3.pielikums

Ministru kabineta

2013.gada \_\_\_\_.\_\_\_\_\_\_\_\_\_

noteikumiem Nr.\_\_\_\_

(prot Nr.\_\_\_ \_\_\_.§)

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

1. Daļa

Part 1

|  |
| --- |
| **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* |

Aktīvo vielu izplatītāja oficiālajās 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 augstāk minētās oficiālās pārbaudes laikā un tas nevar atspoguļot atbilstības statusu, ja ir pagājuši vairāk kā pieci gadi kopš oficiālās pārbaudes, kad tika izsniegts šis sertifikāts. Sertifikāta derīguma termiņš var tikt saīsināts, pielietojot 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 three 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 neparādās, lūdzu, sazinieties ar Zāļu Valsts aģentūru.

*The authenticity of this certificate may be verified in the Union 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 and signature of the authorised person of the Competent Authority of Latvia  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (vārds, uzvārds, amats, atbildīgā iestāde, tālruņa numurs, e-pasta adrese jautājumiem)  (name, title, national authority, phone number, email in case of enquiries) |

Veselības ministre I.Circene

10.05.2013. 13:23

501

I.Mača

67876117, [Inguna.Maca@vm.gov.lv](mailto:Inguna.Maca@vm.gov.lv)