## Italian Medicines Agency

CERTIFICATE NUMBER: IT-API/26/H/2024

# 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, Italy, GPS: 45.171068, 9.004391* 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 *2023-11-29*, it is considered that it complies with:

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

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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<sup>&</sup>lt;sup>1</sup>The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.

 $<sup>^2</sup>$ Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.

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

#### Part 2

### **Human Medicinal Products**

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

DEXAMETHASONE(en)

DESOXIMETASONE(en)

TRIAMCINOLONE DIACETATE(en)

MELPHALAN HYDROCHLORIDE(en)

FLUMETASONE(en)

TRIAMCINOLONE ESACETONIDE(en)

DESONIDE(en)

BETAMETHASONE DIPROPIONATE(en)

EXEMESTANE(en)

FLUDROCORTISONE ACETATE(en)

HYDROCORTISONE ACETATE(en)

PREDNISOLONE ACETATE STERILE(en)

DIFLUPREDNATE(en)

FLUNISOLIDE(en)

FLUOROMETHOLONE(en)

MOMETASONE FUROATE(en)

MEGESTROL ACETATE(en)

METHYLTESTOSTERONE(en)

PREDNISOLONE ACETATE(en)

PREDNISOLONE 17-VALERATE 21-ACETATE(en)

CLOBETASONE BUTYRATE(en)

HALCINONIDE(en)

BECLOMETASONE DIPROPIONATE MONOHYDRATE(en)

CLOCORTOLONE PIVALATE(en)

PREDNISOLONE-21-HEXANOATE(en)

DIFLORASONE DIACETATE(en)

HALOMETASONE MONOHYDRATE(en)

AMCINONIDE(en)

BUDESONIDE(en)

FLUPREDNIDENE ACETATE(en)

FLUNISOLIDE HEMIHYDRATE(en)

FULVESTRANT(en)

PREDNICARBATE(en)

TIROFIBAN HYDROCHLORIDE MONOHYDRATE(en)

HYDROCORTISONE ACETATE STERILE(en)

CANNABIDIOL (BY EXTRACTION)(en)

BETAMETHASONE VALERATE(en)

CHLORMADINONE ACETATE(en)

DELMADINONE ACETATE(en)

FLUDROCORTISONE(en)

OSATERONE ACETATE(en)

FLUMETASONE PIVALATE(en)

FLUTICASONE FUROATE(en)

PREDNISOLONE METASULFOBENZOATE SODIUM(en)

HYDROCORTISONE HYDROGEN SUCCINATE(en)

MEDROXYPROGESTERONE ACETATE(en)

METHYLPREDNISOLONE ACEPONATE(en)

URSODEOXYCHOLIC ACID(en)

TRIAMCINOLONE HEXACETONIDE STERILE(en)

FLUDROXYCORTIDE(en)

FLUOCINOLONE ACETONIDE(en)

FLUTICASONE PROPIONATE(en)

FORMOTEROL FUMARATE DIHYDRATE(en)

TRIAMCINOLONE(en)

TRIAMCINOLONE ACETONIDE STERILE(en)

METHYLPREDNISOLONE ACETATE STERILE(en)

NORURSODEOXYCHOLIC ACID(en)

PARAMETHASONE ACETATE(en)

DIFLUCORTOLONE VALERATE(en)

BUSULFAN(en)

SALMETEROL XINAFOATE(en)

CLOBETASOL PROPIONATE(en)

BECLOMETASONE DIPROPIONATE(en)

DESONIDE DISODIUM PHOSPHATE(en)

MIVACURIUM CHLORIDE(en)

LOTEPREDNOL ETABONATE(en)

METHYLPREDNISOLONE(en)

TRIAMCINOLONE ACETONIDE(en)

CYPROTERONE ACETATE(en)

DIFLORASONE(en)

MEDROXYPROGESTERONE ACETATE STERILE(en)

BECLOMETASONE DIPROPIONATE STERILE(en)

**BUDESONIDE STERILE(en)** 

CANNABIDIOL (SYNTHETIC)(en)

LOTEPREDNOL ETABONATE STERILE(en)

CYSTEAMINE BITARTRATE MONOHYDRATE(en)

### 3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance: DEXAMETHASONE

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Secondary Packaging (placing the sealed primary package within an outer packaging material 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 Active Substance: DESOXIMETASONE **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 3.6 **Quality Control Testing** 3.6.1 Physical / Chemical testing Active 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 **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:

2.0	drying Ouglity Control Togting
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Activo	e Substance:MELPHALAN HYDROCHLORIDE
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: drying
3.6	Quality Control Testing
Activ	3.6.4 Biological Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  e Substance:FLUMETASONE
3.1	v v
	<ul> <li>3.1.3 Salt formation / Purification steps:</li></ul>
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		
	5.0.1 Thysical / Chemical testing		
Activ	Active Substance:TRIAMCINOLONE ESACETONIDE		
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: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		
	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: drying,micronisation		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	3.6.1 Physical / Chemical testing		
Activ	3.6.1 Physical / Chemical testing e Substance:BETAMETHASONE DIPROPIONATE		

	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
	21011 Thyorean Cooling
Activo	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:
	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: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:
	Other: Hormones or substances with hormonal activity

	3.1.3 Salt formation / Purification steps:
2	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
3.0	
	3.6.1 Physical / Chemical testing
Activ	e Substance:HYDROCORTISONE ACETATE
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
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
2.6	which is in direct contact with the substance)
3.6	Quality Control 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
	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
3.4	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)
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	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	e Substance:DIFLUPREDNATE
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: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	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Active	Active Substance:FLUOROMETHOLONE		
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		
Active	e Substance:MOMETASONE FUROATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
0.1	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:		
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:		
2.5	drying		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		

Activ	Active 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	
	<ul> <li>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</li> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Activ	e Substance:METHYLTESTOSTERONE  Manufacture of Active Substance by Chemical Synthesis	
0.1	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	
3.5	General Finishing Steps	
	<ul> <li>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</li> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>	
3.6	material 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	material 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	
	material 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	
	material 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	

	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:PREDNISOLONE 17-VALERATE 21-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
3.3	<u> </u>
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material 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: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
	Other: Hormones or substances with hormonal activity  3.1.3 Salt formation / Purification steps:  IdraGMDP, Ref key: 167910 Issuance Date 2024-01-26 Signatory: Confidential Page 12 of 39

	crystallisation
3.5	General Finishing Steps
	<ul> <li>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</li> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	e Substance:HALCINONIDE
3.1	Manufacture of Active Substance by Chemical Synthesis
	<ul> <li>3.1.2 Manufacture of crude active substance</li> <li>3.1.1 Manufacture of active substance intermediates</li></ul>
3.5	General Finishing Steps
	<ul> <li>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</li> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	e Substance:BECLOMETASONE DIPROPIONATE MONOHYDRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	<ul> <li>3.1.2 Manufacture of crude active substance</li> <li>3.1.1 Manufacture of active substance intermediates</li></ul>
	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 mater which is in direct contact with the substance)  3.5.1 Physical processing steps:	ial
which is in direct contact with the substance) 3.5.1 Physical processing steps:	ial
3.5.1 Physical processing steps:	
draing	
drying	
.6 Quality Control Testing	
3.6.1 Physical / Chemical testing	
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etive Substance:CLOCORTOLONE PIVALATE	
.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	
.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)	
	i1
3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging mater	iai
which is in direct contact with the substance)	
3.5.1 Physical processing steps: drying	
.6 Quality Control Testing	
3.6.1 Physical / Chemical testing	
5.6.1 Thysicar, Chemical testing	
etive Substance:PREDNISOLONE-21-HEXANOATE	
.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	
.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 mater	ial
which is in direct contact with the substance)	•
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3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	e Substance:DIFLORASONE DIACETATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	<ul><li>3.1.2 Manufacture of crude active substance</li><li>3.1.1 Manufacture of active substance intermediates</li><li>3.1.3 Salt formation / Purification steps:</li></ul>
	crystallisation
3.5	General Finishing Steps
	<ul> <li>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</li> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>
3.6	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing
Activ	e Substance:HALOMETASONE MONOHYDRATE
3.1	Manufacture of Active Substance by Chemical Synthesis
	<ul> <li>3.1.2 Manufacture of crude active substance</li> <li>3.1.1 Manufacture of active substance intermediates</li></ul>
3.5	General Finishing Steps
	<ul> <li>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)</li> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>
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 Requirements:
	7.Other:
	Other: Hormones or substances with hormonal activity
	3.1.3 Salt formation / Purification steps:
	crystallisation
2.5	
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:BUDESONIDE
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
2.5	·
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
Active	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
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	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			
	3.6.1 Physical / Chemical testing		
Activ	Active Substance:FLUNISOLIDE HEMIHYDRATE		
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		
3.3			
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Activ	material 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	material 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)
3.6	Quality Control Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activ	e Substance:PREDNICARBATE
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
	<u> </u>
Activ	e Substance:TIROFIBAN HYDROCHLORIDE 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
	3.1.3 Salt formation / Purification steps:
3.5	crystallisation  General Finishing Steps
<b>5.</b> 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 Online Eu	Quality Control Testing         draGMDP, Ref key: 167910       Issuance Date 2024-01-26       Signatory: Confidential       Page 18 of 39

	3.6.4 Biological Testing
	3.6.2 Microbiological testing excluding sterility testing
	3.6.1 Physical / Chemical testing
Activo	e Substance:HYDROCORTISONE ACETATE STERILE
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
3.4	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
1	·
Active	e Substance:CANNABIDIOL (BY EXTRACTION)
3.2	Extraction of Active Substance from Natural Sources
	3.2.6 Purification of extracted substance
	Plant
	3.2.5 Modification of extracted substance
	Plant
	3.2.1 Extraction of substance from plant source
	3.2.7 Other:
	Cannabis sativa L, apical parts with inflorescences
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)
	which is in direct contact with the substance)
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	3.6.2 Microbiological testing excluding sterility testing	
	3.6.1 Physical / Chemical testing	
Activ	Active Substance:BETAMETHASONE VALERATE	
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:	
	3.5.1 Physical processing steps: drying,micronisation	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
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Activ	e Substance: CHLORMADINONE 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:	
	drying,micronisation	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Activ	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:
	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:FLUDROCORTISONE
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
<b>J.</b> J	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
	material 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
	e Substance:OSATERONE 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:
	drying
3.6	Quality Control Testing
	3.6.1 Physical / 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	General Finishing Steps  3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging
3.5	-
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  3.6.1 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: drying  Quality Control 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	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material 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 Activ 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:

material 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 Active Substance: FLUTICASONE FUROATE **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** Physical processing steps: 3.5.1 drying Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 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 Active 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)

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	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
<b>0.</b> 0	
	<ul><li>3.6.2 Microbiological testing excluding sterility testing</li><li>3.6.1 Physical / Chemical testing</li></ul>
	5.0.1 Thysical / Chemical testing
	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:
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
Activ	
	e Substance:MEDROXYPROGESTERONE ACETATE
Activ	e Substance:MEDROXYPROGESTERONE ACETATE  Manufacture of Active Substance by Chemical Synthesis
	e Substance:MEDROXYPROGESTERONE ACETATE  Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of crude active substance
	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
	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:
	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:
	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
	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:
	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	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
3.1	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
3.1	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
3.1	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)
3.1	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)
3.1	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
3.1	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 which is in direct contact with the substance)
3.1	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 which is in direct contact with the substance)  3.5.1 Physical processing steps:
3.5	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 which is in direct contact with the substance)  3.5.1 Physical processing steps: drying,micronisation
3.5	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 which is in direct contact with the substance)  3.5.1 Physical processing steps: drying,micronisation  Quality Control Testing

	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
	5.0.1 Thysical Chemical tooling
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
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Activ	e Substance:TRIAMCINOLONE HEXACETONIDE STERILE
3.1	Manufacture of Active Substance by Chemical Synthesis
0.1	
	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:
	Oth and Hamman and an exploitan and switch hamman all activities
Onling	Other: Hormones or substances with hormonal activity  draGMDP, Ref key: 167910 Issuance Date 2024-01-26 Signatory: Confidential Page 25 of 39

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		
2.6	which is in direct contact with the substance)		
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	Active 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)		
	9,		
	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)		
	<ul><li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li><li>3.5.1 Physical processing steps:</li></ul>		
	<ul> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>		
3.6	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	<ul> <li>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)</li> <li>3.5.1 Physical processing steps:</li></ul>		
	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		
Activ	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:		
Activ	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  e Substance:FLUOCINOLONE ACETONIDE  Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of crude active substance		
Activ	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  e Substance:FLUOCINOLONE ACETONIDE  Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates		
Activ	3.5.2 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	3.5.2 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	3.5.2 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	3.5.2 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	3.5.2 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:		
Activo 3.1	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:
	drying,micronisation
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:
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
	5.0.1 Thysical / Chemical testing
Activ	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
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

l I	3.6.1 Physical / Chemical testing		
	5.0.1 Thysical / Chemical testing		
Activo	Active 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:		
	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 Substance:TRIAMCINOLONE ACETONIDE STERILE			
Active	e Substance:TRIAMCINOLONE ACETONIDE STERILE		
Active 3.1	e Substance:TRIAMCINOLONE ACETONIDE STERILE  Manufacture of Active Substance by Chemical Synthesis		
	Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of crude active substance		
	Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates		
	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:		
	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:		
	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		
	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:		
	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:		
3.1	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		
3.1	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  Manufacture of sterile Active Substance		
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  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		
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  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		
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  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)		
3.1	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  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		
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  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)		
3.1	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  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:		
3.1	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  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)		
3.4	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  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		

	3.6.1 Physical / Chemical testing		
	5.0.1 Thysical / Chemical Coung		
Activ	Active 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:		
3.4	Crystallisation  Manufacture of sterile Active Substance		
3.4			
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: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		
2.5	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:PARAMETHASONE ACETATE		
1 1 U U V			

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	
	3.6.1 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:	
3.5	3.1.3 Salt formation / Purification steps: crystallisation	
3.5	3.1.3 Salt formation / Purification steps: crystallisation General Finishing Steps	
3.5	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	
3.5	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	3.1.3 Salt formation / Purification steps:	
3.5	3.1.3 Salt formation / Purification steps:	
3.5	3.1.3 Salt formation / Purification steps:	
	3.1.3 Salt formation / Purification steps:	
3.6	3.1.3 Salt formation / Purification steps:	
3.6	3.1.3 Salt formation / Purification steps:	
3.6	3.1.3 Salt formation / Purification steps:	
3.6	3.1.3 Salt formation / Purification steps:	

	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:	
	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	
Active	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)	
	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	
Active	e Substance:CLOBETASOL PROPIONATE	
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	
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)	

	2.5.2 Drimary Poolsosing (analoging / goaling the native substance within a necleasing material	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)	
	which is in direct contact with the substance)  3.5.1 Physical processing steps:	
3.6	drying,micronisation  Ovality Control Testing	
3.0		
	3.6.1 Physical / Chemical testing	
Active	e Substance:BECLOMETASONE DIPROPIONATE	
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 which is in direct contact with the substance)	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
A ctive	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	
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Active Substance:MIVACURIUM CHLORIDE  3.1 Manufacture of Active Substance by Chemical Synthesis  3.1.2 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 within a packaging material which is in direct contact with the substance) 3.5.1 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  3.6.2 Microbiological Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  Active Substance:I.OTEPREDNOI. FTABONATE  3.1 Manufacture of Active Substance by Chemical Synthesis  3.1.1 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  3.5.3 General Finishing Steps  3.5.3 General Finishing Steps  3.5.4 General Finishing Steps  3.5.5 Primary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance within a packaging material which is in direct contact with the substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying  3.6.1 Physical / Chemical testing		2.6.1 Dhysical / Chamical testing	
3.1. Manufacture of Active Substance by Chemical Synthesis  3.1.1 Manufacture of erude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps:		3.6.1 Physical / Chemical testing	
3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.2 Salt formation / Purification steps:	Active Substance:MIVACURIUM CHLORIDE		
3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: crystallisation  3.5.3 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  3.6.2 Quality Control Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.3 Merobiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  3.1.2 Manufacture of Active Substance by Chemical Synthesis  3.1.3 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  3.5.3 General Finishing Steps  3.5.4 Secondary Packaging (placing the sealed primary package within an outer packaging material 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  3.6.1 Physical processing steps: drying 3.6.2 Ouality Control Testing 3.6.3 Physical / Chemical testing	3.1	Manufacture of Active Substance by Chemical Synthesis	
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 within a packaging material which is in direct contact with the substance)  3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)  3.6.1 Physical processing steps: drying  3.6.2 Microbiological testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing 3.6.1 Physical / Chemical testing  Active Substance:LOTEPREDNOL ETABONATE  3.1.2 Manufacture of Active Substance by Chemical Synthesis  3.1.3 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 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		3.1.2 Manufacture of crude 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 identification or traceability (lot numbering) of the active substance within a packaging material which is in direct contact with the substance)  3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)  3.5.1 Physical processing steps:		3.1.1 Manufacture of active substance intermediates	
3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material 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 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing 3.1.1 Manufacture of Active Substance by Chemical Synthesis 3.1.2 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 ontainer. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.1 Physical processing steps: drying 3.6 Quality Control Testing 3.6.1 Physical / Chemical testing		3.1.3 Salt formation / Purification steps:	
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material 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	General Finishing Steps	
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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 3.6.2 Quality Control Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  Active Substance:LOTEPREDNOL FTABONATE  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  3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance within a packaging material which is in direct contact with the substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying  3.6.1 Physical / Chemical testing		material or container. This also includes any labelling of the material which could be used for	
which is in direct contact with the substance)  3.5.1 Physical processing steps:		identification or traceability (lot numbering) of the active substance)	
3.5.1 Physical processing steps: drying 3.6. Quality Control Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing 3.6.1 Physical / Chemical testing  Active 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  3.6.1 Physical / Chemical testing  Active Substance:METHYLPREDNISOLONE		3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
drying  3.6. Quality Control Testing  3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  Active Substance:LOTEPREDNOL ETABONATE  3.1 Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of active substance 3.1.1 Manufacture of active substance 3.1.1 Manufacture of active substance intermediates  Special Requirements: 7.0ther: 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			
3.6.4 Biological Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  Active 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: 7.0ther: 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  3.6.1 Physical / Chemical testing  Active Substance:METHYLPREDNISOLONE		3.5.1 Physical processing steps:	
3.6.4 Biological Testing 3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  Active Substance:LOTEPREDNOL ETABONATE  3.1 Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of 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  3.6.1 Quality Control Testing  3.6.1 Physical / Chemical testing		drying	
3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing  Active Substance:LOTEPREDNOL ETABONATE  3.1 Manufacture of Active Substance by Chemical Synthesis  3.1.2 Manufacture of active substance 3.1.1 Manufacture of 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	3.6	Quality Control Testing	
Active 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  3.6 Quality Control Testing  3.6.1 Physical / Chemical testing		3.6.4 Biological Testing	
Active 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  3.6 Quality Control Testing  3.6.1 Physical / Chemical testing  **Active Substance:METHYLPREDNISOLONE**			
3.1.2 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  3.6.1 Physical / Chemical testing  Active Substance: METHYLPREDNISOLONE		3.6.1 Physical / Chemical testing	
3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates  Special Requirements: 7.0ther: 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	Active	Active Substance:LOTEPREDNOL ETABONATE	
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	3.1	Manufacture of Active Substance by Chemical Synthesis	
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  3.6.1 Physical / Chemical testing  Active Substance: METHYLPREDNISOLONE		3.1.2 Manufacture of crude active substance	
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		3.1.1 Manufacture of active substance intermediates	
Other: Hormones or substances with hormonal activity  3.1.3 Salt formation / Purification steps:		Special Requirements:	
3.1.3 Salt formation / Purification steps:		7.Other:	
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3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material 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:		3.1.3 Salt formation / Purification 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		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	3.5	General Finishing 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: drying  3.6 Quality Control Testing  3.6.1 Physical / Chemical testing  Active Substance:METHYLPREDNISOLONE		3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
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 Substance:METHYLPREDNISOLONE		material or container. This also includes any labelling of the material which could be used for	
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 Substance:METHYLPREDNISOLONE		identification or traceability (lot numbering) of the active substance)	
3.5.1 Physical processing steps: drying  3.6 Quality Control Testing  3.6.1 Physical / Chemical testing  Active Substance:METHYLPREDNISOLONE		3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
3.6 Quality Control Testing  3.6.1 Physical / Chemical testing  Active Substance:METHYLPREDNISOLONE		which is in direct contact with the substance)	
3.6.1 Physical / Chemical testing  Active Substance:METHYLPREDNISOLONE		3.5.1 Physical processing steps:	
3.6.1 Physical / Chemical testing  Active Substance:METHYLPREDNISOLONE		drying	
Active Substance:METHYLPREDNISOLONE	3.6	Quality Control Testing	
		3.6.1 Physical / Chemical testing	
3.1 Manufacture of Active Substance by Chemical Synthesis	Active Substance:METHYLPREDNISOLONE		
	2.1		
3.1.3 Salt formation / Purification steps:	3.1	manufacture of receive Substance by Chemical Synthesis	
lline EudraGMDP, Ref key: 167910 Issuance Date 2024-01-26 Signatory: Confidential Page 33 of 39	3.1		

	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: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		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material 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	
	G. I. A. CVIDOTEDONE A CETATE	
	Active Substance: CYPROTERONE 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	
Online	3.1.3 Salt formation / Purification steps:	
Online Eu	draGMDP, Ref key: 167910 Issuance Date 2024-01-26 Signatory: Confidential Page 34 of 39	

	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)	
	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	
	e Substance:DIFLORASONE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	<ul> <li>3.1.2 Manufacture of crude active substance</li> <li>3.1.1 Manufacture of active substance intermediates</li></ul>	
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	Active Substance:MEDROXYPROGESTERONE ACETATE STERILE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	<ul> <li>3.1.2 Manufacture of crude active substance</li> <li>3.1.1 Manufacture of active substance intermediates</li></ul>	
	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 on the each lite (let numbering) of the eating substance)		
	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 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		
	3.0.1 Thysical / 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:		
	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)		
	which is in direct contact with the substance) 3.5.1 Physical processing steps:		
	which is in direct contact with the substance)		
3.6	which is in direct contact with the substance) 3.5.1 Physical processing steps:		
3.6	which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, micronisation		
	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: drying, micronisation  Quality Control Testing		
	which is in direct contact with the substance)  3.5.1 Physical processing steps:		
Activ	which is in direct contact with the substance)  3.5.1 Physical processing steps:		
Activ	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  e Substance:BUDESONIDE STERILE  Manufacture of Active Substance by Chemical Synthesis		
Activ	which is in direct contact with the substance)  3.5.1 Physical processing steps:		
Activ	which is in direct contact with the substance)  3.5.1 Physical processing steps:		
Activ	which is in direct contact with the substance)  3.5.1 Physical processing steps:		
Activ	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  e Substance:BUDESONIDE STERILE  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	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  e Substance:BUDESONIDE STERILE  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		
Activ	which is in direct contact with the substance)  3.5.1 Physical processing steps:		
Activ	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  e Substance:BUDESONIDE STERILE  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		

Secondary Packaging (placing the sealed primary package within an outer packaging material 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 Active 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 3.1.1 Manufacture of active substance intermediates **General Finishing Steps** 3.5 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 Substance: LOTEPREDNOL ETABONATE 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: 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** Secondary Packaging (placing the sealed primary package within an outer packaging material 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:CYSTEAMINE BITARTRATE MONOHYDRATE	
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	

3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material

4. Other Activities - Active Substances:

**Quality Control Testing** 

3.6.1 Physical / Chemical testing

3.6

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

identification or traceability (lot numbering) of the active substance)

which is in direct contact with the substance)

3.6.2 Microbiological testing excluding sterility testing

Clarifying remarks (for public users)

Imported active substances (AS) marked as confidential undergo further processing within the importing site. Terminal sterilization by gamma irradiation is outsourced for Medroxyprogesterone acetate sterile, Triamcilonone acetonide and as alternative to the sterile filtration, 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 performer 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 2023/11/29, except for AIFA's reevaluation of the risk profile.

Competent Authority of
Confidential Agenzia Italiana del Farmaco Tel:Confidential Fax:Confidential