State Institute For Drug Control

CERTIFICATE NUMBER: ***SK/017V/2023***

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 Slovakia confirms the following:
The manufacturer: ***Saneca Pharmaceuticals a.s.***
Site address: ***Nitrianska 100, Hlohovec, 920 01, Slovakia***
OMS Organisation Id. / OMS Location Id.: ***ORG-100002257*** / ***LOC-100000752***
DUNS Number: ***36-717-7816***

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 ***2023-09-28***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

Part 2

Human Medicinal Products

Manufacture of active substance. Names of substances subject to inspection:
L-ASPARTIC ACID POTASIUM MAGNESIUM SALT(en)
ATORVASTATIN CALCIUM SALT(en)
SODIUM STEARYL FUMARATE(en)
BENZYLPETHIDINE BASE(en)
FENIPENTOL(en)
PENTOXIFYLLINE(en)
ETOFYLLINE(en)
DOXAZOSIN MESYLATE(en)
TRAMADOL HYDROCHLORIDE(en)
RIVASTIGMINE HYDROGENTARTRATE(en)
DULOXETINE HYDROCHLORIDE(en)
MORPHINE SULPHATE(en)
MORPHINE BASE(en)
OXYCODONE HYDROCHLORIDE(en)
PETHIDINE HYDROCHLORIDE(en)
HYDROMORPHONE HYDROCHLORIDE(en)
CODEINE PHOSPHATE HEMIHYDRATE(en)
DIHYDROCODEINE HYDROGEN TARTRATE(en)
FENTANYL CITRATE(en)
METHADONE HYDROCHLORIDE(en)
CODEINE BASE(en)
HYDROCODONE BITARTRATE(en)
DIHYDROCODEINE PHOSPHATE(en)
NALBUPHINE HYDROCHLORIDE(en)
MIRABEGRON(en)
NALOXONE HYDROCHLORIDE DIHYDRATE(en)
NALMEFENE HYDROCHLORIDE MONOHYDRATE(en)
PHOLCODINE MONOHYDRATE(en)
RIVASTIGMINE(en)
NALTREXONE(en)
NALTREXONE HYDROCHLORIDE(en)
TRIHEXYPHENIDYL HYDROCHLORIDE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:L-ASPARTIC ACID POTASIUM MAGNESIUM SALT

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: filtration
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: filtration

	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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:ATORVASTATIN CALCIUM SALT

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: precipitation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:SODIUM STEARYL FUMARATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: precipitation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:BENZYLPETHIDINE BASE

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 3.1.4 Other: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:FENIPENTOL

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 3.1.4 Other: distillation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: filtration 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:PENTOXIFYLLINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.4 Other: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:ETOFYLLINE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.4 Other: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:DOXAZOSIN MESYLATE

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: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:TRAMADOL HYDROCHLORIDE

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: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:RIVASTIGMINE HYDROGENTARTRATE

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: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:DULOXETINE HYDROCHLORIDE

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: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:MORPHINE SULPHATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

	3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:MORPHINE BASE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.4 Other: precipitation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.1 Extraction of substance from plant source *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.2.6 Purification of extracted substance Plant *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other:

	narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:OXYCODONE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:*

	7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:PETHIDINE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:*

	7.Other: narcotic and psychotropic substance

Active Substance:HYDROMORPHONE HYDROCHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:CODEINE PHOSPHATE HEMIHYDRATE

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

	7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance
Active Substance:DIHYDROCODEINE HYDROGEN TARTRATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:*

	7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:FENTANYL CITRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation

	Special Requirements: 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance
Active Substance:METHADONE HYDROCHLORIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**

	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:CODEINE BASE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.4 Other: precipitation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:*

	7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:NALTREXONE

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 3.1.4 Other: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:HYDROCODONE BITARTRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other:

	narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:DIHYDROCODEINE PHOSPHATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.3 Salt formation / Purification steps: crystallisation *Special Requirements:*

	7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:NALBUPHINE HYDROCHLORIDE

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: centrifuging, 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

	3.6.2 Microbiological testing excluding sterility testing

Active Substance:MIRABEGRON

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 3.1.4 Other: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:NALOXONE HYDROCHLORIDE DIHYDRATE

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: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:NALMEFENE HYDROCHLORIDE MONOHYDRATE

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: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:PHOLCODINE MONOHYDRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.1.4 Other: crystallisation *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: centrifuging, drying, sieving *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) *Special Requirements:* 7.Other: narcotic and psychotropic 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) *Special Requirements:* 7.Other: narcotic and psychotropic substance
3.6	**Quality Control Testing**

	3.6.1 Physical / Chemical testing *Special Requirements:* 7.Other: narcotic and psychotropic substance 3.6.2 Microbiological testing excluding sterility testing *Special Requirements:* 7.Other: narcotic and psychotropic substance

Active Substance:RIVASTIGMINE

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 3.1.4 Other: distilation off
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: distillation 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:NALTREXONE HYDROCHLORIDE

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: centrifuging, 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 3.6.2 Microbiological testing excluding sterility testing

Active Substance:TRIHEXYPHENIDYL HYDROCHLORIDE	
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: milling/ micronisation 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 3.6.2 Microbiological testing excluding sterility testing

2023-12-13

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

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