

Medicines and Healthcare products Regulatory Agency

REGISTRATION OF MANUFACTURER, IMPORTER OR DISTRIBUTOR OF ACTIVE SUBSTANCES TO BE USED AS STARTING MATERIALS IN MEDICINAL PRODUCTS FOR HUMAN USE

Registrant Details

1. Registration Number UK API 4
2. Name or corporate name of registrant GLAXO OPERATIONS UK LIMITED
3. Permanent or legal address of registrant GLAXO OPERATIONS UK LIMITED, 79 NEW OXFORD STREET, LONDON, WC1A 1DG, UNITED KINGDOM

GLAXOSMITHKLINE, COBDEN STREET, MONTROSE, DD10 8EA, UNITED KINGDOM
4. Address(es) of site(s) where registered activities take place GLAXO OPERATIONS UK LTD (WARE) T/A GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM

GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM
5. National legal basis of registration Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916)
6. Name of responsible officer of the competent authority of the member state validating the registration Confidential
7. Date 22/07/2026

This registration form is valid only when presented with all pages. The authenticity of this registration form may be verified in MHRA-GMDP.

The registration holder referred to in section 2 shall communicate annually to the competent authority an inventory of the changes which have taken place as regards the information provided in this registration form. Any changes that may have an impact on the quality or safety of the listed active substances must be notified immediately.

SCOPE OF REGISTRATION

Name and address of the site

GLAXOSMITHKLINE, COBDEN STREET, MONTROSE, DD10 8EA, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

Active substance

ABACAVIR SULPHATE
2000005612

A	Manufacture of Active Substance by Chemical Synthesis
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	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation and salt formation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

UMECLIDINIUM BROMIDE

4000014045

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

DUTASTERIDE

1000007791

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation

E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

ROPINIROLE

1000003050

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Re-crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Milling
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

CLOBETASOL PROPIONATE

2000008014

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.

	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

BETAMETHASONE VALERATE

2000008358

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, micronisation.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

LACIDIPINE

1000007375

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FLUTICASONE FUROATE

2000014516

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

SALBUTAMOL SULPHATE

2000007742

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Sulphate salt formation and crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

FLUTICASONE PROPIONATE

2000008220

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying, Sieving.
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

VILANTEROL TRIFENATATE

4000013535

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates
	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Drying
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing

Active substance

ZANAMIVIR

1000000992

A	Manufacture of Active Substance by Chemical Synthesis
	A.1 Manufacture of Active Substance Intermediates

	A.2 Manufacture of Crude Active Substance
	A.3 Salt Formation / Purification Steps (e.g. Crystallisation) Crystallisation
E	General Finishing Steps
	E.1 Physical Processing Steps Rehumidification, Blending, Sieving
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
ABACAVIR SULPHATE (2000005612)	PIRAMAL ENTERPRISES LIMITED , SURVEY NOS. 7-70, 70/1 AND 70/2, DIGWAL VILLAGE, KOHIR MANDAL, KOHIR CROSS ROAD, SANGAREDDY DISTRICT, TELANGANA, IN-502321, INDIA	
CLOBETASOL PROPIONATE (2000008014)	SYMBIOTEC PHARMALAB PVT LIMITED , PLOT NO. 385/2 PIGDAMBER, NEAR HOTEL MASHAL, OFF A B ROAD, RAU, INDORE DISTRICT, MADHYA PRADESH, IN-453331, INDIA	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	ABACAVIR SULPHATE (2000005612)
	UMECLIDINIUM BROMIDE (4000014045)
	DUTASTERIDE (1000007791)
	ROPINIROLE (1000003050)
	CLOBETASOL PROPIONATE (2000008014)
	BETAMETHASONE VALERATE (2000008358)
	LACIDIPINE (1000007375)
	CLOBETASONE BUTYRATE (2000008013)
	FLUTICASONE FUROATE (2000014516)
	SALBUTAMOL SULPHATE (2000007742)
	FLUTICASONE PROPIONATE (2000008220)
	VILANTEROL TRIFENATATE (4000013535)
	ZANAMIVIR (1000000992)

Name and address of the site

1. MANUFACTURING OPERATIONS

Active substance

DOLUTEGRAVIR SODIUM

4000014056

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation for GW Manufacturing and Shanghai Desano Chemical
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FLUTICASONE PROPIONATE

2000008220

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

VILANTEROL TRIFENATATE

4000013535

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

FLUTICASONE FUROATE

2000014516

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

UMECLIDINIUM BROMIDE

4000014045

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

SALMETEROL XINAFOATE

2000008392

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging

F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

Active substance

CABOTEGRAVIR SODIUM

2000017021

E	General Finishing Steps
	E.1 Physical Processing Steps Micronisation
	E.2 Primary Packaging
	E.3 Secondary Packaging
F	Quality Control Testing
	F.1 Physical / Chemical testing
	F.2 Microbiological testing (excluding sterility testing)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

3rd Country Manufacturer

3rd Country Distributor

DOLUTEGRAVIR
SODIUM
(4000014056)

**SHANGHAI DESANO CHEMICAL
PHARMACEUTICAL COMPANY LIMITED, 417
BINHAI ROAD, LAOGANG TOWN, PUDONG NEW
AREA, SHANGHAI, CN 201302, CHINA**

**GLAXOWELLCOME MANUFACTURING PTE
LIMITED, 1 PIONEER SECTOR 1, JURONG,
SINGAPORE, SG-628413, SINGAPORE**

**GLAXOWELLCOME MANUFACTURING PTE
LIMITED, 1 PIONEER SECTOR 1, JURONG,
SINGAPORE, SG-628413, SINGAPORE**

**SHIONOGI PHARMACHEMICALS CO. LIMITED,
224-20, HIRAISHIEBISUNO, KAWAUCHI-CHO,
TOKUSHIMA, JP 771-0132, JAPAN**

FLUTICASONE
PROPIONATE
(2000008220)

**GLAXOWELLCOME MANUFACTURING PTE
LIMITED, 1 PIONEER SECTOR 1, JURONG,
SINGAPORE, SG-628413, SINGAPORE**

ZIDOVUDINE
(1000009208)

**APITORIA PHARMA PRIVATE LIMITED, UNIT-II,
SURVEY NO. 10 & 13, IDA, KAZIPALLY,
GADDAPOTHARAM VILLAGE, JINNARAM MANDAL,
SANGAREDDY DISTRICT, TELANGANA, IN-502319,
INDIA**

VILANTEROL TRIFENATATE (4000013535)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
LAMIVUDINE (1000003255)	MATRIX PHARMACORP PRIVATE LIMITED (UNIT 2) , C/O MATRIX PHARMACORP PRIVATE LIMITED, (UNIT 2), SURVEY NO. 10/42, GADDAPOTHARAM, KAZIPALLY INDUSTRIAL AREA, TELANGANA, SANGAREDDY DISTRICT, IN-502319, INDIA	MATRIX PHARMACORP PRIVATE LIMITED (UNIT 2) , C/O MATRIX PHARMACORP PRIVATE LIMITED, (UNIT 2), SURVEY NO. 10/42, GADDAPOTHARAM, KAZIPALLY INDUSTRIAL AREA, TELANGANA, SANGAREDDY DISTRICT, IN-502319, INDIA
	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE
FLUTICASONE FUROATE (2000014516)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
PAZOPANIB (1000011372)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
UMECLIDINIUM BROMIDE (4000014045)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
SALMETEROL XINAFOATE (2000008392)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
DAPRODUSTAT (3000018715)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
CABOTEGRAVIR SODIUM (2000017021)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	DOLUTEGRAVIR SODIUM (4000014056)
	FLUTICASONE PROPIONATE (2000008220)
	ZIDOVUDINE (1000009208)
	RILPIVIRINE HYDROCHLORIDE (2000016484)

VILANTEROL TRIFENATATE (4000013535)
 LAMIVUDINE (1000003255)
 FLUTICASONE FUROATE (2000014516)
 PAZOPANIB (1000011372)
 UMECLIDINIUM BROMIDE (4000014045)
 SALMETEROL XINAFOATE (2000008392)
 DAPRODUSTAT (3000018715)
 CABOTEGRAVIR SODIUM (2000017021)
 ABACAVIR SULFATE (4000003016)

Name and address of the site

GLAXO OPERATIONS UK LIMITED, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
FLUTICASONE FUROATE (2000014516)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
ZANAMIVIR (1000000992)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
ACICLOVIR (3000006349)	MATRIX PHARMACORP PRIVATE LIMITED (UNIT 2) , C/O MATRIX PHARMACORP PRIVATE LIMITED, (UNIT 2), SURVEY NO. 10/42, GADDAPOTHARAM, KAZIPALLY INDUSTRIAL AREA, TELANGANA, SANGAREDDY DISTRICT, IN-502319, INDIA	
HYDROCORTISONE (1000008762)	PHARMACIA & UPJOHN (PFIZER GLOBAL MANUFACTURING) , 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES	
SUMATRIPTAN SUCCINATE (2000008222)	DIVIS LABORATORIES LIMITED, UNIT 2 CHIPPADA VILLAGE , UNIT 2 CHIPPADA VILLAGE, ANNAVARAM POST, BHEEMUNIPATNAM MANDAL, VISAKHAPATNAM DISTRICT, ANDHRA PRADESH, IN-531162, INDIA	
CLINDAMYCIN PHOSPHATE (2000008016)	ZHEJIANG HISOAR PHARMACEUTICAL CO LIMITED , 1 HAIZHENG AVENUE, JIAOJIANG DISTRICT, TAIZHOU CITY, CN- 318000, CHINA ZHEJIANG HISOAR PHARMACEUTICAL CO. LIMITED , NO. 23, 5TH DONGHAI AVENUE, ZHEJIANG CHEMICAL MATERIALS BASE LINHAI ZONE, LINHAI CITY, ZHEJIANG PROVINCE, CN- 317016, CHINA	

ZIDOVUDINE (1000009208)	APITORIA PHARMA PRIVATE LIMITED , UNIT-II, SURVEY NO. 10 & 13, IDA, KAZIPALLY, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN-502319, INDIA	
HYDROUS BENZOYL PEROXIDE (2000007330)	ARKEMA INC. , 3289 GENESEE STREET, PIFFARD, 14533, UNITED STATES	
BEPIROVIRSEN (3000020981)	WUXI STA PHARMACEUTICAL CO., LIMITED. , 589 NORTH YULONG ROAD, XINBEI DISTRICT, CHANGZHOU, JIANGSU, CN- 213127, CHINA	NITTO DENKO AVECIA INC. , 125 FORTUNE BOULEVARD, MILFORD, 01757, UNITED STATES
CABOTEGRAVIR (1000017903)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
	N.V.AJINOMOTO OMNICHEM , COOPPALLAAN 91, WETTEREN, B-9230, BELGIUM	
FLUTICASONE PROPIONATE (2000008220)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B	Distribution
	FLUTICASONE FUROATE (2000014516)
	ZANAMIVIR (1000000992)
	ZIDOVUDINE (1000009208)
	FLUTICASONE PROPIONATE (2000008220)