Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK API 4 Insp GMP 4/117769-0021 [H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER*(1),(2)*

Part 1

Issued following an inspection in accordance with :
Regulation 331A of The Human Medicines Regulations 2012 (SI 2012/1916)

The competent authority of United Kingdom confirms the following :

The Manufacturer : GLAXOSMITHKLINE

Site address : GLAXOSMITHKLINE, COBDEN STREET, MONTROSE, DD10 8EA, UNITED KINGDOM

Is an active substance manufacturer that has been inspected in accordance with Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 10/11/2020 , it is considered that it complies with

- The principles of GMP for active substances referred to in Regulation B17 and C17 of the Human Medicines Regulations 2012 (SI 2012/1916)

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 MHRA-GMDP. If it does not appear, please contact the issuing authority.

- *(1) Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- *(2) These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

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

- [1000000992] ZANAMIVIR
- [1000007791] DUTASTERIDE
- [2000008220] FLUTICASONE PROPIONATE
- [4000013535] VILANTEROL TRIFENATATE
- [1000008398] ALUMINIUM PHOSPHATE
- [2000008014] CLOBETASOL PROPIONATE
- [2000008358] BETAMETHASONE VALERATE

- [2000014516] FLUTICASONE FUROATE
- [2000008013] CLOBETASONE BUTYRATE
- [1000007375] LACIDIPINE
- [2000007742] SALBUTAMOL SULPHATE
- [4000003016] ABACAVIR SULFATE

3. MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES

ZANAMIVIR

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Rehumidification, Blending, Sieving
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.2 Microbiological testing (excluding sterility testing)

DUTASTERIDE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

FLUTICASONE PROPIONATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, Sieving.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

VILANTEROL TRIFENATATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

ALUMINIUM PHOSPHATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.4 Other Inorganic sterile salt suspension
3.4	Manufacture of sterile active substance
	3.4.2 Terminally sterilised
3.5	General Finishing Steps

	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing
	3.6.3 Microbiological testing (including sterility testing)

CLOBETASOL PROPIONATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, Sieving.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

BETAMETHASONE VALERATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, micronisation.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing

	3.6.1 Physical / Chemical testing

FLUTICASONE FUROATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

CLOBETASONE BUTYRATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, micronisation.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

LACIDIPINE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.2 Manufacture Of Crude Active Substance

	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, Sieving.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

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 (eg. Crystallisation) Sulphate salt formation and crystallisation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, Sieving.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

ABACAVIR SULFATE

3.1	Manufacture of Active Substance by Chemical Synthesis
	3.1.1 Manufacture Of Active Substance Intermediates
	3.1.3 Salt Formation/Purification steps (eg. Crystallisation) Crystallisation and salt formation
3.5	General Finishing Steps
	3.5.1 Physical Processing Steps Drying, Seiving.
	3.5.2 Primary Packaging
	3.5.3 Secondary Packaging
3.6	Quality Control Testing
	3.6.1 Physical / Chemical testing

27/11/2020	Name and signature of the authorised person of the Competent Authority of United Kingdom Confidential Medicines and Healthcare products Regulatory Agency Tel : Confidential