Italian Medicines Agency

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

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with:

Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Italy confirms the following:

The manufacturer: 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 substances ³ referred to in Article 47 of Directive 2001/83/EC.

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

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¹ The certificate referred to in paragraph 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	
	Special Requirements:	
	7. Other:	
	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	drying	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	

3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	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		
	Special Requirements:		
	7. Other:		
2.5	Other: Hormones or substances with hormonal activity		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
2.6	which is in direct contact with the substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	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 Special Requirements:		
	7. Other :		
	Other: Hormones or substances with hormonal activity		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps :		
	drying		
3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)			
			3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material
	which is in direct contact with the substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	e Substance : 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		
	Special Requirements:	
	7. Other:	
	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	drying	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
	identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
3.6	Quality Control Testing	
3.0		
	3.6.1 Physical / Chemical testing	
Activ	e Substance : DROSPIRENONE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
3.1		
	3.1.3 Salt formation / Purification steps:	
	purification 3.1.2 Manufacture of crude active substance	
	3.1.1 Manufacture of active substance intermediates	
	3.1.1 Manufacture of active substance intermediates Special Requirements:	
	3.1.1 Manufacture of active substance intermediatesSpecial Requirements:7. Other:	
3.5	 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity 	
3.5	3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps	
3.5	3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps:	
3.5	3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying	
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3.5	3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for	
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3.5	3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing	
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3.6	3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing	
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	3.1.1 Manufacture of active substance intermediates		
	Special Requirements:		
	7. Other:		
	Other: Hormones or substances with hormonal activity		
3.5	8 1		
	3.5.1 Physical processing steps :		
drying			
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
3.6	which is in direct contact with the substance)		
3.0	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Active	e Substance : CHLORMADINONE 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		
	Special Requirements:		
	7. Other:		
2.5	Other: Hormones or substances with hormonal activity		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	drying		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
	5.6.1 Thysical / Chemical testing		
Active	e Substance : FLUTICASONE 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		
	Special Requirements:		
	7. Other:		
	Other: Hormones or substances with hormonal activity		
3.5	General Finishing Steps		
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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** Physical / Chemical testing 3.6.1 Active Substance: NOMEGESTROL 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 Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity 3.5 **General Finishing Steps** Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps: drying, sieving 3.6 **Quality Control Testing** Physical / Chemical testing 3.6.1 Active Substance: CICLESONIDE 3.1 **Manufacture of Active Substance by Chemical Synthesis** 3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity 3.5 **General Finishing Steps** 3.5.1 Physical processing steps: drying Secondary Packaging (placing the sealed primary package within an outer packaging

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

material or container. This also includes any labelling of the material which could be used for

	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
3.6	which is in direct contact with the substance) Quality Control Testing	
5.0		
	3.6.1 Physical / Chemical testing	
Activ	e Substance : MOMETASONE FUROATE	
3.1	1 Manufacture of Active Substance by Chemical Synthesis	
	3.1.3 Salt formation / Purification steps :	
	purification	
	3.1.2 Manufacture of crude active substance	
	3.1.1 Manufacture of active substance intermediates	
	Special Requirements:	
	7. Other:	
2.5	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	drying	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
	identification or traceability (lot numbering) of the active substance)	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
3.6	which is in direct contact with the substance)	
	Quality Control Testing	
3.0		
3.0	3.6.1 Physical / Chemical testing	
	3.6.1 Physical / Chemical testing	
Activ	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE	
Activ	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis	
Activ	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps :	
Activ	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE 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	
Activ	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements:	
Activ	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other :	
Activo	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other : Other: Hormones or substances with hormonal activity	
Activ	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other :	
Activo	3.6.1 Physical / Chemical testing Bubstance: ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
Activo	3.6.1 Physical / Chemical testing E Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other : Other: Hormones or substances with hormonal activity 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	
Activo	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other : Other: Hormones or substances with hormonal activity 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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Activo	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps : purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other : Other: Hormones or substances with hormonal activity 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)	
Activo	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps :	
3.1 3.5	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps :	
Activo	3.6.1 Physical / Chemical testing e Substance : ABIRATERONE ACETATE Manufacture of Active Substance by Chemical Synthesis 3.1.3 Salt formation / Purification steps :	

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 Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity		
3.5			
	3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)		
3.6	Quality Control Testing		
A ativ	3.6.1 Physical / Chemical testing		
3.1	tive Substance : HALOBETASOL PROPIONATE 1 Manufacture of Active Substance by Chemical Synthesis		
3.1	Manufacture of Active Substance by Chemical Synthesis		
3.1	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other:		
3.5	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements:		
	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)		
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3.5	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance)		
3.5	3.1.3 Salt formation / Purification steps: purification 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates Special Requirements: 7. Other: Other: Hormones or substances with hormonal activity General Finishing Steps 3.5.1 Physical processing steps: drying 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) Quality Control Testing 3.6.1 Physical / Chemical testing		

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

	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
3.3		
	3.5.1 Physical processing steps :	
	drying	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
	identification or traceability (lot numbering) of the active substance)	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct content with the substance)	
3.6	which is in direct contact with the substance) Ouglity Control Testing	
5.0		
	3.6.1 Physical / Chemical testing	
Activ	e Substance : FINASTERIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.3 Salt formation / Purification steps :	
	purification	
	3.1.2 Manufacture of crude active substance	
	3.1.1 Manufacture of active substance intermediates	
	Special Requirements:	
	7. Other:	
	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	drying	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for	
	identification or traceability (lot numbering) of the active substance)	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
2.0	which is in direct contact with the substance)	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
Activ	e Substance : MOMETASONE FUROATE MONOHYDRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis	
	3.1.3 Salt formation / Purification steps :	
	purification	
	3.1.2 Manufacture of crude active substance	
	3.1.1 Manufacture of active substance intermediates	
	Special Requirements:	
	7. Other:	
	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps :	
	drying	

	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
2.6	·		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	e Substance : HALOMETASONE MONOHYDRATE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
	3.1.3 Salt formation / Purification steps :		
	purification		
	3.1.2 Manufacture of crude active substance		
	3.1.1 Manufacture of active substance intermediates		
	Special Requirements:		
	7. Other :		
	Other: Hormones or substances with hormonal activity		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps:		
	drying		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
	which is in direct contact with the substance)		
3.6	Quality Control Testing		
	3.6.1 Physical / Chemical testing		
Activ	e Substance : DUTASTERIDE		
3.1	Manufacture of Active Substance by Chemical Synthesis		
3.1	v v		
	3.1.3 Salt formation / Purification steps :		
	purification		
	3.1.2 Manufacture of crude active substance		
	3.1.1 Manufacture of active substance intermediates		
	Special Requirements:		
	7. Other:		
	Other: Hormones or substances with hormonal activity		
3.5	General Finishing Steps		
	3.5.1 Physical processing steps :		
	drying		
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging		
	material or container. This also includes any labelling of the material which could be used for		
	identification or traceability (lot numbering) of the active substance)		
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material		
Online E	which is in direct contact with the substance) draGMDP, Ref key: 99302 Issuance Date: 2020-08-13 Signatory: Confidential Page 11 of 13		
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3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	
	e 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	
	Special Requirements:	
	7. Other:	
	Other: Hormones or substances with hormonal activity	
3.5	General Finishing Steps	
	3.5.1 Physical processing steps : drying	
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging	
	material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)	
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material	
	which is in direct contact with the substance)	
3.6	Quality Control Testing	
	3.6.1 Physical / Chemical testing	

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.

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2020-08-13	Name and signature of the authorised person of the Competent Authority of Italy
	Confidential Italian Medicines Agency Tel: Confidential For Confidential

Issuance Date: 2020-08-13