*Italian Medicines Agency*

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

# 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, 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 [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. 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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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[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)***
***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)***
***FLUOCINONIDE(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

| | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.3 Salt formation / Purification steps:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>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)<br>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<br>3.6.1 Physical / Chemical testing |

Active Substance:DESOXIMETASONE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:TRIAMCINOLONE DIACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps: |

| | |
|---|---|
| | drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:MELPHALAN HYDROCHLORIDE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Cytotoxic<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.4 Biological Testing<br>3.6.2 Microbiological testing excluding sterility testing<br>3.6.1 Physical / Chemical testing |

Active Substance:FLUMETASONE

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

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|---|---|
| | 3.6.1 Physical / Chemical testing |

Active Substance:TRIAMCINOLONE ESACETONIDE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:DESONIDE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:BETAMETHASONE DIPROPIONATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |

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|---|---|
| | 3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps:<br>crystallisation<br>*Special Requirements:*<br>7.Other:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.4 Biological Testing<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:FLUDROCORTISONE ACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity |

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|---|---|
| | 3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:HYDROCORTISONE ACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps:<br>crystallisation |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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 ACETATE STERILE

| | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.3 Salt formation / Purification steps:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>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)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.3 Microbiological testing including sterility testing<br>3.6.1 Physical / Chemical testing |

Active Substance:DIFLUPREDNATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |

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|---|---|
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:FLUOROMETHOLONE

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

Active Substance:MOMETASONE FUROATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control 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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control 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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **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<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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 17-VALERATE 21-ACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:CLOBETASONE BUTYRATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:CLOCORTOLONE PIVALATE

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

| | |
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| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:DIFLORASONE DIACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.2 Microbiological testing excluding sterility testing<br>3.6.1 Physical / Chemical testing |

Active Substance:HALOMETASONE MONOHYDRATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control 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:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:* |

| | |
|---|---|
| | 7.Other:<br>Other: Hormones or substances with hormonal activity |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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:FLUNISOLIDE HEMIHYDRATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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:<br>purification<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps: |

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| | drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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<br>3.6.1 Physical / Chemical testing |

Active Substance:PREDNICARBATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:TIROFIBAN HYDROCHLORIDE MONOHYDRATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |

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|---|---|
| | 3.6.4 Biological Testing<br>3.6.2 Microbiological testing excluding sterility testing<br>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:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.3 Microbiological testing including sterility testing<br>3.6.1 Physical / Chemical testing |
| Active Substance:CANNABIDIOL (BY EXTRACTION) | |
| **3.2** | **Extraction of Active Substance from Natural Sources** |
| | 3.2.6 Purification of extracted substance<br>Plant<br>3.2.5 Modification of extracted substance<br>Plant<br>3.2.1 Extraction of substance from plant source<br>3.2.7 Other:<br>Cannabis sativa L, apical parts with inflorescences |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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** |

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|---|---|
| | 3.6.2 Microbiological testing excluding sterility testing<br>3.6.1 Physical / Chemical testing |

Active Substance:BETAMETHASONE VALERATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.3 Salt formation / Purification steps:<br>crystallisation<br>*Special Requirements:*<br>7.Other:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:CHLORMADINONE ACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:DELMADINONE ACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |

| | |
|---|---|
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:FLUDROCORTISONE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity |

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|---|---|
| | 3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:FLUMETASONE PIVALATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:FLUOCINONIDE

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

Active Substance:MEDROXYPROGESTERONE ACETATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:METHYLPREDNISOLONE ACEPONATE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |

| | |
|---|---|
| | 3.1.3 Salt formation / Purification steps:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:URSODEOXYCHOLIC ACID

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|---|---|
| **3.2** | **Extraction of Active Substance from Natural Sources** |
| | 3.2.6 Purification of extracted substance<br>Animal<br>3.2.5 Modification of extracted substance<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.2 Microbiological testing excluding sterility testing<br>3.6.1 Physical / Chemical testing |

Active Substance:TRIAMCINOLONE HEXACETONIDE STERILE

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

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| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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** |
| | 3.6.4 Biological Testing<br>3.6.3 Microbiological testing including sterility testing<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:FLUOCINOLONE ACETONIDE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>crystallisation |
| **3.5** | **General Finishing Steps** |
| | 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging |

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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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control 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<br>3.1.1 Manufacture of active substance intermediates<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control 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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying, micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.4 Biological Testing<br>3.6.3 Microbiological testing including sterility 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<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying, micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.4 Biological Testing<br>3.6.3 Microbiological testing including sterility testing<br>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<br>Animal<br>3.2.5 Modification of extracted substance<br>Animal |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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<br>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:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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:DIFLUCORTOLONE VALERATE

| | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:* |

| | |
|---|---|
| | 7.Other:<br>Other: Cytotoxic<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.4 Biological Testing<br>3.6.2 Microbiological testing excluding sterility testing<br>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:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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<br>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<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **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:<br>purification<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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:DESONIDE DISODIUM PHOSPHATE

| | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.4 Biological Testing<br>3.6.2 Microbiological testing excluding sterility testing<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:METHYLPREDNISOLONE

| | |
|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.3 Salt formation / Purification steps: |

| | |
|---|---|
| | crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.1 Physical / Chemical testing |

Active Substance:TRIAMCINOLONE ACETONIDE

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|---|---|
| **3.1** | **Manufacture of Active Substance by Chemical Synthesis** |
| | 3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying,micronisation |
| **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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control 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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying |
| **3.6** | **Quality Control Testing** |
| | 3.6.4 Biological Testing<br>3.6.3 Microbiological testing including sterility testing<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>drying, micronisation |
| **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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)<br>3.5.1 Physical processing steps:<br>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:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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<br>3.1.1 Manufacture of active substance intermediates<br>*Special Requirements:*<br>7.Other:<br>Other: Hormones or substances with hormonal activity<br>3.1.3 Salt formation / Purification steps:<br>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)<br>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:<br>drying, micronisation |
| **3.6** | **Quality Control Testing** |
| | 3.6.3 Microbiological testing including sterility testing<br>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:<br>crystallisation<br>3.1.2 Manufacture of crude active substance<br>3.1.1 Manufacture of active substance intermediates |
| **3.5** | **General Finishing Steps** |
| | 3.5.1 Physical processing steps:<br>drying<br>3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)<br>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<br>3.6.1 Physical / Chemical testing |

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

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.***

***2024-01-26*** 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***