



GSK

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A QUIEN CORRESPONDA

Por medio de la presente informo a ustedes, que respecto a la documentación solicitada para participar de vuestra licitación, presentamos el Certificado GMP del fabricante del principio activo obtenido de la base de datos EudraGMP, la cual es una base de datos comunitaria de autorizaciones de fabricación e importación y de certificados de Normas de Correcta Fabricación de medicamentos (GMP). EudraGMP es mantenida y administrada por EMA.

Sin otro particular, le saluda atentamente,

A handwritten signature in blue ink, appearing to read 'Antonio Morris Peralta'.

ANTONIO MORRIS PERALTA

Director Técnico

GlaxoSmithKline Chile Farmacéutica Ltda.

Medicines and Healthcare Products Regulatory Agency

CERTIFICATE NUMBER: **UK API 4 Insp GMP 4/117769-0016**

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 United Kingdom confirms the following:

The manufacturer: **GLAXOSMITHKLINE**

Site address: **COBDEN STREET, MONTROSE, DD10 8EA, United Kingdom**

Has been inspected under the national inspection programme in accordance with Art. 40 of Directive 2001/83/EC .

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 **2015-01-19** , it is considered that it complies with :

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³
- 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 EudraGMP. 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 :

ZANAMIVIR(en)

SALBUTAMOL SULPHATE(en)

LACIDIPINE(en)

FLUTICASONE PROPIONATE(en)

DUTASTERIDE(en)

CLOBETASONE BUTYRATE(en)

CLOBETASOL PROPIONATE(en)

BETAMETHASONE VALERATE(en)

BETAMETHASONE ALCOHOL(en)

ABACAVIR SULPHATE(en)

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

Active Substance : ZANAMIVIR

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

Active Substance : SALBUTAMOL SULPHATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps : Sulphate salt formation and crystallisation
3.5	General Finishing Steps
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps :

	Drying, Sieving 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance : LACIDIPINE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps : Crystallisation 3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Drying, Sieving 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material 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 : Crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Drying, Sieving 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material 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 : DUTASTERIDE	
3.1	Manufacture of Active Substance by Chemical Synthesis

	3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps : Crystallisation
3.5	General Finishing Steps
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance) 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.1 Physical processing steps : Drying
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance : CLOBETASONE BUTYRATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates 3.1.3 Salt formation / Purification steps : Crystallisation 3.1.2 Manufacture of crude active substance
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Drying, micronisation 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 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance : CLOBETASOL PROPIONATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps : Crystallisation 3.1.2 Manufacture of crude active substance 3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Drying, Sieving 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material 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 : BETAMETHASONE VALERATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.3 Salt formation / Purification steps : Crystallisation
	3.1.2 Manufacture of crude active substance
	3.1.1 Manufacture of active substance intermediates
3.5	General Finishing Steps
	3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
	3.5.1 Physical processing steps : Drying, micronisation
	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
	3.6.2 Microbiological testing excluding sterility testing
Active Substance : BETAMETHASONE ALCOHOL	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps : Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical processing steps : Drying, micronisation
	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 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
Active Substance : ABACAVIR SULPHATE	
3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture of active substance intermediates
	3.1.3 Salt formation / Purification steps :

	Crystallisation and salt formation
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

2015-03-25

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

Confidential
Medicines and Healthcare Products Regulatory Agency
Tel: **Confidential**
Fax: **Confidential**