## Regierung von Oberfranken

CERTIFICATE NUMBER : **DE\_BY\_05\_GMP\_2018\_0067** 

## CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

## Part 1

Issued following an inspection in accordance with:

Art. 111(5) of Directive 2001/83/EC as amended

Art. 80(5) of Directive 2001/82/EC as amended

The competent authority of Germany confirms the following:

The manufacturer : Excella GmbH & Co. KG

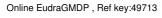
Site address: Nuernberger Str. 12, Feucht, Bayern, 90537, Germany

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC and Art. 80(1) of Directive 2001/82/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2018-05-24**, it is considered that it complies with:

• The principles of GMP for active substances <sup>3</sup> referred to in Article 47 of Directive 2001/83/EC and Article 51 of Directive 2001/82/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.



<sup>&</sup>lt;sup>1</sup> 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.

<sup>&</sup>lt;sup>2</sup> Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

<sup>&</sup>lt;sup>3</sup> These requirements fulfil the GMP recommendations of WHO.

## Part 2

**Human Medicinal Products** 

Veterinary Medicinal Products

Manufacture of active substance. Names of substances subject to inspection:

Aciclovir(en)

Aciclovir sodium(en)

Adapalene(en)

Alfuzosine hydrochloride(en)

Anastrozole(en)

Azathioprine(en)

Baclofen(en)

R-Baclofen(en)

Benzbromarone(en)

Bicalutamide(en)

Bupivacaine hydrochloride(en)

Buspirone hydrochloride(en)

Busulfan(en)

Capecitabine(en)

Cevimeline hydrochloride(en)

Deferoxamine mesylate(en)

Deracoxib(en)

Dobutamine hydrochloride(en)

Doxazosine mesylate(en)

Epinastine hydrochloride(en)

Firocoxib(en)

Ganciclovir(en)

Ganciclovir sodium(en)

Haloperidol(en)

Lanthanum carbonate(en)

Levothyroxine sodium(en)

Methotrexate(en)

Methotrexate sodium(en)

Mianserine hydrochloride(en)

Milnacipran hydrochloride(en)

Mycophenolate mofetil(en)

Parvaquone(en)

Pemetrexed sodium(en)

Plerixavor(en)

Pralatrexate sodium(en)

Rivastigmine(en)

Ropivacaine hydrochloride(en)

Tamoxifen citrate(en)

Temozolomide(en)

Timolol maleate(en)

Trazodone hydrochloride(en)

3. MA	3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Activ	Active Substance : Aciclovir	
3.1	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/Micronisation, Sifting	
	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	
3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing	
	3.6.1 Physical / Chemical testing	
	5.0.1 Physical / Chemical testing	
Activ	e Substance :Aciclovir sodium	
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, Sifting	
	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	
3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing	
3.0		
	3.6.1 Physical / Chemical testing	
Activ	e Substance :Adapalene	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.1 Manufacture of active substance intermediates	
	2.1.2 Manufacture of anyla active substance	
	3.1.2 Manufacture of crude active substance	
	3.1.3 Salt formation / Purification steps:	

	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting  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
Activ	e Substance :Alfuzosine 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:
	Drying, Milling/Micronisation, Sifting
	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
3.6	identification or traceability (lot numbering) of the active substance)
3.0	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance : Anastrozole
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, Sifting
	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
3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing
	3.6.1 Physical / Chemical testing

Activ	e Substance :Azathioprine
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, Sifting
	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
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Activ	e Substance :Baclofen
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, Sifting
	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 :R-Baclofen	
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, Sifting
	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
2.6	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance :Benzbromarone
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, Sifting
	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
Activo	e Substance :Bicalutamide
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, Sifting
	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	e Substance :Bupivacaine 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:
3.5	Kristallisation Congret Finishing Stone
3.3	General Finishing Steps
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	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
Activ	e Substance :Buspirone 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
2.5	
3.5	General Finishing Steps
3.5	General Finishing Steps  3.5.1 Physical processing steps:
3.5	General Finishing Steps  3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting
3.5	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting  3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.5	General Finishing Steps  3.5.1 Physical processing steps:
3.5	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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
3.5	3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting 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
3.5	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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
	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting  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)  Quality Control Testing
	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting  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	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting  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)  Quality Control Testing
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing
3.6	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting  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)  Quality Control Testing  3.6.1 Physical / Chemical testing
3.6	General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  e Substance :Busulfan  Manufacture of Active Substance by Chemical Synthesis
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  e Substance :Busulfan  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:
3.6 Active 3.1	3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  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
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  e Substance :Busulfan  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:
3.6 Active 3.1	3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  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
3.6 Active 3.1	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing 3.6.1 Physical / Chemical testing  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  General Finishing Steps 3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting
3.6 Active 3.1	General Finishing Steps  3.5.1 Physical processing steps:

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	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
3.5	Crystallisation Congrel Finishing Stone
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	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
Activ	e Substance :Deracoxib
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, Sifting
	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
Activ	e Substance :Dobutamine 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:
	Drying, Milling/Micronisation, Sifting
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
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	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging

	identification on tracechility (let nough enine) of the active substance)
3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing
3.0	- •
	3.6.1 Physical / Chemical testing
Active	e Substance :Doxazosine mesylate
3.1	Manufacture of Active Substance by Chemical Synthesis
3.5	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:  Crystallisation  General Finishing Steps
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	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	e Substance :Epinastine hydrochloride
3.1	Manufacture of Active Substance by Chemical Synthesis
3.5	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:  Crystallisation  General Finishing Steps
5.5	<u> </u>
3.6	3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
Active	e Substance :Firocoxib
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, Sifting
	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
	210.11 Thyoremay entermined cooling
Activ	e Substance :Ganciclovir
3.1	Manufacture of Active Substance by Chemical Synthesis
J.1	
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps:
	Crystallisation
3.5	General Finishing Steps
5.5	<u> </u>
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
5.0	
	3.6.1 Physical / Chemical testing
Activ	e Substance :Ganciclovir sodium
	Manufacture of Active Substance by Chemical Synthesis
3.1	
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
3.5	Crystallisation  General Finishing Steps
5.5	
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	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
2.6	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	e Substance :Haloperidol
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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:
2.5	Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	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
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Activ	e Substance :Lanthanum carbonate
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	3.5.1 Physical processing steps:
3.5	3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting
3.5	3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.5	3.5.1 Physical processing steps:  Drying, Milling/Micronisation, Sifting 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5	3.5.1 Physical processing steps: Drying, Milling/Micronisation, Sifting 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
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	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)
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	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  Bubstance :Levothyroxine sodium  Manufacture of Active Substance by Chemical Synthesis 3.1.1 Manufacture of active substance intermediates
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing 3.6.1 Physical / Chemical testing  Manufacture of Active Substance by Chemical Synthesis 3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  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:
3.6 Active 3.1	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  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
3.6	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  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:
3.6 Active 3.1	3.5.1 Physical processing steps:
3.6 Active 3.1	3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting 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)  Quality Control Testing  3.6.1 Physical / Chemical testing  e Substance :Levothyroxine sodium  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  General Finishing Steps  3.5.1 Physical processing steps:     Drying, Milling/Micronisation, Sifting
3.6 Active 3.1	3.5.1 Physical processing steps:

	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
3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing
	3.6.1 Physical / Chemical testing
	5.6.1 Thysical Chemical Costing
	e Substance :Methotrexate
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, Sifting
	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
	e Substance :Methotrexate sodium
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:
2.5	Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	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
	y
Activ	e Substance :Mianserine 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:
3.5	Crystallisation Congrel Finishing Stone
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	Drying, Milling/Micronisation, Sifting
	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
2.6	identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance :Milnacipran 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:
	Drying, Milling/Micronisation, Sifting
	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
Activ	e Substance :Mycophenolate mofetil
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, Sifting
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing		
3.0			
	3.6.1 Physical / Chemical testing		
Active	e Substance :Parvaquone		
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, Sifting		
	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 sodium			
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:		
4	Crystallisation		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	Drying, Milling/Micronisation, Sifting		
	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	Active Substance :Plerixavor		
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, Sifting		
	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		
	- v		
	3.6.1 Physical / Chemical testing		
Activ	Active Substance :Pralatrexate sodium		
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, Sifting		
	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		
Activ	e 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		
	3.1.3 Salt formation / Purification steps:		
	Crystallisation		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	Drying, Milling/Micronisation, Sifting		
	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		
2.6	identification or traceability (lot numbering) of the active substance)		
3.6	Quality Control Testing		

	2 (1 NL : 1/CL : 1/ /	
	3.6.1 Physical / Chemical testing	
Active Substance :Ropivacaine 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:	
	Drying, Milling/Micronisation, Sifting	
	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 :Tamoxifen citrate		
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, Sifting	
	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	
Activ	Active Substance :Temozolomide	
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, Sifting  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			
Activ	Active Substance :Timolol maleate			
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, Sifting			
	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			
2.6	identification or traceability (lot numbering) of the active substance)			
3.6	Quality Control Testing			
	3.6.1 Physical / Chemical testing			
Activ	e Substance :Trazodone 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:			
	Drying, Milling/Micronisation, Sifting			
	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			
3.6	identification or traceability (lot numbering) of the active substance)  Quality Control Testing			
	3.6.1 Physical / Chemical testing			

Clarifying remarks (for public users) The GMP Certificate also covers the manufacturing and testing of active pharmaceutical substances for use in investigational medicinal drug products. 2018-08-14 Name and signature of the authorised person of the Competent Authority of Germany Confidential Regierung von Oberfranken Tel: Confidential Fax: Confidential