Medicines & Healthcare products Regulatory Agency

MHRA

MHRA Register of Written Confirmations For UK Active Substance Manufacturers

The information published in this document was that held by the MHRA on the date of publication.

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T 020 3080 6000 – www.mhra.gov.uk

NOTICES

The Agency’s register is computerised. Every site and every Written Confirmation has a unique number that should be quoted when enquiries are made.

NOTES FOR GUIDANCE

GENERAL

The Written Confirmations have been generated for UK Active Substance Manufacturing sites to support the export of Active Substances to the EEA.

The Written Confirmation Number is a specific number allocated to each site.

The Table of Contents contains a link to the relevant Written Confirmation for each company within this document.

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APTUIT (OXFORD) LIMITED

BASF PHARMA (CALLANISH) LIMITED

BASILDON CHEMICAL COMPANY LIMITED

BAXTER HEALTHCARE LIMITED

BAXTER HEALTHCARE LIMITED

BIO PRODUCTS LABORATORY LIMITED

BIORELIANCE LIMITED

BSPG LABORATORIES LIMITED

BSPG LABORATORIES LIMITED

CATALENT MICRON TECHNOLOGIES LIMITED

CELADON PHARMA LIMITED

CONCEPT LIFE SCIENCES INTEGRATED DISCOVERY AND DEVELOPMENT SERVICES LIMITED

COURTIN & WARNER LIMITED

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VENATOR PIGMENTS UK LIMITED
VIFOR PHARMA UK LIMITED - POTTERS DIVISION

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

6523

1. Name and address of site (including building number, where applicable):

ACRIVASTINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CANNABIDIOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

2. Manufacturer's licence number(s):

API 29350

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

09/06/2021

This written confirmation remains valid until:

09/06/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

29/06/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ZILEUTON
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SESTAMIBI
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVALBUTEROL TARTRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
OCTENIDINE DIHYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CERIUM NITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRIENTINE DIHYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FERRIC MALTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
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MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LUMACAFTOR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIROXIMEL FUMARATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ARFORMOTEROL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CODEINE PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
RACTOPAMINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVALBUTEROL HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BUPRENORPHINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIMETHYL FUMARATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TAZEMETOSTAT
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TOCERANIB PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METHOXYFLURANE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
REBOXETINE METHANESULPHONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POLIDOCANOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ILOPERIDONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

13455310

1. Name and address of site (including building number, where applicable):

ACTIVE PHARMA SUPPLIES LIMITED

UNIT 2, FORWARD INDUSTRIAL ESTATE
TALBOT ROAD
LEYLAND
PR25 2ZJ

2. Manufacturer's licence number(s):

API 42785

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

20/05/2021

This written confirmation remains valid until:

20/05/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

12/10/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

BISOPROLOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TACROLIMUS MONOHYDRATE
GENERAL FINISHING STEPS
SODIUM GLYCEROPHOSPHATE HYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DAPOXETINE HYDROCHLORIDE
GENERAL FINISHING STEPS
NADOLOL
GENERAL FINISHING STEPS
BISOPROLOL
GENERAL FINISHING STEPS
KETOPROFEN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
COAL TAR SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PYRAZINAMIDE
GENERAL FINISHING STEPS
HYDROCORTISONE ACETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DUTASTERIDE
GENERAL FINISHING STEPS
HYDROCORTISONE ACETATE
GENERAL FINISHING STEPS
CHLORHEXIDINE ACETATE
GENERAL FINISHING STEPS
MINOXIDIL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM GLYCEROPHOSPHATE HYDRATE
GENERAL FINISHING STEPS
FLUOXETINE HYDROCHLORIDE
GENERAL FINISHING STEPS
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MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PYRAZINAMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SULPHUR
GENERAL FINISHING STEPS
CARBIMAZOLE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LANSOPRAZOLE
GENERAL FINISHING STEPS
DIPYRIDAMOLE
GENERAL FINISHING STEPS
CHLOROTHIAZIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SULPHUR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

KETOPROFEN
GENERAL FINISHING STEPS
COAL TAR SOLUTION STRONG
GENERAL FINISHING STEPS
QUININE SULPHATE
GENERAL FINISHING STEPS
PILOCARPINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
RESORCINOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVOTHYROXINE SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
QUININE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DEXAMETHASONE SODIUM PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SUCRALFATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ZINC SULPHATE HEPTAHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM CHLORIDE
GENERAL FINISHING STEPS
SODIUM THIOSULPHATE
GENERAL FINISHING STEPS
VANCOMYCIN HYDROCHLORIDE
GENERAL FINISHING STEPS
COAL TAR SOLUTION STRONG
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PHENOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LISINOPRIL DIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM DIHYDROGEN PHOSPHATE
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BACLOFEN
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MENTHOL CRYSTALS
GENERAL FINISHING STEPS
ENALAPRIL MALEATE
GENERAL FINISHING STEPS
SPIRONOLACTONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FLECAINIDE ACETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ZINC OXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ACETYLSALICYLIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYOSCINE HYDROBROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CODEINE PHOSPHATE HEMIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM HYDROXIDE, LIGHT
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

METHADONE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM CARBONATE LIGHT
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRIAMCINOLONE ACETONIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ZOPICLONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CHLOROQUINE PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DISODIUM EDETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POTASSIUM CHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LOPERAMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ATORVASTATIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TOCOPHERYL ACETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FLUOCINOLONE ACETONIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LORAZEPAM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DUTASTERIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PODOPHYLLUM RESIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
COAL TAR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BORIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYDROCORTISONE MICRONISED
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FERROUS SULPHATE HEPTAHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SULPHASALAZINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
THEOPHYLLINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PILOCARPINE NITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
AMLODIPINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LANSOPRAZOLE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DANTROLENE SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SULPHACETAMIDE SODIUM
GENERAL FINISHING STEPS
BETAMETHASONE VALERATE
GENERAL FINISHING STEPS
FERROUS SULPHATE HEPTAHYDRATE
GENERAL FINISHING STEPS
LOPERAMIDE
GENERAL FINISHING STEPS

TETRACAINE
GENERAL FINISHING STEPS
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BISACODYL POWDER
GENERAL FINISHING STEPS
PROCAINE HYDROCHLORIDE
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TRETINOIN MICRONISED
GENERAL FINISHING STEPS
BETAMETHASONE DIPROPIONATE
GENERAL FINISHING STEPS
PREDNISOLONE SODIUM PHOSPHATE
GENERAL FINISHING STEPS
SODIUM OXYBATE
GENERAL FINISHING STEPS
SODIUM CROMOGLICATE
GENERAL FINISHING STEPS
LISINOPRIL DIHYDRATE
GENERAL FINISHING STEPS
LEVOMEPROMAZINE
GENERAL FINISHING STEPS
MEXILETINE HYDROCHLORIDE
GENERAL FINISHING STEPS
GABAPENTIN
GENERAL FINISHING STEPS
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GENERAL FINISHING STEPS
FLECAINIDE ACETATE
GENERAL FINISHING STEPS
FINASTERIDE
GENERAL FINISHING STEPS
PENTOXIFYLLINE
GENERAL FINISHING STEPS
CAPTOPRIL
GENERAL FINISHING STEPS
FLUOCINOLONE ACETONIDE
GENERAL FINISHING STEPS
PROCAINE HYDROCHLORIDE
GENERAL FINISHING STEPS
TOPIRAMATE
GENERAL FINISHING STEPS
HYOSCINE BUTYLBROMIDE
GENERAL FINISHING STEPS
FLUDROCORTISONE ACETATE
GENERAL FINISHING STEPS
BENZOIC ACID
GENERAL FINISHING STEPS
LORAZEPAM
GENERAL FINISHING STEPS
ZONISAMIDE
GENERAL FINISHING STEPS
CHLORHEXIDINE DIGLUCONATE SOLUTION 20%
GENERAL FINISHING STEPS
CLIOQUINOL
GENERAL FINISHING STEPS
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GENERAL FINISHING STEPS
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GENERAL FINISHING STEPS
BENZYL BENZOATE
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GENERAL FINISHING STEPS
THEOPHYLLINE
GENERAL FINISHING STEPS
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MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PHENOBARBITAL
GENERAL FINISHING STEPS
IBUPROFEN
GENERAL FINISHING STEPS
RAMIPRIL
GENERAL FINISHING STEPS
CHLORHEXIDINE DIGLUCONATE SOLUTION 20%
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CAFFEINE CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM VALPROATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

IODINE
GENERAL FINISHING STEPS
BECLOMETHASONE DIPROPIONATE
GENERAL FINISHING STEPS
POTASSIUM CITRATE
GENERAL FINISHING STEPS
ZOPICLONE
GENERAL FINISHING STEPS
MESALAZINE
GENERAL FINISHING STEPS
PHENYLEPHRINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CAFFEINE CITRATE
GENERAL FINISHING STEPS
SUCRALFATE
GENERAL FINISHING STEPS
BACLOFEN
GENERAL FINISHING STEPS
5-AMINOLEVULINIC ACID HYDROCHLORIDE
GENERAL FINISHING STEPS
FORMALDEHYDE SOLUTION
GENERAL FINISHING STEPS
VERAPAMIL HYDROCHLORIDE
GENERAL FINISHING STEPS
MAGNESIUM HYDROXIDE
GENERAL FINISHING STEPS
SODIUM CITRATE
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MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRANEXAMIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CITRIC ACID ANHYDROUS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BENZALKONIUM CHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BETAMETHASONE DIPROPIONATE MICRONISED
GENERAL FINISHING STEPS
KETAMINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
RAMIPRIL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ALLOPURINOL
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BENZOCAINE
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GENERAL FINISHING STEPS
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CODEINE PHOSPHATE HEMIHYDRATE
GENERAL FINISHING STEPS
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GENERAL FINISHING STEPS
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AMITRIPTYLINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GRISEOFULVIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TOPIRAMATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM HYDROXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LIOTHYRONINE SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CLOBETASOL PROPIONATE
GENERAL FINISHING STEPS

GENTAMICIN SULPHATE
GENERAL FINISHING STEPS
MERCAPTOPURINE
GENERAL FINISHING STEPS
ATENOLOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ISOPROPYL MYRISTATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BECLOMETHASONE DIPROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PROPANTHELINE BROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DITHRANOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CHLORAMPHENICOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYOSCINE BUTYLBROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METRONIDAZOLE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRICHLOROACETIC ACID
GENERAL FINISHING STEPS
FORMALDEHYDE SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ATROPINE SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM SULPHATE HEPTAHYDRATE
GENERAL FINISHING STEPS
TERBUTALINE SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GLYCOPYRRONIUM BROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
QUININE HYDROCHLORIDE
GENERAL FINISHING STEPS
PHENOBARBITAL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
IODINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CAMPHOR RACEMIC
GENERAL FINISHING STEPS
POTASSIUM BROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
OLEIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BETAMETHASONE VALERATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CAMPHOR RACEMIC
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENTAMICIN SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MIDAZOLAM HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
UREA
GENERAL FINISHING STEPS
CLINDAMYCIN PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DAPOXETINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM CROMOGLICATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIAZOXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GABAPENTIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
OLEIC ACID
GENERAL FINISHING STEPS
QUININE SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYDROQUINONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DEXPANTHENOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PROFLAVINE HEMISULPHATE
GENERAL FINISHING STEPS
CLINDAMYCIN PHOSPHATE
GENERAL FINISHING STEPS
SALICYLIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NADOLOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CALAMINE
GENERAL FINISHING STEPS
ISONIAZID
GENERAL FINISHING STEPS
THIAMINE HYDROCHLORIDE
GENERAL FINISHING STEPS
LIDOCAINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PROFLAVINE HEMISULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM HYDROXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LIDOCAINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GLACIAL ACETIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MERCAPTOPURINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ATROPINE SULPHATE
GENERAL FINISHING STEPS
CHLOROQUINE PHOSPHATE
GENERAL FINISHING STEPS
ADRENALINE ACID TARTRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MEBEVERINE HYDROCHLORIDE
GENERAL FINISHING STEPS
RANITIDINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GLUCOSE MONOHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CLOPIDOGREL BISULFATE
GENERAL FINISHING STEPS

TRIAMCINOLONE ACETONIDE
GENERAL FINISHING STEPS
CARBIDOPA
GENERAL FINISHING STEPS
TACROLIMUS MONOHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NALOXONE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
L-CITRULLINE
GENERAL FINISHING STEPS
ALUMINIUM OXIDE HYDRATED
GENERAL FINISHING STEPS
SODIUM CYCLAMATE
GENERAL FINISHING STEPS
NORADRENALINE TARTRATE
GENERAL FINISHING STEPS
OMEPRAZOLE
GENERAL FINISHING STEPS
EXEMESTANE
GENERAL FINISHING STEPS
PHENYTOIN SODIUM
GENERAL FINISHING STEPS
GLUCOSE MONOHYDRATE
GENERAL FINISHING STEPS
SODIUM VALPROATE
GENERAL FINISHING STEPS
CITRIC ACID MONOHYDRATE
GENERAL FINISHING STEPS
HYDROCORTISONE MICRONISED
GENERAL FINISHING STEPS
SERTRALINE HYDROCHLORIDE
GENERAL FINISHING STEPS
SODIUM BENZOATE
GENERAL FINISHING STEPS
ISOPROPYL MYRISTATE
GENERAL FINISHING STEPS
ZINC OXIDE
GENERAL FINISHING STEPS
METHADONE HYDROCHLORIDE
GENERAL FINISHING STEPS
CITRIC ACID ANHYDROUS
GENERAL FINISHING STEPS
SPIRONOLACTONE
GENERAL FINISHING STEPS
SODIUM BICARBONATE
GENERAL FINISHING STEPS
ALLOPURINOL
GENERAL FINISHING STEPS
DISODIUM EDETATE
GENERAL FINISHING STEPS
POTASSIUM HYDROXIDE
GENERAL FINISHING STEPS
PYRIDOXINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CHLOROTHIAZIDE
GENERAL FINISHING STEPS

MELATONIN
GENERAL FINISHING STEPS
TEMOZOLOMIDE
GENERAL FINISHING STEPS
MAGNESIUM STEARATE
GENERAL FINISHING STEPS
CHLOROCRESOL
GENERAL FINISHING STEPS
ATENOLOL
GENERAL FINISHING STEPS
COAL TAR SOLUTION
GENERAL FINISHING STEPS
VENLAFAXINE HYDROCHLORIDE
GENERAL FINISHING STEPS
DILTIAZEM HYDROCHLORIDE
GENERAL FINISHING STEPS
NYSTATIN
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

479651

1. Name and address of site (including building number, where applicable):

ALLIANCE MEDICAL RADIOPHARMACY LIMITED

ROYAL PRESTON HOSPITAL
SHAROE GREEN LANE, FULWOOD
PRESTON
PR2 9HT

2. Manufacturer's licence number(s):

API 34938

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

18/11/2020

This written confirmation remains valid until:

31/12/2023

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

21/12/2020

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

FLUDEOXYGLUCOSE (18-F)

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

18372677

1. Name and address of site (including building number, where applicable):

ALMAC SCIENCES (SCOTLAND) LIMITED

FLEMING BUILDING, EDINBURGH TECHNOPOLE
MILTON BRIDGE, NR PENICUIK
EDINBURGH
EH26 0BE

2. Manufacturer's licence number(s):

API 34369

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

03/06/2021

This written confirmation remains valid until:

03/06/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/08/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ACTIVE SUBSTANCES FOR CLINICAL TRIALS

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

7634946

1. Name and address of site (including building number, where applicable):

APTUIT (OXFORD) LIMITED

110-111, 115 E-H, 117 AND 150 INNOVATION DRIVE
MILTON PARK, MILTON
ABINGDON
OX14 4RZ

2. Manufacturer's licence number(s):

API 40699

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

06/09/2021

This written confirmation remains valid until:

06/09/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

11/10/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

LENALIDOMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FENFLURAMINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FROVATRIPTAN SUCCINATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

839548

1. Name and address of site (including building number, where applicable):

APTUIT (OXFORD) LIMITED

150 BROOK DRIVE
MILTON PARK
ABINGDON
OX14 4SD

2. Manufacturer's licence number(s):

API 40699

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

06/09/2021

This written confirmation remains valid until:

06/09/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

11/10/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

PLERIXAFOR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FROVATRIPTAN SUCCINATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FENFLURAMINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

596852

1. Name and address of site (including building number, where applicable):

BASF PHARMA (CALLANISH) LIMITED

BREASCLETE
CALLANISH
ISLE OF LEWIS
HS2 9ED

2. Manufacturer's licence number(s):

API 33889

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

29/11/2022

This written confirmation remains valid until:

29/11/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

13/01/2023

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

EICOSAPENTAENOIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DOCOSAHEXAENOIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1297

1. Name and address of site (including building number, where applicable):

BASILDON CHEMICAL COMPANY LIMITED

KIMBER ROAD
ABINGDON
OX14 1RZ

2. Manufacturer's licence number(s):

API 10336

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

04/04/2022

This written confirmation remains valid until:

04/04/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/08/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

SIMETHICONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SIMETHICONE EMULSION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DIMETHICONE
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1966883

1. Name and address of site (including building number, where applicable):

BAXTER HEALTHCARE LIMITED

2 WAVERTREE BOULEVARD
WAVERTREE TECHNOLOGY PARK
LIVERPOOL
L7 9PE

2. Manufacturer's licence number(s):

API 116

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

09/05/2022

This written confirmation remains valid until:

09/05/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

22/06/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ICODEXTRIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

2282

1. Name and address of site (including building number, where applicable):

BAXTER HEALTHCARE LIMITED

RUTHERFORD CLOSE
WAVERTREE TECHNOLOGY PARK
LIVERPOOL
L13 1EN

2. Manufacturer's licence number(s):

API 116

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

09/05/2022

This written confirmation remains valid until:

09/05/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

22/06/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ICODEXTRIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

18235

1. Name and address of site (including building number, where applicable):

BIO PRODUCTS LABORATORY LIMITED

DAGGER LANE
ELSTREE
BOREHAMWOOD
WD6 3BX

2. Manufacturer's licence number(s):

API 8801

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

29/11/2021

This written confirmation remains valid until:

29/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

24/07/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

FRACTION IV PASTE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CRYOPRECIPITATE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
PURIFIED FACTOR IX INTERMEDIATE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
B+1 PASTE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
HUMAN PROTHROMBIN COMPLEX
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
FRACTION V
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

31007

1. Name and address of site (including building number, where applicable):

BIORELIANCE LIMITED

STIRLING UNIVERSITY INNOVATION PARK
HILLFOOTS ROAD
STIRLING
FK9 4NF

2. Manufacturer's licence number(s):

API 22774

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

29/06/2022

This written confirmation remains valid until:

29/06/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

05/09/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ADENOVIRUS TYPE 4
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES
ADENOVIRUS TYPE 7
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

17652846

1. Name and address of site (including building number, where applicable):

BSPG LABORATORIES LIMITED

DISCOVERY PARK HOUSE
RAMSGATE ROAD
SANDWICH
CT13 9ND

2. Manufacturer's licence number(s):

API 48727

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

31/03/2022

This written confirmation remains valid until:

31/03/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

12/08/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CANNABIDIOL

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

28051993

1. Name and address of site (including building number, where applicable):

BSPG LABORATORIES LIMITED

SPITFIRE HOUSE, HUGIN LANE
DISCOVERY PARK
SANDWICH
CT13 9FG

2. Manufacturer's licence number(s):

API 48727

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

05/12/2022

This written confirmation remains valid until:

05/12/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

03/01/2023

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CANNABIDIOL

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

16389

1. Name and address of site (including building number, where applicable):

CATALENT MICRON TECHNOLOGIES LIMITED

CROSSWAYS BOULEVARD
CROSSWAYS
DARTFORD
DA2 6QY

2. Manufacturer's licence number(s):

API 5451

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

21/06/2022

This written confirmation remains valid until:

21/06/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

18/08/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

AXITINIB
GENERAL FINISHING STEPS
ESTRADIOL HEMIHYDRATE
GENERAL FINISHING STEPS
DOLUTEGRAVIR SODIUM
GENERAL FINISHING STEPS
APIXABAN
GENERAL FINISHING STEPS
CLIOQUINOL
GENERAL FINISHING STEPS
TRETINOIN
GENERAL FINISHING STEPS
ARIPIPRAZOLE
GENERAL FINISHING STEPS
SALBUTAMOL SULPHATE
GENERAL FINISHING STEPS
OXYTETRACYCLINE DIHYDRATE
GENERAL FINISHING STEPS
FOLIC ACID
GENERAL FINISHING STEPS
ACLIDINIUM BROMIDE
GENERAL FINISHING STEPS
ILOPERIDONE
GENERAL FINISHING STEPS
NITISINONE
GENERAL FINISHING STEPS
PAZOPANIB HYDROCHLORIDE
GENERAL FINISHING STEPS
MIFEPRISTONE
GENERAL FINISHING STEPS
LENALIDOMIDE
GENERAL FINISHING STEPS
LOPERAMIDE HYDROCHLORIDE
GENERAL FINISHING STEPS
DABRAFENIB MESYLATE
GENERAL FINISHING STEPS
ISOTRETINOIN
GENERAL FINISHING STEPS
DASATINIB
GENERAL FINISHING STEPS
SALICYLIC ACID
GENERAL FINISHING STEPS
RIMEGEPANT
GENERAL FINISHING STEPS
TRILOSTANE
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

18599281

1. Name and address of site (including building number, where applicable):

CELADON PHARMA LIMITED

13 HOLFORD ESTATE
TAMESIDE DRIVE
BIRMINGHAM
B6 7AY

2. Manufacturer's licence number(s):

API 50530

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

19/10/2022

This written confirmation remains valid until:

19/10/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

13/01/2023

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CANNABICHROMENIC ACID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CANNABIGEROLIC ACID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
TETRAHYDROCANNABINOLIC ACID B
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
TETRAHYDROCANNABINOLIC ACID A
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CANNABIDIOLIC ACID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CANNABINOL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CANNABICHROMENE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CANNABIDIVARIN
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
TETRAHYDROCANNABIVARINIC ACID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CANNABIDIVARINIC ACID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
TETRAHYDROCANNABIVARIN
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CANNABIGEROL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

19230206

1. Name and address of site (including building number, where applicable):

CONCEPT LIFE SCIENCES INTEGRATED DISCOVERY AND DEVELOPMENT SERVICES LIMITED

DISCOVERY PARK HOUSE
RAMSGATE ROAD
SANDWICH
CT13 9ND

2. Manufacturer's licence number(s):

API 48975

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

22/06/2021

This written confirmation remains valid until:

22/06/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

19/10/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ACTIVE SUBSTANCES FOR CLINICAL TRIALS

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

18490046

1. Name and address of site (including building number, where applicable):

COURTIN & WARNER LIMITED

UNIT F, MALLING BROOKS
BROOKS ROAD
LEWES
BN7 2QG

2. Manufacturer's licence number(s):

API 24

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

01/02/2022

This written confirmation remains valid until:

01/02/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

24/05/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CAFFEINE AND SODIUM BENZOATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

CAFFEINE CITRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

18052

1. Name and address of site (including building number, where applicable):

EUROAPI UK LIMITED

37 HOLLANDS ROAD
HAVERHILL
CB9 8PU

2. Manufacturer's licence number(s):

API 8596

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

31/10/2022

This written confirmation remains valid until:

31/10/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

08/12/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

SEVELAMER CARBONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SEVELAMER HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

119738

1. Name and address of site (including building number, where applicable):

EUROFINS SELCIA LIMITED

FYFIELD BUSINESS AND RESEARCH PARK
FYFIELD ROAD
ONGAR
CM5 0GS

2. Manufacturer's licence number(s):

API 27830

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

22/11/2021

This written confirmation remains valid until:

22/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

17/01/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ACTIVE SUBSTANCES FOR CLINICAL TRIALS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

16804

1. Name and address of site (including building number, where applicable):

FINE ORGANICS LIMITED

SEAL SANDS
MIDDLESBROUGH
TS2 1UB

2. Manufacturer's licence number(s):

API 5965

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

16/06/2022

This written confirmation remains valid until:

16/06/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

01/07/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CLORSULON
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

FLUAZURON
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

METARAMINOL BITARTRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

13222

1. Name and address of site (including building number, where applicable):

FUCHS LUBRICANTS (UK) PLC

HANLEY PLANT
NEW CENTURY STREET, HANLEY
STOKE-ON-TRENT
ST1 5HU

2. Manufacturer's licence number(s):

API 2021

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

08/12/2020

This written confirmation remains valid until:

31/12/2023

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

08/01/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

PARAFFIN LIQUID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
PARAFFIN LIGHT LIQUID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
PARAFFIN SOFT WHITE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
PARAFFIN SOFT YELLOW
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

15159

1. Name and address of site (including building number, where applicable):

GLAXO OPERATIONS UK LTD (WARE) T\A GLAXO WELLCOME OPERATIONS

PRIORY STREET
WARE
SG12 0DJ

2. Manufacturer's licence number(s):

API 4

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

13/09/2021

This written confirmation remains valid until:

13/09/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

22/02/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

FLUTICASONE FUROATE
GENERAL FINISHING STEPS
UMECLIDINIUM BROMIDE
GENERAL FINISHING STEPS
CABOTEGRAVIR SODIUM
GENERAL FINISHING STEPS
FLUTICASONE PROPIONATE
GENERAL FINISHING STEPS
DOLUTEGRAVIR SODIUM
GENERAL FINISHING STEPS
SALMETEROL XINAFOATE
GENERAL FINISHING STEPS
VILANTEROL TRIFENATATE
GENERAL FINISHING STEPS
CEFUROXIME AXETIL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

117769

1. Name and address of site (including building number, where applicable):

GLAXOSMITHKLINE

COBDEN STREET
MONTROSE
DD10 8EA

2. Manufacturer's licence number(s):

API 4

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

31/08/2022

This written confirmation remains valid until:

31/08/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

17/01/2023

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CLOBETASOL PROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
BETAMETHASONE VALERATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FLUTICASONE FUROATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
UMECLIDINIUM BROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LAMOTRIGINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DUTASTERIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
VILANTEROL TRIFENATATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
ABACAVIR SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LACIDIPINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
ZANAMIVIR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SALBUTAMOL SULPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FLUTICASONE PROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1731532

1. Name and address of site (including building number, where applicable):

GW PHARMA LIMITED

UNIT 740 AND 750, KENT SCIENCE PARK
SITTINGBOURNE
ME9 8AG

2. Manufacturer's licence number(s):

API 18024

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

09/11/2020

This written confirmation remains valid until:

31/12/2023

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/03/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

DELTA(9)-TETRAHYDROCANNABINOL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

CANNABIDIOL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1733699

1. Name and address of site (including building number, where applicable):

GW PHARMA LIMITED

HOP POCKET LANE
PADDOCK WOOD
TONBRIDGE
TN12 6DQ

2. Manufacturer's licence number(s):

API 18024

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

09/11/2020

This written confirmation remains valid until:

31/12/2023

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/03/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

DELTA(9)-TETRAHYDROCANNABINOL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

CANNABIDIOL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

17092

1. Name and address of site (including building number, where applicable):

INDIVIOR UK LIMITED

DANSOM LANE
HULL
HU8 7DS

2. Manufacturer's licence number(s):

API 36699

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

09/05/2022

This written confirmation remains valid until:

09/05/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

25/08/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

BUPRENORPHINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
BUPRENORPHINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1893

1. Name and address of site (including building number, where applicable):

MACFARLAN SMITH LIMITED

10 WHEATFIELD ROAD
EDINBURGH
EH11 2QA

2. Manufacturer's licence number(s):

API 1108

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

29/11/2021

This written confirmation remains valid until:

29/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

12/09/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ALFENTANIL HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

APOMORPHINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

BUPRENORPHINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

BUPRENORPHINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

COCAINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

COCAINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

CODEINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

CODEINE PHOSPHATE HEMIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

CODEINE SULFATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

DIAMORPHINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

DIAMORPHINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

DIHYDROCODEINE HYDROGEN TARTRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

FENTANYL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

FENTANYL CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

HYDROMORPHONE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

METHYLPHENIDATE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MORPHINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MORPHINE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MORPHINE SULFATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MORPHINE TARTRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

NALOXONE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

OXYCODONE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

OXYCODONE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

PHOLCODINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

REMIFENTANIL HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

SUFENTANIL CITRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

18248054

1. Name and address of site (including building number, where applicable):

NEW HOLLAND EXTRACTION LIMITED

1 TATTERSHALL CASTLE COURT
NEW HOLLAND
BARROW-UPON-HUMBER
DN19 7PZ

2. Manufacturer's licence number(s):

API 49277

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

16/03/2021

This written confirmation remains valid until:

16/03/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

24/05/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

EVENING PRIMROSE OIL

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

24295773

1. Name and address of site (including building number, where applicable):

ONYX SCIENTIFIC LIMITED

WAYFARER ROAD
SUNDERLAND
SR5 3XA

2. Manufacturer's licence number(s):

API 21540

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

29/11/2021

This written confirmation remains valid until:

29/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

14/02/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

DL-3,4-METHYLENEDIOXYMETHAMPHETAMINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

3649399

1. Name and address of site (including building number, where applicable):

PEPCEUTICALS LIMITED

4 FELDSPAR CLOSE
ENDERBY
LEICESTER
LE19 4JS

2. Manufacturer's licence number(s):

API 39930

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

23/03/2021

This written confirmation remains valid until:

23/03/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

20/05/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

ACTIVE SUBSTANCES FOR CLINICAL TRIALS
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

36790

1. Name and address of site (including building number, where applicable):

PHARMARON MANUFACTURING SERVICES (UK) LTD

WINDMILL INDUSTRIAL ESTATE
SHOTTON LANE
CRAMLINGTON
NE23 3JL

2. Manufacturer's licence number(s):

API 22857

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

21/02/2022

This written confirmation remains valid until:

21/02/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/06/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

FLURBIPROFEN SODIUM DIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
NALOXONE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
OPICAPONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
S-(+)-FLURBIPROFEN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIPIPANONE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FLURBIPROFEN
GENERAL FINISHING STEPS
CANNABIDIOL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
NITISINONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FLURBIPROFEN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

330820

1. Name and address of site (including building number, where applicable):

PHYTOVATION LIMITED

UNITS 8/9/10, ZONE 6, CIBYN INDUSTRIAL ESTATE
CAERNARFON
LL55 2BD

2. Manufacturer's licence number(s):

API 30590

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

06/05/2021

This written confirmation remains valid until:

06/05/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

28/05/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

SENNA PODS, POWDERED, STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

18244

1. Name and address of site (including building number, where applicable):

PIRAMAL HEALTHCARE UK LIMITED

WHALTON ROAD
MORPETH
NE61 3YA

2. Manufacturer's licence number(s):

API 29595

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

15/06/2021

This written confirmation remains valid until:

15/06/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/09/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

MISOPROSTOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYDROFLUMETHIAZIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FOSTEMSAVIR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SPIRONOLACTONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CANRENOATE POTASSIUM
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PARECOXIB SODIUM
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HALOPERIDOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FERRIC TRIMALTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

56821

1. Name and address of site (including building number, where applicable):

R MASON CHEMICALS LIMITED

HARELAW INDUSTRIAL ESTATE
STANLEY
DH9 8UL

2. Manufacturer's licence number(s):

API 11718

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

02/02/2022

This written confirmation remains valid until:

02/02/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

25/03/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

SELENIUM SULFIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

345063

1. Name and address of site (including building number, where applicable):

RANSOM NATURALS LIMITED

51-55 BURY MEAD ROAD
HITCHIN
SG5 1RT

2. Manufacturer's licence number(s):

API 39937

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

30/06/2020

This written confirmation remains valid until:

31/12/2023

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

26/10/2020

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

GINGER TINCTURE,STRONG
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
VALERIAN AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
GINGER EXTRACT
GENERAL FINISHING STEPS
BENZOIN TINCTURE
GENERAL FINISHING STEPS
LETTUCE AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
SENEGA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
EUPHORBIA LIQUID EXTRACT
GENERAL FINISHING STEPS
COCILLANA LIQUID EXTRACT
GENERAL FINISHING STEPS
SQUILL LIQUID EXTRACT
GENERAL FINISHING STEPS
BENZOIN EXTRACT
GENERAL FINISHING STEPS
CAMPHORATED OPIUM TINCTURE
GENERAL FINISHING STEPS
SQUILL ALCOHOLIC SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ZINC OXIDE
GENERAL FINISHING STEPS
BUCHU LIQUID EXTRACT
GENERAL FINISHING STEPS
SLIPPERY ELM BARK EXTRACT
GENERAL FINISHING STEPS
SQUILL AQUEOUS SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
MYRRH TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ORANGE TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SENEGA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WHITE PINE COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CARDAMOM TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM TINCTURE
GENERAL FINISHING STEPS
CAPSICUM SOFT EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
IPECACUANHA EXTRACT
GENERAL FINISHING STEPS
IPECACUANHA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
POTASSIUM CHLORIDE
GENERAL FINISHING STEPS
SQUILL VINEGAR
GENERAL FINISHING STEPS
GENTIAN EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
MAGNESIUM SULFATE HEPTAHYDRATE
GENERAL FINISHING STEPS
GENTIAN EXTRACT
GENERAL FINISHING STEPS
CONCENTRATED PEPPERMINT WATER
GENERAL FINISHING STEPS
STRONG AMMONIUM ACETATE SOLUTION
GENERAL FINISHING STEPS
WILD LETTUCE AQUEOUS EXTRACT
GENERAL FINISHING STEPS
WILD CHERRY SYRUP
GENERAL FINISHING STEPS
SQUILL AQUEOUS SOFT EXTRACT
GENERAL FINISHING STEPS
WHITE HOREHOUND LIQUID EXTRACT
GENERAL FINISHING STEPS
SQUILL OXYMEL
GENERAL FINISHING STEPS
LIQUID PARAFFIN
GENERAL FINISHING STEPS
BITTER ORANGE PEEL EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
LAVENDER EXTRACT
GENERAL FINISHING STEPS
KRAMERIA TINCTURE
GENERAL FINISHING STEPS
LAVENDER EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COMFREY LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VALERIAN TINCTURE
GENERAL FINISHING STEPS
IPECACUANHA TINCTURE
GENERAL FINISHING STEPS
ORANGE TINCTURE
GENERAL FINISHING STEPS
SQUILL TINCTURE
GENERAL FINISHING STEPS
COCILLANA EXTRACT
GENERAL FINISHING STEPS
CAMPHORATED OPIUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN
GENERAL FINISHING STEPS
BITTER ORANGE PEEL EXTRACT

GENERAL FINISHING STEPS

SENEGA TINCTURE

GENERAL FINISHING STEPS

WHITE HOREHOUND LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

WILD CHERRY EXTRACT

GENERAL FINISHING STEPS

MYRRH TINCTURE

GENERAL FINISHING STEPS

VALERIAN EXTRACT

GENERAL FINISHING STEPS

CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED

GENERAL FINISHING STEPS

CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED

GENERAL FINISHING STEPS

ACETYLSALICYLIC ACID

GENERAL FINISHING STEPS

ARACHIS OIL

GENERAL FINISHING STEPS

SODIUM BICARBONATE

GENERAL FINISHING STEPS

SQUILL ALCOHOLIC SOFT EXTRACT

GENERAL FINISHING STEPS

COMFREY LIQUID EXTRACT

GENERAL FINISHING STEPS

WHITE PINE COMPOUND

GENERAL FINISHING STEPS

SQUILL ELIXIR

GENERAL FINISHING STEPS

ARNICA FLOWER TINCTURE

GENERAL FINISHING STEPS

PERU BALSAM

GENERAL FINISHING STEPS

CINCHONA EXTRACT

GENERAL FINISHING STEPS

STRONG AMMONIUM ACETATE SOLUTION

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PASSIFLORA INCARNATA AQUEOUS POWDERED EXTRACT

GENERAL FINISHING STEPS

SENEGA ROOT CONCENTRATED INFUSION

GENERAL FINISHING STEPS

BELLADONNA TINCTURE

GENERAL FINISHING STEPS

CARDAMOM TINCTURE,COMPOUND

GENERAL FINISHING STEPS

GENTIAN TINCTURE,COMPOUND

GENERAL FINISHING STEPS

PELARGONIUM SIDOIDES AQUEOUS EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

KRAMERIA TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN TINCTURE,COMPOUND

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

WILD CHERRY EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ARNICA FLOWER TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

IPECACUANHA EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EUPHORBIA LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN TINCTURE,COMPOUND

GENERAL FINISHING STEPS

EUPHORBIA EXTRACT

GENERAL FINISHING STEPS

RHUBARB EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM SOFT EXTRACT

GENERAL FINISHING STEPS

HEDERA LIQUID EXTRACT

GENERAL FINISHING STEPS

IPECACUANHA LIQUID EXTRACT

GENERAL FINISHING STEPS

HEDERA LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

QUASSIA LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GENERAL FINISHING STEPS

SQUILL ELIXIR

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GENTIAN TINCTURE,COMPOUND

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED

GENERAL FINISHING STEPS

PELARGONIUM SIDOIDES AQUEOUS EXTRACT

GENERAL FINISHING STEPS

IPECACUANHA LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COMPOUND RHUBARB TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SALICYLIC ACID

GENERAL FINISHING STEPS

LIQUORICE LIQUID EXTRACT

GENERAL FINISHING STEPS

BELLADONNA TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SENEGA ROOT CONCENTRATED INFUSION

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN EXTRACT COMPOUND

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COCILLANA EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL VINEGAR

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SENEGA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CONCENTRATED PEPPERMINT WATER
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
PEPPERMINT OIL
GENERAL FINISHING STEPS
SENEGA LIQUID EXTRACT
GENERAL FINISHING STEPS
UVA URSI AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
ICHTHAMMOL
GENERAL FINISHING STEPS
COMPOUND RHUBARB TINCTURE
GENERAL FINISHING STEPS
SENEGA EXTRACT
GENERAL FINISHING STEPS
RHUBARB EXTRACT
GENERAL FINISHING STEPS
BENZOIN EXTRACT COMPOUND
GENERAL FINISHING STEPS
BUCHU DRY EXTRACT
GENERAL FINISHING STEPS
GINGER EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CINCHONA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WILD CHERRY SYRUP
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WILD LETTUCE AQUEOUS EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SLIPPERY ELM BARK EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
EUPHORBIA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL OXYMEL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BUCHU LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COCILLANA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VALERIAN TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

119098

1. Name and address of site (including building number, where applicable):

RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED

NOTTINGHAM SITE
THANE ROAD
NOTTINGHAM
NG90 2DB

2. Manufacturer's licence number(s):

API 12862

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

30/11/2021

This written confirmation remains valid until:

30/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

09/12/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

MENTHOL
GENERAL FINISHING STEPS
IBUPROFEN DL-LYSINE
GENERAL FINISHING STEPS
SALICYLIC ACID
GENERAL FINISHING STEPS
DIHYDROCODEINE TARTRATE
GENERAL FINISHING STEPS
LIDOCAINE HYDROCHLORIDE
GENERAL FINISHING STEPS
NAPHAZOLINE
GENERAL FINISHING STEPS
HEXYLRESORCINOL
GENERAL FINISHING STEPS
FLURBIPROFEN
GENERAL FINISHING STEPS
PSEUDOEPHEDRINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CAFFEINE ANHYDROUS
GENERAL FINISHING STEPS
AMYLMETACRESOL
GENERAL FINISHING STEPS
CODEINE PHOSPHATE
GENERAL FINISHING STEPS
HAMAMELIS WATER
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BENZOCAINE
GENERAL FINISHING STEPS
2,4-DICHLOROBENZYL ALCOHOL
GENERAL FINISHING STEPS
TRIPROLIDINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CHLORAMPHENICOL
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1524

1. Name and address of site (including building number, where applicable):

SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS

SHEWALTON ROAD
IRVINE
KA11 5AP

2. Manufacturer's licence number(s):

API 10592

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

14/12/2020

This written confirmation remains valid until:

31/12/2023

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/02/2021

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

POTASSIUM CLAVULANATE DILUTED

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

3922

1. Name and address of site (including building number, where applicable):

SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS

CLARENDON ROAD
WORTHING
BN14 8QH

2. Manufacturer's licence number(s):

API 10592

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

13/07/2022

This written confirmation remains valid until:

13/07/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

16/08/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

POTASSIUM CLAVULANATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

296341

1. Name and address of site (including building number, where applicable):

SOHO FLORDIS UK LIMITED TRADING AS POTTERS

1 BOTANIC COURT
MARTLAND PARK
WIGAN
WN5 0JZ

2. Manufacturer's licence number(s):

API 44893

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

15/11/2021

This written confirmation remains valid until:

15/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

27/01/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

BURDOCK ROOT LIQUID EXTRACT 1:1
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
HYSSOP LIQUID EXTRACT 1:1
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

9727

1. Name and address of site (including building number, where applicable):

SPECIALTY MINERALS

LIFFORD LANE
KINGS NORTON
BIRMINGHAM
B30 3JW

2. Manufacturer's licence number(s):

API 27886

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

23/06/2022

This written confirmation remains valid until:

23/06/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

14/09/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CALCIUM CARBONATE

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1649

1. Name and address of site (including building number, where applicable):

TATA CHEMICALS EUROPE LIMITED

MOND HOUSE
WINNINGTON
NORTHWICH
CW8 4DT

2. Manufacturer's licence number(s):

API 10762

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

28/09/2021

This written confirmation remains valid until:

28/09/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

21/02/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

SODIUM BICARBONATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

1456

1. Name and address of site (including building number, where applicable):

THOMAS SWAN & COMPANY LIMITED

ROTARY WAY
CONSETT
DH8 7ND

2. Manufacturer's licence number(s):

API 10524

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

02/02/2022

This written confirmation remains valid until:

02/02/2025

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

15/03/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CHLOROXYLENOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TITANIUM PEROXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TITANIUM SALICYLATE
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

817429

1. Name and address of site (including building number, where applicable):

VENATOR PIGMENTS UK LIMITED

BIRTLEY
CHESTER LE STREET
DH3 1QX

2. Manufacturer's licence number(s):

API 34855

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

24/11/2021

This written confirmation remains valid until:

24/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

30/09/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

CALAMINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

Written confirmation for active substances exported to the European Union (EU) for medicinal products for human use, in accordance with Article 46b(2)(b) of Directive 2001/83/EC

Written Confirmation number:

296341

1. Name and address of site (including building number, where applicable):

VIFOR PHARMA UK LIMITED - POTTERS DIVISION

1 BOTANIC COURT
MARTLAND PARK
WIGAN
WN5 0JZ

2. Manufacturer's licence number(s):

API 33656

Regarding the Manufacturing Plant under (1) the Active Substance(s) Exported to the EU for Medicinal Products for Human Use are identified in Annex 1.

The Issuing Regulatory Authority Hereby Confirms That:

The standards of good manufacturing practice (GMP) applicable to this manufacturing plant are at least equivalent to those laid down in the EU (= GMP of WHO/ICH Q7);

The manufacturing plant is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the EU; and

In the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country without delay to the EU.

Date of inspection by the MHRA of the plant under (1):

15/11/2021

This written confirmation remains valid until:

15/11/2024

The authenticity of this written confirmation may be verified with the issuing regulatory authority.
This written confirmation is without prejudice to the responsibilities of the manufacturer to ensure the quality of the medicinal product in accordance with Directive 2001/83/EC.

Address of the issuing regulatory authority:

Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

Name and function of responsible person:

Mr James Pound
Deputy Director, Standards & Compliance

E-mail and Telephone no.:

gmpinspectorate@mhra.gov.uk
+44 (0) 20 3080 6000

Signature Stamp of the authority and date

27/01/2022

Annex 1:

The Active Substance(s) Exported to the EU for Medicinal Products for Human Use

Active substance(s):
Activity(ies):

BURDOCK ROOT LIQUID EXTRACT 1:1
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BURDOCK ROOT DRY EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
PASSION FLOWER DRY EXTRACT 5:1
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BLUE FLAG DRY EXTRACT 3:1 CONCENTRATE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CLIVERS LIQUID EXTRACT 1:1
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
ELECAMPANE ROOT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
ECHINACEA ANGUSTIFOLIA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
HYSSOP LIQUID EXTRACT 1:1
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
VERVAIN EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CLIVERS DRY EXTRACT 4:1
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
HOREHOUND EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BONESET LIQUID EXTRACT 1:1
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
