in order to determine whether any additional measures must be taken, involving the importers and distributors of the active substance which might have received such active substance, or the Health Inspectorate and the State Agency of Medicines. The manufacturer, importer and distributor of the active substance shall ensure, during the inspections performed by officials of the Health Inspectorate and State Agency of Medicines, that they have access to the records which include complaints regarding the quality of the active substance. If a serious situation or such situation which might endanger life occurs, the manufacturer, importer and distributor of the active substance shall inform the State Agency of Medicines and the Health Inspectorate thereof without delay.

[*17 January 2017*]

30. The expenses related to testing of active substances shall be covered by such manufacturer, importer or distributor of medicinal products for which the tests are being performed.

**III.1 Requirements for a Pharmacy in Procuring, Recording, Storage and Supervision of Active Substances**

[*17 January 2017*]

30.1 A merchant or a performer of economic activity to which a special permit (licence) for opening (operating) a pharmacy has been issued with the permitted condition of special activity – preparation of medicinal products in the pharmacy:

30.1 1. shall procure active substances for the preparation of medicinal products in the pharmacy from manufacturers, importers and distributors of active substances registered with the State Agency of Medicines;

30.1 2. during inspections performed by officials of the Health Inspectorate shall ensure access to the premises, installations and equipment, as well as documentation;

30.1 3. shall draw up a plan for emergency situations in order to ensure efficient recall of active substances in co-operation with the relevant manufacturer, importer or distributor of the active substance or upon order of the Health Inspectorate;

30.1 4. shall record each transaction involving the active substances received, using invoices of purchase, or electronically, or in any other way, indicating the following information at least:

30.1 4.1. the date of procurement;

30.1 4.2. the name or designation of the active substance;

30.1 4.3. the lot number of the manufacturer;

30.1 4.4. the quantity received;

30.1 4.5. the name and address of the supplier and the original manufacturer;

30.1 4.6. the term of validity, if retesting is performed – its date;

30.1 5. shall ensure that the data referred to in Sub-paragraph 30.1 4 of this Regulation is stored and accessible to officials of the Health Inspectorate for at least one year after expiry of the term of validity of such lot of the active substance to which they apply, and in relation to the active substances for which retesting has been determined – for at least three years after all the relevant series have been utilised, but in relation to narcotic and psychotropic substances – for at least 10 years from the date of the transaction referred to in Sub-paragraph 30.1 4 of this Regulation.

[*17 January 2017*]

30.2 The manager of a pharmacy shall ensure the fulfilment of the following requirements:

30.2 1. the premises, installations and equipment are such as to ensure appropriate storage of active substances in accordance with Sub-paragraphs 30.2 2, 30.2 3 and 30.2 4 of this Regulation. The measuring devices are calibrated and verified;

30.2 2. the fulfilment of the following requirements is ensured in receipt of active substances:

30.2 2.1. the active substances are protected from exposure to weather conditions during unloading. The place of receipt is separated from the place of storage. It is inspected whether the active substances ordered have been received, whether their packaging is not damaged, and whether the relevant certificates of analyses have been appended;

30.2 2.2. the active substances which require specific storage conditions (for example, narcotic and psychotropic substances or substances which require specific storage temperature or air humidity) are identified without delay and stored according to the instructions and the requirements laid down in Sub-paragraph 30.2 3 of this Regulation;

30.2 3. the fulfilment of the following requirements is ensured in storage of active substances:

30.2 3.1. the active substances are stored according to the storage temperature regime stipulated by the manufacturer, taking into account that:

30.2 3.1.1. the room temperature is from 15 °C to 25 °C;

30.2 3.1.2. cool place is from 8 °C to 15 °C;

30.2 3.1.3. cold place is from 2 °C to 8 °C;

30.2 3.2. thermolabile active substances (active substances sensitive against a higher or lower temperature) are stored in a cold room (cold chamber) or refrigerator, ensuring corresponding temperature regime and its registration;

30.2 3.3. light-sensitive active substances are stored in lightproof places (for example, tightly sealed containers, special packaging). If active substances are not in a special lightproof packaging, they shall be stored in a dark place;

30.2 3.4. volatile active substances and moisture-sensitive active substances are stored in a cool place, tightly sealed. Hygroscopic active substances shall be stored in a dry room in hermetically sealed vessels or in plastic packagings, if necessary, the vessel shall be sealed off and coated in paraffin;

30.2 3.5. the temperature regime of the storage room of active substances is periodically supervised and registered;

30.2 3.6. for active substances storage of which requires special storage temperature or air humidity, the storage site is equipped with temperature or humidity recording devices, or with other devices that indicate the periods when the corresponding storage regime is not maintained;

30.2 3.7. it is ensured that the storage area is clean, free of unauthorised items, dust and pest, and precautionary measures are taken in order to prevent leakage or spillage of active substances or damages to the packaging, microbiological contamination and cross-contamination or mixing of active substances;

30.2 4. the active substances which are falsified, of poor quality, have been recalled or should be returned, or which are suspected of being falsified or of poor quality (for example, with damaged packaging (lid, contaminated), or the term of validity of which has expired, are separated from other goods physically or with the help of an equivalent electronic system. The abovementioned active substances shall be supervised in order to prevent unauthorised use thereof in the preparation of medicinal products. Complaints on the quality of the active substance shall be submitted to the supplier of the active substance, informing the Health Inspectorate and the State Agency of Medicines thereof;

30.2 5. in accordance with the laws and regulations regarding the procedures for procuring, receiving, storing, distributing, issuing, recording and destroying narcotic and psychotropic medicinal products and substances the following substances provided for the preparation of medicinal products are recorded and registered in the Strict Accountability Register of Narcotic Substances and Equivalent Psychotropic Substances and Medicinal Products in addition to the substances included in Lists II and III of narcotic and psychotropic substances to be controlled in Latvia:

30.2 5.1. atropine sulphate;

30.2 5.2. silver nitrate;

30.2 5.3. arsenous acid anhydride;

30.2 5.4. crystalline sodium arsenate;

30.2 5.5. tetracaine hydrochloride (dicaine).

[*17 January 2017*]

**IV. Procedures for Registering Importers, Manufacturers and Distributors of Active Substances**

31. Manufacturers, importers and distributors of active substances shall register the type of their activity with the State Agency of Medicines by submitting a registration form (hereinafter – the registration form) (Annex 4). The following information shall be indicated in the registration form:

31.1. the firm name, legal address, and contact information of the importer, manufacturer or distributor of active substances;

31.2. data regarding the active substances intended for import, manufacture or distribution (including export), indicating the name of the active substance (international nonproprietary name (INN) or, if none, chemical name and registration number of the substance with CAS) and the content of the active substance, as well as manufacture, import or distribution activities in accordance with Annex 4 to this Regulation;

31.3. data regarding the premises, technical equipment, and installations intended for activities. The address of the site of activities (manufacturing plant and warehouse) (including the address of the contract manufacturing and control site) and information regarding the laboratory conducting quality control shall be indicated. If active substances are imported or a foreign manufacturer is involved in their manufacture, the firm name, legal address of the foreign manufacturer and the address of the manufacturing plant of the manufacturer of the relevant active substance shall also be indicated.

32. Importers, manufacturers, and distributors of active substances shall summarize the changes made during the year (including from the day of registration) and shall inform the State Agency of Medicines regarding any changes made in relation to the information submitted by submitting the registration form with the indicated changes in accordance with Annex 4 to this Regulation. Changes which may affect the quality or safety of the manufactured, imported or distributed active substances (for example, changes in the information referred to in Sub-paragraphs 31.2 and 31.3 of this Regulation) shall be notified without delay.

33. Importers, manufacturers, and distributors of active substances shall submit the registration form to the State Agency of Medicines at least 60 days before commencing the planned activity. If documentation is incomplete, the State Agency of Medicines is entitled to request additional information.

34. The State Agency of Medicines shall take a decision to register a manufacturer, importer or distributor of active substances and, on the basis of a risk assessment, a decision to perform or not perform an inspection of the manufacturer, importer or distributor of active substances.

35. If the State Agency of Medicines takes a decision to perform the inspection , the State Agency of Medicines shall notify the manufacturer, importer or distributor of active substances regarding the decision taken within 60 days after receipt of the registration form. In such case the manufacturer, importer or distributor of active substances is entitled to commence his or her activity only after the State Agency of Medicines has informed him or her regarding permission to commence activity within the time period specified in the Pharmaceutical Law.

36. The importer, manufacturer, and distributor of active substances are entitled to commence the activity, if a notification of the State Agency of Medicines on performing an inspection has not been received within 60 days after submitting the registration form to the State Agency of Medicines.

37. The registration fact of the manufacturer, importer or distributor of active substances shall be confirmed by a Union Format for Registration (Annex 5) issued by the State Agency of Medicines and entering of information in the EudraGMDP database.

38. The State Agency of Medicines shall issue the registration certificate of manufacturers, importers or distributors of active substances on the day when payment for expert-examination and inspecting of the documentation submitted for the issuance of the registration certificate has been made, if such has taken place. The certificate shall be issued in the form of an electronic document by sending it to the electronic mail address of the submitter of the submission. The certificate shall be issued in the form of a printed document within three working days after receipt of the request for an additional fee according to the price list of paid services of the State Agency of Medicines.

[*17 January 2017*]

39. The State Agency of Medicines shall, within three working days after taking of the decision to register the manufacturer, importer or distributor of active substances, enter the information provided in accordance with Paragraph 37 of this Regulation in the EudraGMDP database.

**V. Closing Provisions**

40. Importers, manufacturers, and distributors of active substances which have commenced their activity prior to the day of coming into force of this Regulation, shall submit the registration form to the State Agency of Medicines and need not apply Paragraphs 33 and 36 of this Regulation. The State Agency of Medicines shall notify the submitter of the registration form regarding the decision taken in relation to performing or not performing an inspection within 60 days after submitting it.

41. A manufacturer of active substances and a manufacturer of medicinal products which has received a licence for the manufacture of active substances, shall submit the registration form to the State Agency of Medicines in which data not submitted to the State Agency of Medicines shall be indicated in relation to the information referred to in Paragraph 32 of this Regulation.

41.1Until 31 December 2022, the State Agency of Medicines may, on the basis of a risk assessment, postpone the inspections of good distribution practice of active substances referred to in Paragraphs 18 and 19 of this Regulation or may perform them remotely. The State Agency of Medicines may postpone the abovementioned inspections if such changes are not intended which broaden the scope of the relevant registration of importers and distributors of active substances and which must be indicated in the certificate of good distribution practice (for example, new premises, new active substances), and also if the competent supervisory authority has not performed activities in the premises of a manufacturer or distributor of active substances located outside a European Economic Area country which affect the validity of the specific certificate of good distribution practice.

[*14 December 2021*]

41.2If the State Agency of Medicines postpones the inspections in the cases referred to in Paragraph 41.1 of this Regulation, it is considered that the relevant certificate of good distribution practice is valid until 31 December 2022.

[*14 December 2021*]

41.3 If the State Agency of Medicines performs the inspections of good distribution practice of active substances referred to in Paragraphs 18 and 19 of this Regulation remotely, the certificate of good distribution practice issued after the inspection shall indicate the conditions according to the course and results of the inspection.

[*4 March 2021*]

42. The Regulation shall come into force on 2 July 2013.

**Informative Reference to European Union Directives**

The Regulation contains legal norms arising from Directive 2011/62/EU of the European Union and of the Council of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products.

Acting for the Prime Minister, Minister for Defence Artis Pabriks

Minister for Health Ingrīda Circene

**Annex 1**

Cabinet Regulation No. 344

25 June 2013

*Letterhead of the Issuing Regulatory Authority*

Izdevējiestādes (trešās valsts kompetentās iestādes) veidlapas galvene

***Written Confirmation for Active Substances Exported to the European Union (EU) for Medicinal Products for Human Use, in Accordance with Article 46b (2) (b) of Directive 2001/83/EC***

**Rakstisks apstiprinājums cilvēkiem paredzēto zāļu aktīvo vielu eksportam uz Eiropas Savienību saskaņā ar Direktīvas 2001/83/EK 46.b panta otrās daļas "b"punktu**

*Confirmation No. (given by the issuing regulatory authority):*

Apstiprinājuma Nr. (piešķir izdevējiestāde):

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|  |

1. *Name and address of site (including building number, where applicable):*

Ražošanas vietas nosaukums un adrese (ieskaitot ēkas numuru, ja piemērojams):

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2. *Manufacturer's licence number(s)1:*

Ražotāja licences numurs(-i):

|  |
| --- |
|  |

*Regarding the manufacturing plant under (1) of the following active substance(s) exported to the EU for medicinal products for human use:*

Attiecībā uz 1.punktā minēto ražotni, kur tiek ražota(-as) šāda(-as) aktīvā(-ās) viela(-as) eksportam uz Eiropas Savienību izmantošanai cilvēkiem paredzētajās zālēs:

|  |  |
| --- | --- |
| *Active substance(-s)*2  Aktīvā(-ās) viela(-as) | *Activity(-ies)*3  Darbība(-as) |
|  |  |
|  |  |
|  |  |

***The issuing regulatory authority hereby confirms that:***

**Izdevējiestāde apliecina, ka:**

*- the standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO and ICH Q7);*

uz šo ražotni attiecināmie labas ražošanas prakses (GMP) standarti ir vismaz līdzvērtīgi standartiem, kas noteikti Eiropas Savienībā (= WHO un ICH Q7 noteiktā GMP);

*- the manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU;*

ražotne ir pakļauta regulārai, stingrai un caurskatāmai kontrolei, un tajā tiek efektīvi īstenota labas ražošanas prakses pārraudzība, tai skaitā ražotnē tiek veiktas atkārtotas un nepaziņotas inspekcijas, lai nodrošinātu sabiedrības veselības aizsardzību, kas ir vismaz līdzvērtīga ar sabiedrības veselības aizsardzību Eiropas Savienībā;

*- in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.4*

neatbilstību atklāšanas gadījumā eksportējošā trešā valsts nekavējoties sniedz informāciju Eiropas Savienībai par atklātajām neatbilstībām.

*Date of inspection of the plant under (1). Name of inspecting authority if different from the issuing regulatory authority:*

1.punktā minētās ražotnes inspekcijas datums. Inspicējošās iestādes nosaukums, ja inspekciju neveic izdevējiestāde:

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*This written confirmation remains valid until:*

Šis rakstiskais apstiprinājums ir derīgs līdz:

|  |
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*The authenticity of this written confirmation may be verified with the issuing regulatory authority.*

Šā rakstiskā apstiprinājuma autentiskumu var apliecināt izdevējiestāde.

*This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.*

Šis rakstiskais apstiprinājums neietekmē ražotāja pienākumus nodrošināt medicīniskā produkta kvalitāti saskaņā ar Direktīvu 2001/83/EK.

*Address of the issuing regulatory authority:*

Izdevējiestādes adrese:

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|  |

*Name and function of responsible person:*

Atbildīgās personas vārds, uzvārds un amats:

|  |
| --- |
|  |

*E-mail, phone and fax:*

E-pasta adrese, tālruņa numurs un faksa numurs:

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| --- | --- | --- |
| *Signature*  Paraksts |  | *Stamp of the issuing regulatory authority and date*  Izdevējiestādes zīmogs un datums |
|  |  |  |

Notes.

1*Where the regulatory authority issues a licence for the site. Record 'not applicable' in case where there is no legal framework for issuing of a licence.*

Ja izdevējiestāde izdod licenci par vietu. Ierakstu "nav piemērojams" norāda, ja nav tiesiskā regulējuma par licences izdošanu.

2*Identification of the specific active substances through an internationally-agreed terminology (preferably international nonproprietary name (INN)).*

Konkrētas aktīvās vielas identifikācija saskaņā ar starptautiski apstiprinātu terminoloģiju (vēlams, starptautiskais nepatentētais nosaukums (INN)).

3*For example, 'Chemical synthesis', 'Extraction from natural sources', 'Biological processes', 'Finishing steps'.*

Piemēram, "Ķīmiska sintēze", "Ekstrakcija no dabīgas izejvielas", "Bioloģiski procesi", "Nobeiguma soļi".

4*qdefect@ema.europa.eu*.

Minister for Health Ingrīda Circene

**Annex 2**

Cabinet Regulation No. 344

25 June 2013

**Third Countries which have been Evaluated by the European Commission and the Legal Provisions of which Regarding Good Manufacturing Practice of Active Substances and Ensuring of Control, Supervisory and Execution Activities Thereof have been Recognised by the European Commission as Equivalent to the Level of Public Health Protection Existing in the European Union**

[*17 January 2017*]

|  |  |
| --- | --- |
| No. | Name of the country |
| 1. | Australia |
| 2. | Japan |
| 3. | Swiss Confederation |
| 4. | United States of America |
| 5. | Brazil |
| 6. | Israel (except the territories which are under administration of Israel since June 1967 – Golan Heights, Gaza Strip, East Jerusalem and remaining West Bank) |

Minister for Health Ingrīda Circene

**Annex 3**

Cabinet Regulation No. 344

25 June 2013

[*17 January 2017*]

|  |  |  |
| --- | --- | --- |
| LATVIJAS REPUBLIKA  ZĀĻU VALSTS AĢENTŪRA  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (adrese, reģistrācijas numurs, tālruņa numurs, faksa numurs, e-pasta adrese) |  | *REPUBLIC OF LATVIA*  *STATE AGENCY OF MEDICINES*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(address, registration number, phone,*  *fax number, e-mail)* |

Sertifikāts Nr. \_\_\_\_\_\_\_\_\_\_\_\_\_

Certificate No.

**AKTĪVO VIELU IZPLATĪTĀJA**

**LABAS IZPLATĪŠANAS PRAKSES ATBILSTĪBAS SERTIFIKĀTS**

**ATTIECĪBĀ UZ CILVĒKIEM PAREDZĒTO ZĀĻU RAŽOŠANĀ IZMANTOJAMĀM AKTĪVAJĀM VIELĀM**

**CERTIFICATE OF GDP COMPLIANCE OF**

**A DISTRIBUTOR OF ACTIVE SUBSTANCES FOR USE AS STARTING**

**MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE**

|  |
| --- |
| **Izdots pēc oficiālas pārbaudes (inspekcijas) saskaņā ar Direktīvas 2001/83/EK 111.pantu**  ***Issued following an inspection in accordance with Art. 111 of Directive 2001/83/EC***  Zāļu valsts aģentūra apliecina:  *The State Agency of Medicines confirms the following*:  aktīvo vielu izplatītājs \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,  *the active substance distributor*  izplatīšanas vietas adrese \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,  *site address*  ir oficiāli pārbaudīts saskaņā ar Direktīvas 2001/83/EK 111.panta 1.punktu, kas pārņemts šādos Latvijas Republikas tiesību aktos:  *has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC transposed in the following national legislation:*  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  un saistībā ar reģistrācijas Nr.  *and in connection with registration No.* |

Oficiālajās aktīvo vielu izplatītāja pārbaudēs, no kurām pēdējā tika veikta \_\_.\_\_.\_\_\_\_. [datums], iegūtā informācija ļauj uzskatīt, ka tas atbilst aktīvo vielu labas izplatīšanas prakses principiem, kas minēti Direktīvas 2001/83/EK 47.pantā.

*From the knowledge gained during inspection of this active substance distributor, the latest of which was conducted on …../...…/...… [date], it is considered that it complies with the principles of good distribution practice for active substances referred to in Article 47 of Directive 2001/83/EC.*

Šis sertifikāts atspoguļo izplatīšanas vietas statusu iepriekš minētās oficiālās pārbaudes laikā, un tas nevar atspoguļot atbilstības statusu, ja ir pagājuši vairāk nekā pieci gadi kopš oficiālās pārbaudes, kad tika izsniegts šis sertifikāts. Sertifikāta derīguma termiņš var tikt saīsināts, piemērojot riska vadības regulējošos principus un veicot ierakstu lauciņā, kas atvēlēts ierobežojumu vai paskaidrojumu atzīmēšanai.

*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 five years have elapsed since the date of that inspection, after which time the issuing authority should be consulted. However, this period of validity may be reduced using regulatory risk management principles by an entry in the 'Restrictions or Clarifying Remarks' field.*

Sertifikāta autentiskumu var apliecināt Eiropas Savienības datubāzē. Ja sertifikāts datubāzē nav atrodams, lūdzu, sazinieties ar Zāļu valsts aģentūru.

*The authenticity of this certificate may be verified in the European Union's database. If it does not appear please contact the issuing authority.*

Jebkādi ierobežojumi vai paskaidrojumi saistībā ar šā sertifikāta jomu:

*Any restrictions or clarifying remarks related to the scope of this certificate:*

|  |
| --- |
|  |
|  |
|  |

|  |  |
| --- | --- |
| \_\_.\_\_.\_\_\_\_.  (datums/*date*) | Zāļu valsts aģentūras pilnvarotās amatpersonas vārds, uzvārds un paraksts  *Name, surname and signature of the authorised person of the Competent Authority of Latvia* |
|  |
| (vārds, uzvārds, amats, atbildīgā iestāde, tālruņa numurs, e-pasta adrese jautājumiem)  *(name, surname, title, national authority, phone number, email in case of enquiries)* |
|  |
|  |

Note. The detail of the document “signature” shall not be completed if the electronic document has been drawn up in accordance with the laws and regulations regarding drawing up of electronic documents.

Minister for Health Ingrīda Circene

**Annex 4**

Cabinet Regulation No. 344

25 June 2013

[*17 January 2017*]

To the State Agency of Medicines

**Submission for Registering Importers, Manufacturers and Distributors of Active Substances**

(mark as appropriate with an x)

|  |  |  |
| --- | --- | --- |
| for registration: | | for changes: |
|  | for manufacture of active substances   for importing of active substances   for distribution of active substances | |

We want to receive the registration certificate in printed form (*mark as appropriate with an X*)

 yes

 no

**1. Information on the submitter:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 1.1. | firm name |  | | | | | |
| 1.2. | legal address |  | | | | | |
| 1.3. | registration number in the Commercial Register or registration number of the firm name of the branch of the foreign merchant in the Enterprise Register | | |  | | | |
| 1.4. | address of the actual site of activity (manufacturing plant and warehouse) | | |  | | | |
|  | (indicate all relevant sites if individual registration does not apply to them) | | |  | | | |
| 1.5. | special authorisation (licence) number (if any) | | |  | | | |
| 1.6. | contact information: |  | |  |  | | |
|  | telephone |  | | | | | |
|  | fax |  | | | | | |
|  | electronic mail address | |  | | |  |  |
|  | website |  | | | | | |

Notes.

1. If a merchant has several sites of activity, the information referred to in Sub-paragraph 1.4 of the submission regarding other sites and the relevant designated persons shall be indicated on a separate page and appended to the submission.

2. The performer of economic activity who need not register with the Commercial Register shall indicate the given name, surname and personal identity number in Sub-paragraph 1.1 of the submission and the address of the declared place of residence – in Sub-paragraph 1.2 of the submission. Sub-paragraph 1.3 of the submission need not be filled in.

**2. Please register the following changes** (mark as appropriate with an x):

2.1. changes in the firm name of the registered person

2.2. changes in the legal address

2.3. changes in the site of activity

2.4. changes in import, manufacture and distribution activities in Paragraphs 3 and 6 of the submission (underline as appropriate)

2.5. commencing of manufacture, import, distribution of a new active substance (underline as appropriate)

2.6. carrying out of manufacture activities of active substances or quality control on contractual basis (underline as appropriate)

2.7. performance of quality control of active substances on contractual basis or changes in the person with whom the contract regarding quality control of active substances has been entered into (underline as appropriate)

2.8. other reason

**3. Information regarding manufacture activities (to be completed by the manufacturer of active substances)** (mark as appropriate with an x and indicate in parenthesis the name of all active substances to which the abovementioned activities apply):

|  |  |
| --- | --- |
|  | A. Manufacture of chemically synthesised active substances |
|  | 1. Manufacture of active substance intermediates |
|  | 2. Manufacture of crude active substance |
|  | 3. Salt formation and purification steps: (free text) (e.g. crystallisation) |
|  | 4. Other activities (free list) |
|  | B. Extraction of active substances from natural sources |
|  | 1. Extraction of substance from plant source |
|  | 2. Extraction of substance from animal source |
|  | 3. Extraction of substance from human source |
|  | 4. Extraction of substance from mineral source |
|  | 5. Modification of extracted substance (specify source B: 1, 2, 3 or 4) |
|  | 6. Purification of extracted substance (specify source B: 1, 2, 3 or 4) |
|  | 7. Other activities (free list) |
|  | C. Manufacture of active substances, using biological processes |
|  | 1. Fermentation |
|  | 2. Cell cultures (indicate the cell type, for example, mammal, bacterial) |
|  | 3. Separation and purification |
|  | 4. Modification |
|  | 5. Other activities (free list) |
|  | D. Manufacture of sterile active substance (note Parts A, B & C, to be completed as applicable) |
|  | 1. Aseptically manufactured |
|  | 2. Terminally sterilised |
|  | E. General finishing steps |
|  | 1. Physical processing steps (specify, e.g. drying, milling, micronisation, sieving) |
|  | 2. Primary packaging (enclosing or sealing the active substance within a packaging material which is in direct contact with the substance) |
|  | 3. Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) |
|  | 4. Other activities (free list) (for activities not described in the previous paragraphs) |
|  | F. Quality control testing (this section should be completed only if any parts of sections A, B, C, D, E are completed) |
|  | 1. Physical, chemical testing |
|  | 2. Microbiological testing: excluding sterility testing (purity of non-sterile active substances) |
|  | 3. Microbiological testing: including sterility testing |
|  | 4. Biological testing |

Note. If an undertaking has several manufacturing plants or manufacturing sites, the information referred to in Paragraph 3 of the submission shall be indicated on a separate sheet for each site and appended to the submission.

**4. Information regarding the contract manufacturers and contract manufacturing sites** (mark as appropriate with an x)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| firm name of the merchant | |  | | |
| legal address | |  | | |
| number, date, issuer of the special authorisation (licence) for manufacturing active substances | | | |  |
| address of the manufacturing site | |  | | |
| name of the manufacturing plant | |  | | |
| given name, surname of the designated person | | |  | |
| telephone |  | | | |
| fax |  | | | |

Note. If a performer of economic activity has several contract manufacturers or contract manufacturing sites, the information referred to in Paragraph 4 of the submission shall be indicated on a separate sheet for each site and the designated person, and shall be appended to the submission.

**5. Information regarding the contract laboratory performing quality control**:

|  |  |  |  |
| --- | --- | --- | --- |
| name of the laboratory | |  | |
| address |  | | |
| given name, surname of the designated person | | |  |
| telephone |  | | |
| fax |  | | |

Note. If a performer of economic activity has several laboratories with which a contract regarding performance of quality control has been entered into, the information referred to in Paragraph 5 of the submission shall be appended on a separate sheet for each laboratory and appended to the submission.

**6. Information regarding import and distribution activities** (to be completed by the importer and distributor of active substances) (mark as appropriate with an x):

A. Import (list of all imported active substances, indicating information regarding corresponding manufacturers and distributors, if applicable)

|  |  |  |
| --- | --- | --- |
| Active substance | Third country manufacturer (name, full address of the manufacturing plant) | Distributor  in a European Economic Area (EEA) state  (name, full address) |
|  |  |  |

B. Distribution

|  |  |  |
| --- | --- | --- |
| Active substance | Manufacturer or importer (firm name, full address of the manufacturing plant or import site) | Distributor in the EEA  (name, full address) |
|  |  |  |

Note. If a performer of economic activity uses his or her manufactured or imported active substance in manufacture of dosage forms at the same manufacturing plant, it need not be indicated in the distribution section.

**The following documents are appended to the submission** (mark as appropriate with an x):

a document attesting the right of the submitter to use the premises (certified copy) – on \_\_\_\_\_ pages

list of the distributed active substances in which the name of the active substance (international nonproprietary name (INN) or, if none, chemical name and registration number of the substance with CAS), the content of the active substance, the firm name and the address of the site of pharmaceutical activity of the manufacturer or importer, the firm name and address of the site of pharmaceutical activity of the distributor are indicated, on \_\_\_\_\_ pages (applies to a distributor of active substances)

list of the manufactured active substances in which the name of the active substance (international nonproprietary name (INN) or, if none, chemical name and registration number of the substance with CAS), the content of the active substance and its manufacture activities (letters and digits) are indicated in accordance with Paragraph 3 of the submission, on \_\_\_\_\_ pages (applies to a manufacturer of active substances)

list of the imported active substances in which the name of the active substance (international nonproprietary name (INN) or, if none, chemical name and registration number of the substance with CAS), the content of the active substance, the firm name and full address of the manufacturing plant of the third country manufacturer, as well as the firm name and site of pharmaceutical activity of a distributor in the EEA are indicated, on \_\_\_\_\_ pages (applies to an importer of active substances)

other additional information (if any) (indicate what additional information) on \_\_\_\_ pages

a document with which the manufacturer, importer or distributor of active substances authorises the person to submit the submission and documents to the State Agency of Medicines, on \_\_\_\_\_\_ pages

I hereby attest that the information provided in the submission, the documents appended to the submission and other information is complete and true, and it conforms to the requirements laid down in Cabinet Regulation No. 344 of 25 June 2013, Procedures for Importing and Distributing Active Substances:

|  |  |
| --- | --- |
| given name, surname |  |
| position |  |
| address |  |
| telephone, fax, e-mail |  |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| (place, date) |  | (signature)  (signature of the person with the right of representation) |

Notes.

1. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

2. Upon submitting a submission regarding changes in the registration certificate of importers, manufacturers, and distributors of active substances, such parts of the form shall be completed to which data on changes apply.

Minister for Health Ingrīda Circene

**Annex 5**

Cabinet Regulation No. 344

25 June 2013

**REPUBLIC OF LATVIA**

**STATE AGENCY OF MEDICINES**

|  |
| --- |
|  |
| (legal address, registration number, telephone and fax number) |

*<Letterhead of Validating Authority>*

**Aktīvo vielu ražotāju, importētāju VAI izplatītāju reģistrācijas APLIECĪBA**

***Union Format for Registration of Manufacturer, Importer or Distributor***

***of Active Substances***

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. | Reģistrācijas numurs |  | | | | |
|  | *Registration number* |  |  |  |  |  |
| 2. | Reģistrētās personas firma | |  | | | |
|  | *Name or corporate name of registrant* | |  |  |  |  |
| 3. | Reģistrētās personas juridiskā adrese | |  | | | |
|  | *Permanent or legal address of registrant* | |  |  |  |  |
| 4. | Faktiskās darbības norises vietas adrese | |  | | | |
|  | *Address(es) of site(s) where registered activities take place*  Norāda visas attiecīgās vietas, ja uz tām neattiecas atsevišķa reģistrēšana  *All relevant sites should be listed if not covered by separate registrations* | | |  |  |  |
| 5. | Reģistrācijas juridiskais pamatojums | |  | | | |
|  | *National legal basis of registration* | |  |  |  |  |
| 6. | Amatpersonas vārds, uzvārds,  kura apstiprina reģistrāciju | |  | | | |
|  | *Name, surname of the responsible officer*  *of the competent authority of the member state validating the registration* | |  |  |  |  |
| 7. | Paraksts |  | | | | |
|  | *Signature* |  |  |  |  |  |
| 8. | Datums |  | | | | |
|  | *Date* |  |  |  |  |  |

Šī reģistrācijas forma ir derīga tikai pilnā apjomā, iekļaujot visas lapas. Šīs reģistrācijas formas autentiskumu iespējams pārbaudīt Eiropas Savienības datubāzē vai atbildīgajā iestādē, kas izsniegusi reģistrācijas apliecību.

*This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in the European Union's database or with the validating authority.*

2.punktā minētajam reģistrācijas apliecības īpašniekam reizi gadā jāsniedz atbildīgajā iestādē šajā reģistrācijas apliecībā sniegtās informācijas izmaiņu pilns izklāsts.

Par jebkurām izmaiņām, kuras var ietekmēt minēto aktīvo vielu kvalitāti vai drošumu, jāziņo nekavējoties.

*The registration holder referred to in Section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form.*

*Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.*

**Reģistrēšanas joma**

***SCOPE OF REGISTRATION***

|  |  |
| --- | --- |
| Darbības vietas nosaukums un adrese |  |
| *Name and address of the site* |  |

|  |  |
| --- | --- |
| **1. RAŽOŠANAS DARBĪBAS**  ***MANUFACTURING OPERATIONS***  Aktīvā(-ās) viela(-as):  *Active substance(s):*  Ražošanas darbības norāda par katru aktīvo vielu atsevišķi  *Manufacturing activities are indicated for each activity separately* | |
| A | Ķīmiski sintezēto aktīvo vielu ražošana  *Manufacture of active substance by chemical synthesis* |
|  | 1. Aktīvo vielu starpproduktu ražošana  *Manufacture of active substance intermediates*  2. Tehnisko (neattīrīto) aktīvo vielu ražošana  *Manufacture of crude active substance*  3. Sāļu iegūšana un attīrīšanas posmi: (brīvs uzskaitījums) (piemēram, kristalizācija)  *Salt formation and purification steps: (free text) (e.g. crystallisation*)  4. Citas darbības (brīvs uzskaitījums)  *Other (free text)* |
| B | Aktīvo vielu izdalīšana no dabiskiem avotiem  *Extraction of active substance from natural sources* |
|  | 1. Vielas izdalīšana no augu valsts avotiem  *Extraction of substance from plant source*  2. Vielas izdalīšana no dzīvnieku valsts avotiem  *Extraction of substance from animal source*  3. Vielas izdalīšana no materiāla, kas ņemts no cilvēka  *Extraction of substance from human source*  4. Vielas izdalīšana no minerālu avotiem  *Extraction of substance from mineral source*  5. Izdalītās vielas modifikācija (norādiet avotu 1, 2, 3, 4)  *Modification of extracted substance (specify source 1, 2, 3, 4)*  6. Izdalītās vielas attīrīšana (norādiet avotu 1, 2, 3, 4)  *Purification of extracted substance (specify source 1, 2, 3, 4)*  7. Citas darbības (brīvs uzskaitījums)  *Other (free text)* |
| C | Aktīvo vielu ražošana, izmantojot bioloģiskos procesus  *Manufacture of active substance using biological processes* |
|  | 1. Fermentācija  *Fermentation*  2. Šūnu kultūras (norādiet šūnu tipu) (piemēram, zīdītāju, baktēriju)  *Cell culture (specify cell type) (e.g. mammalian, bacterial)*  3. Atdalīšana un attīrīšana  *Isolation, purification*  4. Modifikācija  *Modification*  5. Citas darbības (brīvs uzskaitījums)  *Other (free text*) |
| D | Sterilo aktīvo vielu ražošana (attiecīgi aizpildot iepriekšējos punktus)  *Manufacture of sterile active substance (note Parts A, B & C, to be completed as applicable)* |
|  | 1. Aseptiski ražotas  *Aseptically prepared*  2. Sterilizētas  *Terminally sterilised* |
| E | Vispārīgie nobeiguma posmi  *General finishing steps* |
|  | 1. Fizikālās apstrādes posmi (norādiet) (piemēram, žāvēšana, malšana, mikronizēšana, sijāšana)  *Physical processing steps (specify) (e.g. drying, milling, micronisation, sieving)*  2. Pirmējā iepakošana (aktīvo vielu ievietošana vai noslēgšana iepakojumā, kurš atrodas tiešā kontaktā ar aktīvo vielu)  *Primary packaging (enclosing or sealing the active substance within a packaging material which is in direct contact with the substance)*  3. Sekundārā iepakošana (noslēgtā pirmējā iepakojuma ievietošana sekundārā iepakojumā vai konteinerā, ieskaitot arī jebkuru materiāla marķēšanu, kas var tikt izmantota aktīvās vielas identifikācijai vai izsekojamībai (sērijas numurs))  *Secondary packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)*  4. Citas darbības (brīvs uzskaitījums) (darbībām, kas nav aprakstītas iepriekšējos punktos)  *Other (free text) (for operations not described above)* |
| F | Kvalitātes kontroles veikšana (šo punktu aizpilda tikai tad, ja ir norādīts kāds no iepriekšējiem punktiem)  *Quality control testing (this section should be completed only if any parts of sections A, B, C, D, E are completed)* |
|  | 1. Fizikāli vai ķīmiski  *Physical, chemical testing*  2. Mikrobioloģiski: neietverot sterilitāti (nesterilo aktīvo vielu tīrība)  *Microbiological testing (excluding sterility testing)*  3. Mikrobioloģiski: ietverot sterilitāti  *Microbiological testing (including sterility testing)*  4. Bioloģiski  *Biological testing* |

|  |  |  |  |
| --- | --- | --- | --- |
| **2. IMPORTĒŠANAS UN IZPLATĪŠANAS DARBĪBAS**  ***IMPORTATION AND DISTRIBUTION OPERATIONS*** | | | |
| A | Importēšana (visu importēto aktīvo vielu saraksts, norādot informāciju par atbilstošajiem ražotājiem un izplatītājiem, ja piemērojams)  *Importation (list of all imported active substances together with details of the relevant manufacturers, and where applicable, distributors)* | | |
|  | Aktīvā viela  *Active substance* | Trešās valsts ražotājs (firma, adrese)  *Third country manufacturer (name & address)* | Izplatītājs (firma, adrese)  *Distributor (name & address)* |
|  |  |  |
| B | Izplatīšana  *Distribution* | | |
|  | Aktīvā(-ās) viela(-as) (visu aktīvo vielu saraksts, kurām piemēro izplatīšanas darbības)  *Active substance(s) (list all active substances for which distribution operations apply)* | | |

|  |  |  |  |
| --- | --- | --- | --- |
| Ierobežojumi vai paskaidrojumi saistībā ar reģistrēto darbību jomu |  | | |
| *Any restrictions or clarifying remarks related to the scope of these registered operations* |  |  |  |
| Amatpersonas vārds, uzvārds, kura atbild par reģistrācijas apstiprināšanu |  |  | |
| *Name of responsible officer of the competent authority of the member state validating the registration* | |  |  |
| Paraksts |  | | |
| *Signature* |  |  |  |

Note. The detail of the document “signature” shall not be completed if the electronic document has been prepared in accordance with the laws and regulations regarding drawing up of electronic documents.

Minister for Health Ingrīda Circene