

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

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| 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 |
| 4. Address(es) of site(s) where registered activities take place | GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM |
| | GLAXO OPERATIONS UK LTD (WARE) TA GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM |
| | GLAXOSMITHKLINE, COBDEN STREET, MONTROSE, DD10 8EA, UNITED KINGDOM |
| 5. National legal basis of registration | GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, NORTH LONSDALE ROAD, ULVERSTON, LA12 9DR, UNITED KINGDOM |
| 6. Name of responsible officer of the competent authority of the member state validating the registration | Regulation 327 of The Human Medicines Regulations 2012 (SI 2012/1916) |
| 7. Date | Confidential |
| | 17/02/2025 |

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

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, HARMIRE ROAD, BARNARD CASTLE, DL12 8DT, UNITED KINGDOM

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance	3rd Country Manufacturer	3rd Country Distributor
RANITIDINE HYDROCHLORIDE (2000007813)	GLAXOWELLCOME MANUFACTURING PTE LIMITED , 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
CLINDAMYCIN PHOSPHATE (2000008016)	ZHEIJANG 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	
SUMATRIPTAN SUCCINATE (2000008222)	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	
PARICALCITOL (1000017064)	SAFC PHARMA , 645 SCIENCE DRIVE, MADISON, 53711, UNITED STATES	
ZIDOVUDINE (1000009208)	APITORIA PHARMA PRIVATE LIMITED , UNIT-II, SURVEY NO. 10 & 13, IDA, KAZIPALLY, GADDAPOTHARAM VILLAGE, JINNARAM MANDAL, SANGAREDDY DISTRICT, TELANGANA, IN-502319, INDIA	
ACICLOVIR (3000006349)	MYLAN LABORATORIES LIMITED , UNIT 7, PLOT NO 14, 99 AND 100, PHASE II, INDUSTRIAL DEVELOPMENT AREA PASHAMYLARAM, PATANCHERU, SANGAREDDY DISTRICT, TELANGANA, IN-502 307, INDIA	
NEOMYCIN SULPHATE (2000008175)	PHARMACIA & UPJOHN (PFIZER GLOBAL MANUFACTURING) , 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES	
HYDROCORTISONE (1000008762)	PHARMACIA & UPJOHN (PFIZER GLOBAL MANUFACTURING) , 7000 PORTAGE ROAD, KALAMAZOO, 49001, UNITED STATES	
FLUTICASONE PROPIONATE (2000008220)	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	
ARGATROBAN MONOHYDRATE (2000015815)	MITSUBISHI TANABE PHARMA CORPORATION , 14 SUNAYAMA, HASAKI- MACHI, KASHIMA-GUN, IBARAKI-KEN, JP 314-0255, JAPAN	

HYDROUS BENZOYL
PEROXIDE (2000007330)

ARKEMA INC., 3289 GENESEE STREET, PIFFARD, 14533, UNITED STATES

AKZO NOBEL CHEMICALS SA DE CV, 49 AVENUE MORELOS, COL.
TECAMACHALCO, LOS REYES LA PAZ, MX-56500, MEXICO

CABOTEGRAVIR
(1000017903)

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
ZANAMIVIR (1000000992)
CLOTRIMAZOLE (1000003999)
ZIDOVUDINE (1000009208)
FLUTICASONE PROPIONATE (2000008220)
FLUTICASONE FUROATE (2000014516)

Name and address of the site

GLAXO OPERATIONS UK LTD (WARE) T/A GLAXO WELLCOME OPERATIONS, PRIORY STREET, WARE, SG12 0DJ, UNITED KINGDOM

1. MANUFACTURING OPERATIONS

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

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

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

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)

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

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

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)

2. IMPORTATION AND DISTRIBUTION OPERATIONS

A Importation

Active Substance

3rd Country Manufacturer

3rd Country Distributor

FLUTICASONE
PROPRIONATE
(2000008220)

**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	
DAPRODUSTAT (3000018715)	GLAXOWELLCOME MANUFACTURING PTE LIMITED, 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
DABRAFENIB MESYLATE (2000017501)	GLAXOWELLCOME MANUFACTURING PTE LIMITED, 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
LAMIVUDINE (1000003255)	ASTRIX LABORATORIES LIMITED, SURVEY NO 10/42 GADDAPATHARAM, KAZIPALLY, MEDAK DISTRICT, HYDERABAD, ANDHRA PRADESH, IN-502 319, INDIA	GLAXOWELLCOME MANUFACTURING PTE LIMITED, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE
VILANTEROL TRIFENATATE (4000013535)	GLAXOWELLCOME MANUFACTURING PTE LIMITED, 1 PIONEER SECTOR 1, JURONG, SINGAPORE, SG-628413, SINGAPORE	
CABOTEGRAVIR SODIUM (2000017021)	GLAXOWELLCOME MANUFACTURING PTE LIMITED, 1 PIONEER SECTOR 1, JURONG, Data Not Available, 628413, SINGAPORE	
FLUTICASONE FUROATE (2000014516)	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	

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

DOLUTEGRAVIR
SODIUM
(4000014056)

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

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

SALMETEROL
XINAFOATE
(2000008392)

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

- B Distribution
- FLUTICASONE PROPIONATE (2000008220)
 - ABACAVIR SULFATE (4000003016)
 - PAZOPANIB (1000011372)
 - UMECLIDINIUM BROMIDE (4000014045)
 - DAPRODUSTAT (3000018715)
 - FOSAMPRENAVIR (1000000423)
 - DABRAFENIB MESYLATE (2000017501)
 - LAMIVUDINE (1000003255)
 - VILANTEROL TRIFENATATE (4000013535)
 - ELTROMBOPAG OLAMINE (2000018050)
 - LAPATINIB DITOSYLATE (2000009158)
 - CABOTEGRAVIR SODIUM (2000017021)
 - FLUTICASONE FUROATE (2000014516)
 - ZIDOVUDINE (1000009208)
 - RILPIVIRINE HYDROCHLORIDE (2000016484)
 - DOLUTEGRAVIR SODIUM (4000014056)
 - SALMETEROL XINAFOATE (2000008392)

Name and address of the site

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

1. MANUFACTURING OPERATIONS

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

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

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

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

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

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

ABACAVIR SULPHATE

2000005612

A	Manufacture of Active Substance by Chemical Synthesis
	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

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

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

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**

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

CLOBETASONE
BUTYRATE (2000008013)

SYMBIOTEC PHARMALAB PVT LIMITED, PLOT NO. 385/2 PIGDAMBER, NEAR
HOTEL MASHAL, OFF A B ROAD, RAU, INDORE DISTRICT, MADHYA
PRADESH, IN-453331, INDIA

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-502 321, INDIA

2. IMPORTATION AND DISTRIBUTION OPERATIONS

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

Name and address of the site

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS, NORTH LONSDALE ROAD, ULVERSTON, LA12
9DR, UNITED KINGDOM

1. MANUFACTURING OPERATIONS**Active substance**

CEFUROXIME AXETIL
2000008117

A	Manufacture of Active Substance by Chemical Synthesis
	A.4 Other Physical form conversion from crystalline to amorphous form via spray drying
E	General Finishing Steps

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

2. IMPORTATION AND DISTRIBUTION OPERATIONS

B Distribution
 CEFUROXIME AXETIL (2000008117)