**Bazuar në Ligjin për Produkte Medicinale dhe Paisje Medicinale 04/L-190 dhe UA MSH Nr 7/2015**

Na osnovu Zakona br. 04/L-190 i AU MZ Br.7/2015 / Refering to the Law 04/L-190 and AI MOH No.7/2015

**Aplikacioni për autorizim të prodhimit të prodhukteve**

**medicinale**

Medicinal products manufacturing authorisation application

Zahtev za davanje odobrenja za proizvodnju lekova

|  |  |
| --- | --- |
| Emri i prodhuesit / Proizvodac / Manufacturer |        |
| Adresa / Adresa / Address |       |
| Vendi / Mesto / Place |       |
| Telefoni / Telefon / Telephone |       |
| E-mail |       |
| Emri i Pronarit / Vlasnik / Owner |       |
| Personi përgjegjës për lirimin e serisë / Nadlezno lice za izdavanje serije / Responsible person for batch release |       |
| Nr i licencës së punës së personit përgjegjës / Br. Radne licence nadleznog lica / Nr. of work licence for responsible person |       |
| Operimi me barna narkotike / Rad sa narkoticnim lekovima /Operation with narcotic drugs (rrumbullako me laps Po ose Jo) | PO / Da / Yes  | JO / Ne / No  |

**Deklarata e kompanisë** / Deklaracia / Declaration**:**

*Deklarojmë që informatat e prezentuara në aplikacion janë të sakta dhe do t’i përmbahemi dispozitave të legjislacionit ekzistues. / Pod odgovornoscu deklariramo da su podaci tacni i da ce se naš rad bazirati na zakon. / We hereby that all mentioned above are true and our operation will be based on the law.*

 Personi përgjegjës për lirimin e serisë \_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_

 Nadlezno lice za izdavanje serije / Nënshkrimi / Potpis / Signature Vula / Pexat / Stamp

 Responsible person for batch release

 Pronari i kompanisë / Vlasnik / Owner \_\_\_\_\_\_\_\_\_\_\_\_\_     \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Nënshkrimi /Potpis / Signature

**Dokumentacioni për për autorizim të prodhimit të produkteve medicinale** bazuar në nenin 20 të U.A 07/2015

Dokumentacija za odobrenje proizvodnje lekova na osnovu odeljka 20 A.U 07/2015 / Documentation for manufacutring authorisation of medicinal products bazed on A.I No.7/2015.

|  |
| --- |
| Aplikacionit për autorizim të prodhimit të produkteve medicinale duhet ti bashkangjiten:Zahtev za odobrenje proizvodnje lekova treba da se priloži / Medicinal products manufacturing authorisation application should be aatched: |
| 1. | Specifikimet për produktin medicinal dhe formën farmaceutike që do të prodhohet.Specifikaciju medicinskih proizvoda I farmaceutskih obliku koji ce da se proizvode / Specifications of the medicinal product and pharmaceutical form wich are to be manufactured |  |
| 2. | Dokumentimi i hollësishëm i prodhuesit për hapsira të përshtatshme dhe të mjaftueshme, pajisje teknike dhe hapsirat për kontroll në pajtueshmëri me kërkesat ligjore.Podatke o lokaciji proizvodnje koji pokazuju pogodne i dovolinje objekte tehnicku opremu u skladu sa zakonskim zahtevima/ Manufacturing site particulars documenting suitable and sufficient premises technical equipment and control facilities compying with the legal requierements  |  |
| 3. | Deklaratë me shkrim nga aplikuesi ku deklaron se do ti mundësojë personit përgjegjës për lirimin e serisë ti kryej punët në mënyrë të pavarur dhe ti siguroj të gjitha burimet e nevojshme.Pismenu izjavu podnosioca zahteva kojom izjavljuje da ce omoguciti nadleznom licu za izdavanje serije da vrsi svjoe aktivnosti nezavisno i da ce da obezbedi sve moguce izvore / A written statement by the applicant declaring that he shall enable the person responsible for batch release to carry out his avtivities independently and ensure all requisite resources. |  |
| 4. | Deklaratë me shkrim nga aplikuesi që ai do të kryej aktivitetet e prodhimit nëpërputhje me praktikën e mirë të prodhimit.Pismenu izjavu podnosioca zahteva da ce za da vrsi aktivnosti proizvodnje u skladu sa dobrom praksom za prozvodnju / A written statement by the appliucant that he shall carry out the manufacturing activities in compliance with good manufacturing practice. |  |
| 5. | Deklaratë me shkrim nga aplikuesi se për prodhimin e produkteve medicinale do të përdoren vetëm substancat aktive në linje me praktikën e mirë të prodhimit.Pismenu izjavu podnosioca zahteva da ce se za proizvodnju medicinskih proizvoda koristiti samo atkivne supstance koje su proizvedne u skladu sa dobrom praksom o proizvodnji / A written statement by the applicant that for manufacture of medicinal products only active substances wich are produced in line with good manufacturin practice will by used. |  |
| 6. | Deklaratë me shkrim nga aplikuesi se ai do të prodhoj vetëm produkte medicinale për të cilat posedon autorizim prodhimi valid.Pismena izjava podnosioca zahteva kojom izjavljuje da ce proizvoditi samo medicinske proizvode za koje poseduje vazece ovolascenje za proizvodnju / A written statement by the applicant declarin that hw shall manuvacture only medicinal products for witch he holds a valid manufacturing authorisation. |  |
| 7. | Dëshmia e pagesës sipas U.A të tarifave.Dokaz o plaćanju u A.U naknada / Fee payment proof based on tariff A.I |  |

Vërejtje: Auditorët e pmp –së AKPPM mund të kërkojnë të dhëna shtesë. Napomena: KMA gmp revizori mogu zatražiti dodatne podatke / Note: KMA gmp auditors may request additional data.

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|  Emri i aplikuesit  |  | Nënshkrimi i aplikuesit  |

***Shojcë 1 / Appendix* 1**

**INFORMATION ON THE SCOPE OF MANUFACTURING AND THE TYPE OF PRODUCT/PROCESS**

|  |
| --- |
| 1. **Medicinal products for human use**

**or****B. Veterinary medicinal products** |

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| --- |
| 1. Manufacturing operations |

|  |  |
| --- | --- |
| 1.1.  | Sterile products  |
|  | ***1.1.1.******Asepticaly prepared***1.1.1.1. Large volume liquids 1.1.1.2. Lyophilisates 1.1.1.3. Semi-soilds 1.1.1.4. Small volume liquids 1.1.1.5. Solids and implants 1.1.1.6. Other asepticaly prepared products        \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.1.2.******Terminally sterilised***1.1.2.1. Large volume liquids 1.1.2.2. Semi-solids 1.1.2.3. Small valume liquids 1.1.2.4. Solids and implants 1.1.2.5. Other terminalny sterilised prepared products       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.1.3.******Batch certification***  |
| 1.2. | **Non-sterile products** |
|  | ***1.2.1.******Non-sterile products***1.2.1.1. Capsules, hard shell 1.2.1.2. Capsules, soft shell 1.2.1.3. Chewing gums 1.2.1.4. Impregnated matrices 1.2.1.5. Liquids for external use 1.2.1.6. Liquids for internal use 1.2.1.7. Medicinal gases 1.2.1.8. Other solid dosage forms 1.2.1.9. Pressurized preparations 1.2.1.10. Radionuclide generators 1.2.1.11. Semi-solids 1.2.1.12. Suppositories 1.2.1.13. Tablets 1.2.1.14. Transdermal patches 1.2.1.15. Intraruminal devices 1.2.1.16. Veterinary premixes 1.2.1.17. Other non-sterile medicinal products        \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.2.2.******Batch certification***  |
| 1.3. | **Biological medicinal products** |
|  | ***1.3.1.*** ***Biological medicinal products***1.3.1.1. Blood products 1.3.1.2. Immunological products 1.3.1.3. Cell therapy products 1.3.1.4. Gene therapy products  1.3.1.5. Biotechnology products 1.3.1.6. Human and animals extracted products 1.3.1.7. Other biological medicinal products        \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.3.2.******Tylko certyfikacja serii***1.3.2.1. Blood products 1.3.2.2. Immunological products 1.3.2.3. Cell therapy products 1.3.2.4. Gene therapy products  1.3.2.5. Biotechnology products 1.3.2.6. Human and animals extracted products 1.3.2.7. Other biological medicinal products        \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1.4. | **Other products or processing activity (other item not covered by the manufacture of the above range, in particular sterilization of active substances, the manufacture of biological active starting materials, herbal medicinal products or medicinal products, homeopathic products in bulk or total production).** |
|  | ***1.4.1.******Manufacturing of:*** 1.4.1.1. Herbal products  1.4.1.2. Homeopathic products  1.4.1.3. Biologically active starting materials  1.4.1.4. Other  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.4.2.******Sterilisation of active substances/excipients/finished product:*** 1.4.2.1. Filtration  1.4.2.2. Dry heat  1.4.2.3. Most heat  1.4.2.4. Chemical  1.4.2.5. Gamma irradiation  1.4.2.6. Electron beam ***1.4.3. Other***       ­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1.5. | **Packaging** |
|  | ***1.5.1.******Primary packaging*** 1.5.1.1. Capsules, hard shell  1.5.1.2. Capsules, soft shell  1.5.1.3. Chewing gums  1.5.1.4. Impregnated matrices  1.5.1.5. Liquids for external use  1.5.1.6. Liquids for internal use  1.5.1.7. Medicinal gases  1.5.1.8. Other solid dosage forms  1.5.1.9. Pressurized preparations  1.5.1.10. Radionuclide generators  1.5.1.11. Semi-solids  1.5.1.12. Suppositories  1.5.1.13. Tablets  1.5.1.14. Transdermal patches  1.5.1.15. Intraruminal devices  1.5.1.16. Veterinary premixes  1.5.1.17. Other non-sterile medicinal products      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.5.2. Secondary packaging***  |
| 1.6. | **Quality control testing** |
|  | 1.6.1. Microbiological: sterility 1.6.2. Microbiological: non-sterility 1.6.3. Chemical-physical  1.6.4. Biological   |

**INFORMATION ON THE SCOPE OF MANUFACTURING AND THE TYPE OF INVESTIGATIONAL MEDCINAL PRODUCT**

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| --- |
|  Manufacturing of investigational medicinal products for hunam use  Investigational medicinal products phase I, II, III |

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| --- |
| **1. Manufacturnig operations** |

|  |  |
| --- | --- |
| 1.1. | Sterile investigational medicinal products |
|  | ***1.1.1.******Asepticaly prepared***1.1.1.1. Large volume liquids 1.1.1.2. Lyophilisates 1.1.1.3. Semi-soilds 1.1.1.4. Small volume liquids 1.1.1.5. Solids and implants 1.1.1.6. Other asepticaly prepared products      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.1.2.******Terminally sterilised***1.1.2.1. Large volume liquids 1.1.2.2. Semi-solids 1.1.2.3. Small valume liquids 1.1.2.4. Solids and implants 1.1.2.5. Other terminalny sterilised prepared products      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.1.3.******Batch certification***   |
| 1.2. | **Non-sterile investigational medcinal products** |
|  | ***1.2.1.******Non-sterile products***1.2.1.1. Capsules, hard shell 1.2.1.2. Capsules, soft shell 1.2.1.3. Chewing gums 1.2.1.4. Impregnated matrices 1.2.1.5. Liquids for external use 1.2.1.6. Liquids for internal use 1.2.1.7. Medicinal gases 1.2.1.8. Other solid dosage forms 1.2.1.9. Pressurized preparations 1.2.1.10. Radionuclide generators 1.2.1.11. Semi-solids 1.2.1.12. Suppositories 1.2.1.13. Tablets 1.2.1.14. Transdermal patches 1.2.1.15. Intraruminal devices 1.2.1.16. Veterinary premixes  1.2.1.17. Other non-sterile medicinal products ***1.2.2.******Batch certification***   |
| 1.3. | **Biological investigational medicinal products** |
|  | ***1.3.1.*** ***Biological medicinal products***  1.3.1.1. Blood products 1.3.1.2. Immunological products 1.3.1.3. Cell therapy products 1.3.1.4. Gene therapy products 1.3.1.5. Biotechnology products 1.3.1.6. Human and animals extracted products 1.3.1.7. Other biological medicinal products       \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.3.2.******Batch certification***   1.3.2.1. Blood products 1.3.2.2. Immunological products 1.3.2.3. Cell therapy products 1.3.2.4. Gene therapy products 1.3.2.5. Biotechnology products 1.3.2.6. Human and animals extracted products 1.3.2.7. Other biological medicinal products      \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 1.4. | **Other investigational medicinal products (other item not covered by the manufacture of the above range, in particular sterilization of active substances, the manufacture of biological active starting materials, herbal medicinal products or medicinal products, homeopathic products in bulk or total production).** |
|  | ***1.4.1.******Manufacturing of:*** 1.4.1.1. Herbal products  1.4.1.2. Homeopathic products  1.4.1.3. Biologically active starting materials  1.4.1.4. Other        \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.4.2.******Sterilisation of active substances/excipients/finished product:*** 1.4.2.1. Filtration   1.4.2.2. Dry heat   1.4.2.3. Most heat   1.4.2.4. Chemical   1.4.2.5. Gamma irradiation  1.4.2.6. Electron beam  ***1.4.3. Other***      ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** |
| 1.5. | Packaging |
|  | ***1.5.1.******Primary packaging*** 1.5.1.1. Capsules, hard shell  1.5.1.2. Capsules, soft shell  1.5.1.3. Chewing gums  1.5.1.4. Impregnated matrices  1.5.1.5. Liquids for external use  1.5.1.6. Liquids for internal use  1.5.1.7. Medicinal gases  1.5.1.8. Other solid dosage forms  1.5.1.9. Pressurized preparations  1.5.1.10. Radionuclide generators  1.5.1.11. Semi-solids  1.5.1.12. Suppositories  1.5.1.13. Tablets  1.5.1.14. Transdermal patches  1.5.1.15. Intraruminal devices  1.5.1.16. Veterinary premixes  1.5.1.17. Other non-sterile medicinal products        \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***1.5.2. Secondary packaging*** |
| 1.6. | **Quality control testing** |
|  | 1.6.1. Microbiological: sterility 1.6.2. Microbiological: non-sterility 1.6.3. Chemical-physical 1.6.4. Biological  |

**LIST OF MEDICINAL PRODUCTS MANUFACTRED WITHIN MANUFACTRURING SITE**

(In case of medicinal products for human use and veterinary medicinal products, fulfill the separately for both kind)

**Name of manufacturing site:**

Address:

|  |  |  |
| --- | --- | --- |
| **No.** | **Name of medicnal product** | **Number and expiry date of Marketing Authorisation** |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |
|       |       |       |

Shënim : Vlen për subjektet të cilat riaplikojnë për autorizim prodhimi

**LIST OF INVESTIGATIONL MEDICINAL PRODUCTS MANUFACTRED WITHIN MANUFACTRURING SITE**

**Name of manufacturing site:**

Address:

|  |  |
| --- | --- |
| **No.** | **Name of investigational medicinal product** |
|       |       |
|       |       |
|       |        |
|       |       |
|       |       |

Shënim : Vlen për subjektet të cilat riaplikojnë për autorizim prodhimi