

Italian Medicines Agency

CERTIFICATE NUMBER: **IT-API/149/H/2020**

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: **STERLING S.P.A**

Site address: **via della Carboneria, 30, CORCIANO, 06073, Italy**

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 **2018-10-18** , it is considered that it complies with :

- The principles of GMP for active substances³ referred to in Article 47 of Directive 2001/83/EC .

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

¹ The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.

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 :

ETONOGESTREL(en)
TRILOSTANE(en)
BUDESONIDE(en)
DIENOGEST(en)
DROSPIRENONE(en)
DEFLAZACORT(en)
CHLORMADINONE ACETATE(en)
FLUTICASONE FUROATE(en)
NOMEGESTROL ACETATE(en)
CICLESONIDE(en)
MOMETASONE FUROATE(en)
ABIRATERONE ACETATE(en)
EXEMESTANE(en)
HALOBETASOL PROPIONATE(en)
FLUTICASONE PROPIONATE(en)
FULVESTRANT(en)
NORGESTIMATE(en)
FINASTERIDE(en)
MOMETASONE FUROATE MONOHYDRATE(en)
HALOMETASONE MONOHYDRATE(en)
DUTASTERIDE(en)
NORELGESTROMIN(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : ETONOGESTREL

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 <i>Special Requirements:</i> 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 : TRILOSTANE	
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 <i>Special Requirements:</i> 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 : BUDESONIDE	
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 <i>Special Requirements:</i> 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 : DIENOGEST	

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 <i>Special Requirements:</i> 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 : DROSPIRENONE	
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 <i>Special Requirements:</i> 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 : DEFLAZACORT	
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

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

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

	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
	3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates <i>Special Requirements:</i> 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 : ABIRATERONE ACETATE	
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 <i>Special Requirements:</i> 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,sieving
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

Active Substance : EXEMESTANE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates <i>Special Requirements:</i> 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 : HALOBETASOL PROPIONATE	
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 <i>Special Requirements:</i> 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 : FLUTICASONE PROPIONATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps :

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

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

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

3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance : NORELGESTROMIN	
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 <i>Special Requirements:</i> 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

4. Other Activities - Active Substances :

Importation of: 17 ALPHA-HYDROXYPROGESTERONE ACETATE (confidential), DIFLORASONE (confidential), FLUMETASONE (confidential), LEVONORGESTREL (confidential), TESTOSTERONE (confidential)

Clarifying remarks (for public users)

Imported active substances marked as confidential undergo further processing within the importing site. The Inspectorate adopted a risk-based approach for planning of inspections, therefore the validity of the GMP certificate for this manufacturing site is not more than 48 months from the last general GMP inspection, which was conducted on 2018/10/18. It will still be AIFA's right to re-evaluate the validity of the GMP certificate based on risk profile changes.

2020-08-13

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

Confidential
Italian Medicines Agency
Tel: *Confidential*
Fax: *Confidential*

EudraGMP