

State Institute for Drug Control

CERTIFICATE NUMBER: **sukls240195/2019**

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: **Synthon, s.r.o.**

Site address: **Brněnská 32/čp. 597, Blansko, 678 01, Czechia**

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

Section 101 paragraph 3 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some Related Acts, as amended

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2019-05-16**, it is considered that it complies with :

- The principles of GMP for active substances³ 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.

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/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 :

ZOLEDRONIC ACID MONOHYDRATE CAS 165800-06-6(en)
ANAGRELIDE HYDROCHLORIDE MONOHYDRATE CAS 823178-43-4(en)
ANASTROZOLE CAS 120511-73-1(en)
AXITINIB CAS 319460-85-0(en)
BENDAMUSTINE HYDROCHLORIDE CAS 3543-75-7(en)
BICALUTAMIDE CAS 90357-06-5(en)
BISOPROLOL FUMARATE CAS 104344-23-2(en)
BORTEZOMIB ANHYDRATE CAS 179324-69-7(en)
CLADRIBINE CAS 4291-63-8(en)
DASATINIB CAS 302962-49-8(en)
DONEPEZIL HYDROCHLORIDE MONOHYDRATE CAS 884740-09-4(en)
ENZALUTAMIDE CAS 915087-33-1(en)
EPLERENONE CAS 107724-20-9(en)
ERLOTINIB HYDROCHLORIDE CAS 183319-69-9(en)
EVEROLIMUS CAS 159351-69-6(en) Everolimus CAS 159351-69-6(en)
EXEMESTANE CAS 107868-30-4(en)
FINGOLIMOD HYDROCHLORIDE CAS 162359-56-0(en)
FLUMAZENIL CAS 78755-81-4(en)
FLUVOXAMINE MALEATE CAS 61718-82-9(en)
GEFITINIB CAS 184475-35-2(en)
GLATIRAMER ACETATE CAS 147245-92-9(en)
GLATIRAMER ACETATE (MIXTURE WITH MANNITOL IN PROPORTION 1:2)(en)
IMATINIB MESILATE CAS 220127-57-1(en)
IVABRADINE HYDROCHLORIDE CAS 148849-67-6(en)
RACEMIC LENALIDOMIDE CAS 191732-72-6(en)
LETROZOLE CAS 112809-51-5(en)
LEVOCETIRIZINE DIHYDROCHLORIDE CAS 130018-87-0(en)
LINEZOLID CAS 165800-03-3(en)
MIRABEGRON CAS 223673-61-8(en)
MONTELUKAST SODIUM CAS 151767-02-1(en)
IBANDRONATE SODIUM (MONOHYDRATE) CAS 138926-19-9(en)
PALIPERIDONE CAS 144598-75-4(en)
PEMETREXED CAS 137281-23-3(en)
PEMETREXED DISODIUM CAS 357166-30-4(en)
POMALIDOMIDE CAS 19171-19-8(en)
PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE CAS 191217-81-9(en)
RIVASTIGMINE TARTRATE CAS 129101-54-8(en)
SEVELAMER CAS 52757-95-6(en)
SUGAMMADEX CAS 343306-79-6(en)
API INTERMEDIATE SYD980 CAS 1345681-58-4(en)
TAMSULOSIN HYDROCHLORIDE CAS 106463-17-6(en)
VALSARTAN DISODIUM CAS 137862-53-4(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : ZOLEDRONIC ACID MONOHYDRATE CAS 165800-06-6	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, drying 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 : ANAGRELIDE HYDROCHLORIDE MONOHYDRATE CAS 823178-43-4	
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
3.5	General Finishing Steps
	3.5.1 Physical processing steps : filtration using charcoal, drying, 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
Active Substance : ANASTROZOLE CAS 120511-73-1	
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 3.1.4 Other : carbonfiltration
3.5	General Finishing Steps

	3.5.1 Physical processing steps : centrifugation, drying, 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
Active Substance : AXITINIB CAS 319460-85-0	
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, washing
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying 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 : BENDAMUSTINE HYDROCHLORIDE CAS 3543-75-7	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, drying 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 : BICALUTAMIDE CAS 90357-06-5	
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 3.1.4 Other : carbonfiltration
3.5	General Finishing Steps
	3.5.1 Physical processing steps : centrifugation, drying, 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
Active Substance : BISOPROLOL FUMARATE CAS 104344-23-2	
3.5	General Finishing Steps
	3.5.1 Physical processing steps : weighing 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 : BORTEZOMIB ANHYDRATE CAS 179324-69-7	
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 3.1.4 Other : carbonfiltration
3.5	General Finishing Steps
	3.5.1 Physical processing steps : crystallization, filtration, 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 : CLADRIBINE CAS 4291-63-8	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, filtration, drying, milling, micronization 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 : DASATINIB CAS 302962-49-8	
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 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 : DONEPEZIL HYDROCHLORIDE MONOHYDRATE CAS 884740-09-4	
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 : transformation into acetate, charcoal filtration, neutralization, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying, milling 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 : ENZALUTAMIDE CAS 915087-33-1	
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, milling 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 : EPLERENONE CAS 107724-20-9	
3.5	General Finishing Steps
	3.5.1 Physical processing steps : weighing 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 : ERLOTINIB HYDROCHLORIDE CAS 183319-69-9	
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 : precipitation of final compound in form of hydrochloride, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : centrifugation, drying, milling 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 : Everolimus CAS 159351-69-6	
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 : chromatographic purification, carbonfiltration
3.5	General Finishing Steps
	3.5.1 Physical processing steps : chromatographic purification, carbonfiltration, filtration, drying, milling 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 : EXEMESTANE CAS 107868-30-4	
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 3.1.4 Other : carbonfiltration
3.5	General Finishing Steps

	3.5.1 Physical processing steps : drying, milling, micronization 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 : FINGOLIMOD HYDROCHLORIDE CAS 162359-56-0	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, drying, milling 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 : FLUMAZENIL CAS 78755-81-4	
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
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 : FLUVOXAMINE MALEATE CAS 61718-82-9	
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 : transformation into acetate, neutralization, charcoal filtration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying, milling 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 : GEFITINIB CAS 184475-35-2	
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 : GLATIRAMER ACETATE CAS 147245-92-9	
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 : filtration using charcoal, acetate formation
3.5	General Finishing Steps
	3.5.1 Physical processing steps :

	lyophilisation, 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 : GLATIRAMER ACETATE (MIXTURE WITH MANNITOL IN PROPORTION 1:2)	
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 : charcoal filtration 3.1.4 Other : ultrafiltration
3.5	General Finishing Steps
	3.5.1 Physical processing steps : lyophilisation, 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 : IMATINIB MESILATE CAS 220127-57-1	
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 : charcoal filtration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying, milling 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 : IVABRADINE HYDROCHLORIDE CAS 148849-67-6	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, drying, milling 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 : RACEMIC LENALIDOMIDE CAS 191732-72-6	
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 : centrifugation, drying, milling 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 : LETROZOLE CAS 112809-51-5	
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, micronization
	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 : LEVOCETIRIZINE DIHYDROCHLORIDE CAS 130018-87-0	
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
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, filtration, drying, milling
	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 : LINEZOLID CAS 165800-03-3	
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
	3.1.4 Other : carbonfiltration
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying, milling
	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 : MIRABEGRON CAS 223673-61-8	
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 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 : MONTELUKAST SODIUM CAS 151767-02-1	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, drying, milling 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 : IBANDRONATE SODIUM (MONOHYDRATE) CAS 138926-19-9	
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 : hydrolysis, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps :

	filtration, drying, milling 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 : PALIPERIDONE CAS 144598-75-4	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, drying, milling 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 : PEMETREXED CAS 137281-23-3	
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
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying 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 : PEMETREXED DISODIUM CAS 357166-30-4	

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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : filtration, carbonfiltration, crystallization, drying 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 : POMALIDOMIDE CAS 19171-19-8	
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 : digestion
3.5	General Finishing Steps
	3.5.1 Physical processing steps : isolation, drying, 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
Active Substance : PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE CAS 191217-81-9	
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 : carbonfiltration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : carbonfiltration, crystallization, drying, milling 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 : RIVASTIGMINE TARTRATE CAS 129101-54-8	
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 : charcoal filtration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying, milling 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 : SEVELAMER CAS 52757-95-6	
3.5	General Finishing Steps
	3.5.1 Physical processing steps : weighing 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 : SUGAMMADEX CAS 343306-79-6	
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, milling 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 : API INTERMEDIATE SYD980 CAS 1345681-58-4	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps : crystallisation, chromatography
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying 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 : TAMSULOSIN HYDROCHLORIDE CAS 106463-17-6	
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 : charcoal filtration, crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying, milling 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 CAS 137862-53-4	
3.1	Manufacture of Active Substance by Chemical Synthesis

	3.1.3 Salt formation / Purification steps : neutralisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : drying, milling 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 context of extinction of the certificate ref. no suks72906/2019, issued on 24.07.2019 to the company Synthon, s.r.o., Brněnská 32/čp. 597, 678 01 Blansko. On 09.09.2019 mistakes were found in the certificate in the name of the active substance Mirabegron CAS 223673-61-8 (incorrectly reported Mirabergon CAS 223673-61-8).

2019-09-10

Name and signature of the authorised person of the
Competent Authority of Czech Republic

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