Italian Medicines Agency

CERTIFICATE NUMBER: IT-API/15/H/2023

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

The competent authority of Italy confirms the following:

The manufacturer: *Farmabios S.p.A.*

Site address: Via Pavia 1, Gropello Cairoli, 27027

OMS Organisation Id. / OMS Location Id.: ORG-100011643 / LOC-100021232

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 2021-10-01, 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.

Online EudraGMDP, Ref key: 157365

Issuance Date 2023-01-20

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

 $^{^2}$ Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.

³These requirements fulfil the GMP recommendations of WHO.

Part 2

Human Medicinal Products

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

DEXAMETHASONE(en)

DIFLUCORTOLONE VALERATE(en)

FLUDROCORTISONE ACETATE(en)

PREDNISOLONE METASULFOBENZOATE SODIUM(en)

MEGESTROL ACETATE(en)

PREDNISOLONE ACETATE(en)

MELPHALAN HYDROCHLORIDE(en)

LOTEPREDNOL ETABONATE STERILE(en)

PARAMETHASONE ACETATE(en)

PREDNISOLONE-21-HEXANOATE(en)

FLUDROXYCORTIDE(en)

BETAMETHASONE DIPROPIONATE(en)

FLUPREDNIDENE ACETATE(en)

OSATERONE ACETATE(en)

FLUOCINOLONE ACETONIDE(en)

MEDROXYPROGESTERONE ACETATE(en)

BUSULFAN(en)

DELMADINONE ACETATE(en)

TRIAMCINOLONE BENETONIDE (en)

HYDROCORTISONE HYDROGEN SUCCINATE(en)

LOTEPREDNOL ETABONATE(en)

HALCINONIDE(en)

BECLOMETASONE DIPROPIONATE MONOHYDRATE(en)

BUDESONIDE STERILE(en)

DESONIDE(en)

HALOMETASONE MONOHYDRATE(en)

AMCINONIDE(en)

BUDESONIDE(en)

FLUOCINONIDE(en)

FLUOROMETHOLONE(en)

FORMOTEROL FUMARATE DIHYDRATE(en)

HYDROCORTISONE ACETATE(en)

MOMETASONE FUROATE(en)

PREDNICARBATE(en)

CLOBETASOL PROPIONATE(en)

CLOBETASONE BUTYRATE(en)

HYDROCORTISONE ACETATE STERILE(en)

DIFLORASONE DIACETATE(en)

BETAMETHASONE VALERATE(en)

FLUMETASONE PIVALATE(en)

FLUNISOLIDE HEMIHYDRATE(en)

FLUTICASONE PROPIONATE(en)

METHYLPREDNISOLONE ACEPONATE(en)

URSODEOXYCHOLIC ACID(en)

PREDNISOLONE ACETATE STERILE(en)

CANNABIDIOL (SYNTHETIC)(en)

DESOXIMETASONE(en)

FLUNISOLIDE(en)

SALMETEROL XINAFOATE(en)

DIFLORASONE(en)

TRIAMCINOLONE ACETONIDE STERILE(en)

NORURSODEOXYCHOLIC ACID(en)

CYSTEAMINE BITARTRATE MONOHYDRATE(en)

CHLORMADINONE ACETATE(en)

DIFLUPREDNATE(en)

FLUDROCORTISONE(en)

PREDNISOLONE 17-VALERATE 21-ACETATE(en)

TIROFIBAN HYDROCHLORIDE MONOHYDRATE(en)

TRIAMCINOLONE(en)

MEDROXYPROGESTERONE ACETATE STERILE(en)

CLOCORTOLONE PIVALATE(en)

BECLOMETASONE DIPROPIONATE(en)

FLUMETASONE(en)

METHYLPREDNISOLONE ACETATE STERILE(en)

ISOPROTERENOL HYDROCHLORIDE(en)

DESONIDE DISODIUM PHOSPHATE(en)

EXEMESTANE(en)

FLUTICASONE FUROATE(en)

TRIAMCINOLONE HEXACETONIDE(en)

FULVESTRANT(en)

METHYLTESTOSTERONE(en)

TRIAMCINOLONE ACETONIDE(en)

TRIAMCINOLONE DIACETATE(en)

CYPROTERONE ACETATE(en)

BECLOMETASONE DIPROPIONATE STERILE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: DEXAMETHASONE

11001		
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.3 Salt formation / Purification steps:	
	crystallisation	
	3.1.2 Manufacture of crude active substance	
	Special Requirements:	
	7.Other:	
	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps:	
	drying	
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:DIFLUCORTOLONE VALERATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	drying Ovality Control Testing
3.0	Quality Control Testing
	3.6.1 Physical / Chemical testing
A atir	e Substance:FLUDROCORTISONE ACETATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	7.Other: Other: Hormones or substances with hormonal activity
	Other: Hormones or substances with hormonal activity
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:

3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
l	
Activ	e Substance:PREDNISOLONE METASULFOBENZOATE SODIUM
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
3.0	
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:MEGESTROL ACETATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	drying,micronisation Ouglity Control Testing
3.0	Quality Control Testing
	3.6.1 Physical / Chemical testing

Activ	e Substance:PREDNISOLONE ACETATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps: drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:MELPHALAN HYDROCHLORIDE
2.1	
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1	3.1.2 Manufacture of crude active substance
3.1	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.1	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements:
5.1	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other:
5.1	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic
3.1	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps:
3.1	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing Steps
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance)
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying Quality Control Testing
3.5	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying Quality Control Testing 3.6.4 Biological Testing
3.5	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying Quality Control Testing

3.1	Manufacture of Active Substance by Chemical Synthesis		
3.1	3.1.2 Manufacture of crude active substance		
	3.1.1 Manufacture of active substance intermediates		
	Special Requirements:		
	7.Other:		
	Other: Hormones or substances with hormonal activity		
	3.1.3 Salt formation / Purification steps:		
	crystallisation		
3.4	Manufacture of sterile Active Substance		
	3.4.1 Aseptically prepared		
3.5	General Finishing 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		
	identification or traceability (lot numbering) of the active substance)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
	3.5.1 Physical processing steps:		
	drying, micronisation		
3.6	Quality Control Testing		
	3.6.3 Microbiological testing including sterility testing		
	3.6.1 Physical / Chemical testing		
Activ	Active Substance:PARAMETHASONE ACETATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.3 Salt formation / Purification steps:		
	crystallisation		
	3.1.2 Manufacture of crude active substance		
	3.1.1 Manufacture of active substance intermediates		
	Special Requirements:		
	7.Other:		
	Other: Hormones or substances with hormonal activity		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	drying		
	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)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
3.6	which is in direct contact with the substance) Quality Control Testing		
3.0	Zuming Control Leading		
	2.6.1 Physical / Chamical testing		
	3.6.1 Physical / Chemical testing		
Activ	3.6.1 Physical / Chemical testing e Substance:PREDNISOLONE-21-HEXANOATE		

	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:FLUDROXYCORTIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:BETAMETHASONE DIPROPIONATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
	crystallisation
	Special Requirements:
	7.Other:

	Other: Hormones or substances with hormonal activity
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying,micronisation
3.6	Quality Control Testing
	3.6.4 Biological Testing
	3.6.1 Physical / Chemical testing
	y and the second
Activ	e Substance:FLUPREDNIDENE ACETATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
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	3.5.1 Physical processing steps:
	3.5.1 Physical processing steps: drying
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	3.5.1 Physical processing steps: drying 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
	3.5.1 Physical processing steps: drying 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 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.6	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing
	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing
	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing
Activ	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing
Activ	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:OSATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis
Activ	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:OSATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance
Activ	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:OSATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
Activ	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:OSATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements:
Activ	3.5.1 Physical processing steps:
Activ	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing 8 Substance:OSATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity
Activ	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:OSATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
Activ 3.1	3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:OSATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation

. !	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	5.0.1 Thysical / Chemical testing
Activ	e Substance:FLUOCINOLONE ACETONIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
• 1	drying micronication
3.6	drying, micronisation Quality Control Testing
3.6	Quality Control Testing
3.6	
	Quality Control Testing 3.6.1 Physical / Chemical testing
	Quality Control Testing
	Quality Control Testing 3.6.1 Physical / Chemical testing
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements:
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other:
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
Activo	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing Steps
Activo	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing Steps 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
Activo	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance)
Activ	3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
Activ	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:MEDROXYPROGESTERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance)

	drying,micronisation	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Activ	Active Substance:BUSULFAN	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.2 Manufacture of crude active substance	
	3.1.1 Manufacture of active substance intermediates	
	Special Requirements:	
	7.Other:	
	Other: Cytotoxic	
	3.1.3 Salt formation / Purification steps:	
	crystallisation	
3.5	General Finishing 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	
	identification or traceability (lot numbering) of the active substance)	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
	3.5.1 Physical processing steps:	
2.6	drying	
3.6	Quality Control Testing	
	3.6.4 Biological Testing	
	3.6.2 Microbiological testing excluding sterility testing	
	3.6.1 Physical / Chemical testing	
A otiv	e Substance:DELMADINONE ACETATE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.2 Manufacture of crude active substance	
	3.1.1 Manufacture of active substance intermediates	
	Special Requirements:	
	7.Other:	
	Other: Hormones or substances with hormonal activity	
	3.1.3 Salt formation / Purification steps:	
3.5	crystallisation General Finishing Steps	
3.3		
	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)	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
	3.5.1 Physical processing steps:	
3.6	drying Quality Control Testing	
.7.0	CHIAMICA COMPONICATION	

	3.6.1 Physical / Chemical testing
A -4:	- Calada a catella MCINOLONE DENETONIDE
	e Substance:TRIAMCINOLONE BENETONIDE Manufacture of Active Substance by Chamical Suntherin
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation 3.1.2 Manufacture of crude active substance
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	,
Activ	e Substance:HYDROCORTISONE HYDROGEN SUCCINATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
3.5	crystallisation Conord Finishing Stone
3.3	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:LOTEPREDNOL ETABONATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps: crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying **Quality Control Testing** 3.6 3.6.1 Physical / Chemical testing Active Substance: HALCINONIDE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation 3.5 **General Finishing Steps** 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying **Quality Control Testing** 3.6 3.6.1 Physical / Chemical testing Active Substance:BECLOMETASONE DIPROPIONATE MONOHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation **General Finishing Steps** 3.5 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

which is in direct contact with the substance)

	3.5.1 Physical processing steps:
•	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:BUDESONIDE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
	crystallisation
3.4	Manufacture of sterile Active Substance
	3.4.1 Aseptically prepared
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	drying, micronisation Quality Control Testing
3.0	3.6.1 Physical / Chemical testing
	5.6.1 Physical / Chemical testing
Activ	e Substance:DESONIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
	·J

3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:HALOMETASONE MONOHYDRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
2.5	crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
2.6	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:AMCINONIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Re <mark>qu</mark> irements: 7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:BUDESONIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
2.5	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance:FLUOCINONIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
2.5	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance) 3.5.1 Physical processing steps:
	drying micronisation
3.6	drying,micronisation Ouality Control Testing
3.6	Quality Control Testing
3.6	
	Quality Control Testing
	Quality Control Testing 3.6.1 Physical / Chemical testing
Active	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:FLUOROMETHOLONE Manufacture of Active Substance by Chemical Synthesis
Active	Quality Control Testing 3.6.1 Physical / Chemical testing e Substance:FLUOROMETHOLONE

	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
2.5	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	Quality Control Testing
3.0	
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
A ativ	e Substance:FORMOTEROL FUMARATE DIHYDRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps:
	crystallisation
	<u>-</u>
3.5	General Finishing Steps
3.5	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
3.5	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	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)
3.5	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.5	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5	3.5.3 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying Quality Control Testing
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying Quality Control Testing 3.6.1 Physical / Chemical testing
3.6	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6 Active 3.1	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6 Active 3.1	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6 Active 3.1	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6 Active 3.1	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6 Active 3.1	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:

	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
	3.6.1 Physical / Chemical testing
Activ	e Substance:MOMETASONE FUROATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	Quality Control results
	3.6.1 Physical / Chemical testing e Substance: PREDNICARBATE
	3.6.1 Physical / Chemical testing
Activ	3.6.1 Physical / Chemical testing e Substance: PREDNICARBATE
Activ	3.6.1 Physical / Chemical testing e Substance: PREDNICARBATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
Activ 3.1	3.6.1 Physical / Chemical testing E Substance: PREDNICARBATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
Activ 3.1	a.6.1 Physical / Chemical testing e Substance:PREDNICARBATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
Activ 3.1 3.5	3.6.1 Physical / Chemical testing E Substance: PREDNICARBATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying

Active 3.1	e Substance: CLOBETASOL PROPIONATE Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
Active	3.6.1 Physical / Chemical testing e Substance:CLOBETASONE BUTYRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance:HYDROCORTISONE ACETATE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:

	7.Other:
	Other: Hormones or substances with hormonal activity
3.4	Manufacture of sterile Active Substance
	3.4.1 Aseptically prepared
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.3 Microbiological testing including sterility testing 3.6.1 Physical / Chemical testing
Active	e Substance:DIFLORASONE DIACETATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps:
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	,
3.6	3.5.1 Physical processing steps: drying
	3.5.1 Physical processing steps: drying Quality Control Testing 3.6.2 Microbiological testing excluding sterility testing
	3.5.1 Physical processing steps: drying Quality Control Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing
Active	3.5.1 Physical processing steps: drying Quality Control Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing Substance:BETAMETHASONE VALERATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation Special Requirements: 7.Other:
Active	3.5.1 Physical processing steps: drying Quality Control Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing Substance:BETAMETHASONE VALERATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation Special Requirements:

	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying,micronisation
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.0.1 Thysical / Chemical testing
Activ	e Substance:FLUMETASONE PIVALATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	~ ~ · · · · · · · · · · · · · · · · ·
	2.6.1 Dhysical / Chamical testing
	3.6.1 Physical / Chemical testing
A ativ	
Active	3.6.1 Physical / Chemical testing e Substance:FLUNISOLIDE HEMIHYDRATE
Active 3.1	
	e Substance:FLUNISOLIDE HEMIHYDRATE
	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis
	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance
	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other:
	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity
	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity
3.1	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing Steps
3.1	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing Steps 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
3.1	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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
3.1	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance)
3.1	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.1	e Substance:FLUNISOLIDE HEMIHYDRATE Manufacture of Active Substance by Chemical Synthesis 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance)

2.6	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:FLUTICASONE PROPIONATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:MIVACURIUM CHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.4 Biological Testing3.6.2 Microbiological testing excluding sterility testing3.6.1 Physical / Chemical testing
Activ	e Substance:METHYLPREDNISOLONE ACEPONATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying,micronisation
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:URSODEOXYCHOLIC ACID
3.2	Extraction of Active Substance from Natural Sources
	3.2.6 Purification of extracted substance
	Animal
	3.2.5 Modification of extracted substance
	Animal
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying,micronisation
3.6	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:PREDNISOLONE ACETATE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	Ci y Starrisation
	3.1.2 Manufacture of crude active substance

	7.Other:
	Other: Hormones or substances with hormonal activity
3.4	Manufacture of sterile Active Substance
	3.4.1 Aseptically prepared
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
2.6	drying,micronisation
3.6	Quality Control Testing
	3.6.3 Microbiological testing including sterility testing
	3.6.1 Physical / Chemical testing
A ation	Substance CANNADIDIOI (SVNTHETIC)
	e Substance:CANNABIDIOL (SYNTHETIC)
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance
3.5	3.1.1 Manufacture of active substance intermediates General Finishing Steps
3.3	
	3.5.1 Physical processing steps:
	drying 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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance:DESOXIMETASONE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
	3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other:
	 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity
	3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
3.5	3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:

	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	5.0.1 Thysical / Chemical testing
Activ	e Substance:FLUNISOLIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	d <mark>ryin</mark> g Quality Control Testing
3.0	7 7
	3.6.1 Physical / Chemical testing
l	G. L. GALLACTED OF MINATO ATE
Activ	e Substance:SALMETEROL XINAFOATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	1 3.3.2 Primary Packaging (enclosing / seamng the active substance within a nackaging material
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	which is in direct contact with the substance) Quality Control Testing

	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:DIFLORASONE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps: drying
3.6	Quality Control Testing
3.0	
	3.6.1 Physical / Chemical testing
Activ	e Substance:TRIAMCINOLONE ACETONIDE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements: 7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
1	•
3.4	crystallisation Manufacture of sterile Active Substance
3.4	crystallisation
3.4	crystallisation Manufacture of sterile Active Substance
	crystallisation Manufacture of sterile Active Substance 3.4.1 Aseptically prepared
	Crystallisation Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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
	Crystallisation Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance)
	Crystallisation Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.5	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, micronisation
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:

	3.6.3 Microbiological testing including sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:NORURSODEOXYCHOLIC ACID
3.2	Extraction of Active Substance from Natural Sources
	3.2.6 Purification of extracted substance
	Animal
	3.2.5 Modification of extracted substance
	Animal
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance: CYSTEAMINE BITARTRATE MONOHYDRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	3.1.3 Salt formation / Purification steps: crystallisation
3.1	3.1.3 Salt formation / Purification steps:
3.1	3.1.3 Salt formation / Purification steps: crystallisation
3.1	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance
	3.1.3 Salt formation / Purification steps:
	3.1.3 Salt formation / Purification steps:
	3.1.3 Salt formation / Purification steps:
	3.1.3 Salt formation / Purification steps:
	3.1.3 Salt formation / Purification steps:
	3.1.3 Salt formation / Purification steps:
	3.1.3 Salt formation / Purification steps:
	3.1.3 Salt formation / Purification steps:
3.5	3.1.3 Salt formation / Purification steps:
3.5	3.1.3 Salt formation / Purification steps:
3.5	3.1.3 Salt formation / Purification steps:
3.5 3.6 Activ	3.1.3 Salt formation / Purification steps:
3.5	3.1.3 Salt formation / Purification steps:
3.5 3.6 Activ	3.1.3 Salt formation / Purification steps:
3.5 3.6 Activ	3.1.3 Salt formation / Purification steps:

7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying,micronisation Quality Control Testing 3.6.1 Physical / Chemical testing
3.1.3 Salt formation / Purification steps:
Ceneral Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.5.1 Physical processing steps: drying,micronisation Quality Control Testing 3.6.1 Physical / Chemical testing
drying,micronisation Quality Control Testing 3.6.1 Physical / Chemical testing
Quality Control Testing 3.6.1 Physical / Chemical testing
3.6.1 Physical / Chemical testing
· ·
Substance:DIFLUPREDNATE
Substance:DIFLUPREDNATE
Manufacture of Active Substance by Chemical Synthesis
3.1.2 Manufacture of crude active substance
3.1.1 Manufacture of active substance intermediates
Special Requirements:
7.Other:
Other: Hormones or substances with hormonal activity
3.1.3 Salt formation / Purification steps:
crystallisation
General Finishing 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
identification or traceability (lot numbering) of the active substance)
3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
which is in direct contact with the substance)
3.5.1 Physical processing steps:
drying
Quality Control Testing
3.6.1 Physical / Chemical testing
Substance:FLUDROCORTISONE
Manufacture of Active Substance by Chemical Synthesis
3.1.2 Manufacture of crude active substance
3.1.1 Manufacture of active substance intermediates
Special Requirements:
7.Other:
Other: Hormones or substances with hormonal activity
3.1.3 Salt formation / Purification steps:
crystallisation
General Finishing Steps aGMDP, Ref key: 157365 Issuance Date 2023-01-20 Signatory: Confidential Page 28 of 38

3.6	Quality Control Testing
	drying
	3.5.1 Physical processing steps:
	which is in direct contact with the substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	identification or traceability (lot numbering) of the active substance)
	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)
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
3.3	
3.5	crystallisation General Finishing Steps
	3.1.3 Salt formation / Purification steps:
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Parification stans:
	3.1.2 Manufacture of crude active substance
3.1	
Activ	e Substance:TIROFIBAN HYDROCHLORIDE MONOHYDRATE Manufacture of Active Substance by Chemical Synthesis
	3.6.1 Physical / Chemical testing
3.6	Quality Control Testing
	drying
	3.5.1 Physical processing steps:
	which is in direct contact with the substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	identification or traceability (lot numbering) of the active 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
3.0	0 1
3.5	crystallisation General Finishing Steps
	3.1.3 Salt formation / Purification steps:
	Other: Hormones or substances with hormonal activity
	7.Other:
	Special Requirements:
	3.1.1 Manufacture of active substance intermediates
	3.1.2 Manufacture of crude active substance
3.1	Manufacture of Active Substance by Chemical Synthesis
Activ	e Substance:PREDNISOLONE 17-VALERATE 21-ACETATE
	3.6.1 Physical / Chemical testing
3.6	Quality Control Testing
	drying
	3.5.1 Physical processing steps:
	which is in direct contact with the substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	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)

	3.6.4 Biological Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:TRIAMCINOLONE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
3.5	crystallisation
3.3	General Finishing 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
	identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	5.612 Tily Steat / Chemical testing
Activ	e Substance:MEDROXYPROGESTERONE ACETATE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
3.5	crystallisation
3.3	General Finishing 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
	identification or traceability (lot numbering) of the active substance) 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)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.4 Biological Testing
	3.6.3 Microbiological testing including sterility testing
	3.6.1 Physical / Chemical testing

Activ	e Substance:CLOCORTOLONE PIVALATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements: 7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
2.5	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	drying Quality Control Testing
5.0	3.6.1 Physical / Chemical testing
	5.0.1 Filysical / Chemical testing
Activ	e Substance:BECLOMETASONE DIPROPIONATE
3.1	Manufacture of Active Substance by Chemical Synthesis
3.1	Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps:
3.1	3.1.3 Salt formation / Purification steps: purification
3.1	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance
3.1	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.1	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance
3.1	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements:
3.1	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other:
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps:
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 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
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 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)
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.5	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.5	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing
3.5	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing

	crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:METHYLPREDNISOLONE ACETATE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	Special Requirements: 7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps: crystallisation
3.4	Manufacture of sterile Active Substance
J. 4	
2.5	3.4.1 Aseptically prepared
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying, micronisation
3.6	Quality Control Testing
	3.6.4 Biological Testing
	3.6.3 Microbiological testing including sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:ISOPROTERENOL HYDROCHLORIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:

	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:DESONIDE DISODIUM PHOSPHATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
A 24:	e Substance:EXEMESTANE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
2.7	crystallisation
3.5	General Finishing 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
	identification or traceability (lot numbering) of the active substance)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance:FLUTICASONE FUROATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
3.6	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
	C. L. T. T. T. M. C. D. C. V. C. L. C. T. C. V. C. V. C. T. C. V. V. C. V. V. V. C.
	e Substance:TRIAMCINOLONE HEXACETONIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
3.5	crystallisation General Finishing Steps
3.3	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	motorial or container. This also includes and labelling after way and 1.1.1. and 1.1.
	material or container. This also includes any labelling of the material which could be used for
	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) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active	e Substance:FULVESTRANT
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps:
	purification
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
3.5	General Finishing Steps
	3.5.1 Physical processing steps:
	drying
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
3.6	which is in direct contact with the substance)
3.0	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Active	e Substance:METHYLTESTOSTERONE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
3.5	crystallisation General Finishing Steps
3.3	
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
2.0	drying Ovality Control Testing
3.6 Online Eu	Quality Control Testing draGMDP, Ref key: 157365 Issuance Date 2023-01-20 Signatory: Confidential Page 35 of 38

	3.6.1 Physical / Chemical testing
Activ	e Substance:TRIAMCINOLONE ACETONIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:TRIAMCINOLONE DIACETATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements:
	7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	Other: Hormones or substances with hormonal activity
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:
3.6	Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps:

	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements: 7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
3.5	General Finishing Steps
3.3	
	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)
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)
	3.5.1 Physical processing steps:
3.6	drying Quality Control Testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:BECLOMETASONE DIPROPIONATE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
	Special Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	11.
2.4	Crystallisation Manufacture of starile Active Substance
3.4	Manufacture of sterile Active Substance
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared
3.4	Manufacture of sterile Active Substance
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing Steps
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance)
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:
3.5	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, micronisation
	Manufacture of sterile Active Substance 3.4.1 Aseptically prepared General Finishing 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 identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps:

4. Other Activities - Active Substances:

Importation of: CHOLIC ACID (confidential), BETAMETHASONE (confidential), HYDROCORTISONE (confidential), METHYLPREDNISOLONE (confidential), PREDNISOLONE (confidential), TESTOSTERONE (confidential)

Clarifying remarks (for public users)

Manufactured active substances (AS) marked as confidential are for clinical use. Imported AS marked as confidential undergo further processing within the importing site. Terminal sterilization by gamma irradiation is outsourced for MEDROXYPROGESTERONE ACETATE STERILE and as an alternative even for BECLOMETASONE DIPROPIONATE STERILE. According to Italian legislation, all the sterile active substances and/or biological active substances and/or active substances deriving from human and animal tissues, organs, fluids are authorized according to art. 40 of Dir. 2001/83/EC and the production process is performed in accordance with the EU-GMP, including its Annex 1, as laid down in Dir. 2003/94/EC. On a risk-based approach, the validity of the GMP certificate for this manufacturing site is not more than 30 months from the latest general GMP inspection conducted on 2021/10/01, except for AIFA2s re-evaluation of the risk profile.

2023-01-20

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

Confidential
Agenzia Italiana del Farmaco
Tel:Confidential
Fax:Confidential

Online EudraGMDP, Ref key: 157365

Issuance Date 2023-01-20