Italian Medicines Agency

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

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:
The manufacturer: ***Farmabios S.p.A.***
Site address: ***Via Pavia 1, Gropello Cairoli, 27027***
OMS Organisation Id. / OMS Location Id.: ***ORG-100011643*** / ***LOC-100021232***

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

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-10-01***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. This certificate is valid only when presented with all pages and both Parts 1 and 2.The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

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

Part 2

Human Medicinal Products

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

DEXAMETHASONE(en)
DIFLUCORTOLONE VALERATE(en)
FLUDROCORTISONE ACETATE(en)
PREDNISOLONE METASULFOBENZOATE SODIUM(en)
MEGESTROL ACETATE(en)
PREDNISOLONE ACETATE(en)
MELPHALAN HYDROCHLORIDE(en)
LOTEPREDNOL ETABONATE STERILE(en)
PARAMETHASONE ACETATE(en)
PREDNISOLONE-21-HEXANOATE(en)
FLUDROXYCORTIDE(en)
BETAMETHASONE DIPROPIONATE(en)
FLUPREDNIDENE ACETATE(en)
OSATERONE ACETATE(en)
FLUOCINOLONE ACETONIDE(en)
MEDROXYPROGESTERONE ACETATE(en)
BUSULFAN(en)
DELMADINONE ACETATE(en)
TRIAMCINOLONE BENETONIDE(en)
HYDROCORTISONE HYDROGEN SUCCINATE(en)
LOTEPREDNOL ETABONATE(en)
HALCINONIDE(en)
BECLOMETASONE DIPROPIONATE MONOHYDRATE(en)
BUDESONIDE STERILE(en)
DESONIDE(en)
HALOMETASONE MONOHYDRATE(en)
AMCINONIDE(en)
BUDESONIDE(en)
FLUOCINONIDE(en)
FLUOROMETHOLONE(en)
FORMOTEROL FUMARATE DIHYDRATE(en)
HYDROCORTISONE ACETATE(en)
MOMETASONE FUROATE(en)
PREDNICARBATE(en)
CLOBETASOL PROPIONATE(en)
CLOBETASONE BUTYRATE(en)
HYDROCORTISONE ACETATE STERILE(en)
DIFLORASONE DIACETATE(en)
BETAMETHASONE VALERATE(en)
FLUMETASONE PIVALATE(en)
FLUNISOLIDE HEMIHYDRATE(en)
FLUTICASONE PROPIONATE(en)
MIVACURIUM CHLORIDE(en)

METHYLPREDNISOLONE ACEPONATE(en)
URSODEOXYCHOLIC ACID(en)
PREDNISOLONE ACETATE STERILE(en)
CANNABIDIOL (SYNTHETIC)(en)
DESOXIMETASONE(en)
FLUNISOLIDE(en)
SALMETEROL XINAFOATE(en)
DIFLORASONE(en)
TRIAMCINOLONE ACETONIDE STERILE(en)
NORURSODEOXYCHOLIC ACID(en)
CYSTEAMINE BITARTRATE MONOHYDRATE(en)
CHLORMADINONE ACETATE(en)
DIFLUPREDNATE(en)
FLUDROCORTISONE(en)
PREDNISOLONE 17-VALERATE 21-ACETATE(en)
TIROFIBAN HYDROCHLORIDE MONOHYDRATE(en)
TRIAMCINOLONE(en)
MEDROXYPROGESTERONE ACETATE STERILE(en)
CLOCORTOLONE PIVALATE(en)
BECLOMETASONE DIPROPIONATE(en)
FLUMETASONE(en)
METHYLPREDNISOLONE ACETATE STERILE(en)
ISOPROTERENOL HYDROCHLORIDE(en)
DESONIDE DISODIUM PHOSPHATE(en)
EXEMESTANE(en)
FLUTICASONE FUROATE(en)
TRIAMCINOLONE HEXACETONIDE(en)
FULVESTRANT(en)
METHYLTESTOSTERONE(en)
TRIAMCINOLONE ACETONIDE(en)
TRIAMCINOLONE DIACETATE(en)
CYPROTERONE ACETATE(en)
BECLOMETASONE DIPROPIONATE STERILE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance:DEXAMETHASONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging

	material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

Active Substance:DIFLUCORTOLONE VALERATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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: 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:PREDNISOLONE METASULFOBENZOATE SODIUM

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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:PREDNISOLONE ACETATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active 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

Active 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**
	3.6.4 Biological Testing 3.6.2 Microbiological testing excluding sterility 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:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, micronisation
3.6	**Quality Control Testing**
	3.6.3 Microbiological testing including sterility testing 3.6.1 Physical / Chemical testing

Active Substance:PARAMETHASONE ACETATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:PREDNISOLONE-21-HEXANOATE

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

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) 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:BETAMETHASONE DIPROPIONATE

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

	Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying,micronisation
3.6	**Quality Control Testing**
	3.6.4 Biological Testing 3.6.1 Physical / Chemical testing

Active Substance:FLUPREDNIDENE ACETATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: 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: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

Active Substance:FLUOCINOLONE ACETONIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying,micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:MEDROXYPROGESTERONE 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

Active Substance:BUSULFAN

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Cytotoxic 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: 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 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

Active Substance:TRIAMCINOLONE BENETONIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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: 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: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:HALCINONIDE

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:BECLOMETASONE DIPROPIONATE MONOHYDRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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:BUDESONIDE STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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: 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

Active Substance:HALOMETASONE MONOHYDRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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: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
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:BUDESONIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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:FLUOCINONIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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

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 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**
	3.6.1 Physical / Chemical testing

Active 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 which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:MOMETASONE FUROATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

Active 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) 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:CLOBETASONE BUTYRATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

Active Substance:DIFLORASONE DIACETATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: 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**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

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: drying,micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:FLUMETASONE PIVALATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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:FLUTICASONE PROPIONATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:MIVACURIUM CHLORIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: 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 Substance:METHYLPREDNISOLONE ACEPONATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying,micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

Active 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) 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

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
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

Active Substance:DESOXIMETASONE

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: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: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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 Substance:DIFLORASONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active Substance:TRIAMCINOLONE ACETONIDE STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, micronisation
3.6	**Quality Control Testing**
	3.6.4 Biological Testing

	3.6.3 Microbiological testing including sterility testing 3.6.1 Physical / Chemical testing

Active Substance:NORURSODEOXYCHOLIC ACID

3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance Animal 3.2.5 Modification of extracted substance Animal
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

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 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: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

Active 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

Active 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**

	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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: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**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or 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: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: 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 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:MEDROXYPROGESTERONE ACETATE STERILE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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 3.6.3 Microbiological testing including sterility testing 3.6.1 Physical / Chemical testing

Active Substance:CLOCORTOLONE PIVALATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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: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

Active Substance:FLUMETASONE

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

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: crystallisation
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, micronisation
3.6	**Quality Control Testing**
	3.6.4 Biological Testing 3.6.3 Microbiological testing including sterility testing 3.6.1 Physical / Chemical testing

Active Substance:ISOPROTERENOL HYDROCHLORIDE

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 Substance:DESONIDE DISODIUM PHOSPHATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Active 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

Active Substance:FLUTICASONE FUROATE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)
3.6	**Quality Control Testing**
	3.6.2 Microbiological testing excluding sterility testing 3.6.1 Physical / Chemical testing

Active Substance:TRIAMCINOLONE HEXACETONIDE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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:FULVESTRANT

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material 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:METHYLTESTOSTERONE

3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates *Special Requirements:* 7.Other: Other: Hormones or substances with hormonal activity 3.1.3 Salt formation / Purification steps: 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

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

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: drying
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

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 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: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) 3.5.1 Physical processing steps: drying, micronisation
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

4. Other Activities - Active Substances:
Importation of: CHOLIC ACID (confidential), BETAMETHASONE (confidential), HYDROCORTISONE (confidential), METHYLPREDNISOLONE (confidential), PREDNISOLONE (confidential), TESTOSTERONE (confidential)

Clarifying remarks (for public users)

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

2023-01-20

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

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Confidential
Agenzia Italiana del Farmaco
Tel:***Confidential***
Fax:***Confidential***