State Institute for Drug Control

CERTIFICATE NUMBER: ***sukls277813/2022***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Czechia confirms the following:
The manufacturer: ***Farmak a.s.***
Site address: ***Na Vlcinci 16/3, Klasterni Hradisko, Olomouc, 779 00, Czechia***
Additional details on units inspected: ***Buildings No. 13, 22c, 23, 31, 33, 34 a 401***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012043 / LOC-100022687***

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-11-05***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Manufacture of active substance. Names of substances subject to inspection:
ADENOSINE, TESTED MICROBIOLOGICALLY AND FOR PYROGENES, CAS 58-61-7(en)
ALFUZOSIN HYDROCHLORIDE, CAS 81403-68-1(en)
BRIMONIDINE TARTRATE, CAS 70359-46-5(en)
BROMFENAC SODIUM SESQUIHYDRATE, CAS 120638-55-3(en)
BUTAMIRATE CITRATE, CAS 18109-81-4(en)
DEFERASIROX, CAS 201530-41-8(en)
DOFETILIDE, CAS 115256-11-6(en)
DOSULEPIN HYDROCHLORIDE, CAS 897-15-4(en)
DOXAZOSIN MESILATE, CAS 77883-43-3(en)
ESZOPICLONE, CAS 138729-47-2(en)
HYMECROMONE, CAS 90-33-5(en)
CHLORPROTHIXENE, CAS 113-59-7(en)
CHLORPROTHIXENE HYDROCHLORIDE, CAS 6469-93-8(en)
KETOROLAC TROMETAMOL, CAS 74103-07-4(en)
MAGNESIUM LACTATE, CAS 18917-93-6(en)
MEPHENOXALONE, CAS 70-07-5(en)
MOXONIDINE, CAS 75438-57-2(en)
N-(3-MORFOLIN-4-YLPROPYL)-4-SULFAMOYLBENZAMIDE HYDROCHLORIDE (MSBA.HCL), C AS 1073637-77-0(en)
REGADENOSON, CAS 313348-27-5(en)
REGADENOSONE MONOHYDRATE CAS 875148-45-1(en)
RILUZOLE, CAS 1744-22-5(en)
RIVAROXABAN, CAS 366789-02-8(en)
SACUBITRIL SODIUM SALT, CAS 149690-05-1(en)
SELEGILINE, CAS 14611-51-9(en)
SELEGILINE HYDROCHLORIDE, CAS 14611-52-0(en)
TIZANIDINE BASE CAS 51322-75-9(en)
TIZANIDINE HYDROCHLORIDE, CAS 64461-82-1(en)
TREAMID (XC268BG)(en)
VALSARTAN DISODIUM SALT CAS 137862-53-4(en)
WARFARIN SODIUM AMORPHOUS, CAS 129-06-6(en)
WARFARIN SODIUM CLATHRATE, CAS 67430-45-9(en)
XC-8, CAS 1464897-15-1(en)
ZILEUTON, CAS 111406-87-2(en)
ZOLPIDEM TARTRATE, CAS 99294-93-6(en)
ZOPICLONE, CAS 43200-80-2(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:ADENOSINE, TESTED MICROBIOLOGICALLY AND FOR PYROGENES, CAS 58-61-7

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation

3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:ALFUZOSIN HYDROCHLORIDE, CAS 81403-68-1

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:BRIMONIDINE TARTRATE, CAS 70359-46-5

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:BROMFENAC SODIUM SESQUIHYDRATE, CAS 120638-55-3

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:BUTAMIRATE CITRATE, CAS 18109-81-4

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:DEFERASIROX, CAS 201530-41-8

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps:

	drying, milling, micronisation, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:DOFETILIDE, CAS 115256-11-6

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:DOSULEPIN HYDROCHLORIDE, CAS 897-15-4

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:DOXAZOSIN MESILATE, CAS 77883-43-3

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:ESZOPICLONE, CAS 138729-47-2

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:HYMECROMONE, CAS 90-33-5

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)

	3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:CHLORPROTHIXENE, CAS 113-59-7

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:CHLORPROTHIXENE HYDROCHLORIDE, CAS 6469-93-8

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:KETOROLAC TROMETAMOL, CAS 74103-07-4

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates

	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:MAGNESIUM LACTATE, CAS 18917-93-6

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:MEPHENOXALONE, CAS 70-07-5

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:MOXONIDINE, CAS 75438-57-2

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, micronisation, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:N-(3-MORFOLIN-4-YLPROPYL)-4-SULFAMOYLBENZAMIDE HYDROCHLORIDE (MSBA.HCL), CAS 1073637-77-0

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:REGADENOSON, CAS 313348-27-5

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance

	3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:REGADENOSONE MONOHYDRATE CAS 875148-45-1

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:RILUZOLE, CAS 1744-22-5

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying,milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:RIVAROXABAN, CAS 366789-02-8

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:SACUBITRIL SODIUM SALT, CAS 149690-05-1

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying,milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:SELEGILINE, CAS 14611-51-9

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

	which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:SELEGILINE HYDROCHLORIDE, CAS 14611-52-0

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:TIZANIDINE BASE CAS 51322-75-9

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:TIZANIDINE HYDROCHLORIDE, CAS 64461-82-1

3.1	**Manufacture of Active Substance by Chemical Synthesis**

	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, micronization, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:TREAMID (XC268BG)

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:VALSARTAN DISODIUM SALT CAS 137862-53-4

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:WARFARIN SODIUM AMORPHOUS, CAS 129-06-6

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:WARFARIN SODIUM CLATHRATE, CAS 67430-45-9

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:XC-8, CAS 1464897-15-1

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance

	3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:ZILEUTON, CAS 111406-87-2

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:ZOLPIDEM TARTRATE, CAS 99294-93-6

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation, salt formation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, milling, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)

3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing
Active Substance:ZOPICLONE, CAS 43200-80-2	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying, sieving 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 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)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Clarifying remarks (for public users)

This certificate has been issued in connection with extinction of certificate ref. no. sukls260434/2021 issued on 03.01.2022 to the company Farmak, a.s. Na vlčinci 16/3, Klášterní Hradisko, 779 00 Olomouc. The production buildings are specified in more details in the newly issued certificate.

2022-12-19

Name and signature of the authorised person of the Competent Authority of Czechia

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State Institute for Drug Control
Tel:***Confidential***
Fax: ***Confidential***