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.

Please note the site register will be updated on a Monthly basis.

Date of Publication: 09 Aug 2024

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.

Table of Contents

PHARMARON MANUFACTURING SERVICES (UK) LTD
PHYTOVATION LIMITED
PIRAMAL HEALTHCARE UK LIMITED
QUEST INGREDIENTS LIMITED
R MASON CHEMICALS LIMITED
RANSOM NATURALS LIMITED
RECKITT BENCKISER HEALTHCARE (UK) LIMITED
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED
RUTLAND BIODYNAMICS LIMITED
SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS
SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS
SOHO FLORDIS UK LIMITED TRADING AS POTTERS
SPECIALTY MINERALS
STERLING PHARMA SOLUTIONS LIMITED
TATA CHEMICALS EUROPE LIMITED
THOMAS SWAN & COMPANY LIMITED
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:

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:

31/12/2024

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

MHRA

12/10/2021

Annex 1:

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

Active substance(s):
Activity(ies):

FLUOXETINE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BENZOIC ACID
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SULPHUR
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BACLOFEN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PHENOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
MEXILETINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LISINOPRIL DIHYDRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BISACODYL POWDER
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NALOXONE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GABAPENTIN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVOMEPROMAZINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM CITRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM CHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
ENALAPRIL MALEATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MENTHOL CRYSTALS
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POTASSIUM BROMIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CALAMINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CLINDAMYCIN PHOSPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM VALPROATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
BETAMETHASONE DIPROPIONATE MICRONISED
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PROCAINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SILVER NITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
ZOPICLONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LANSOPRAZOLE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIPYRIDAMOLE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM CROMOGLICATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
KETOPROFEN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYDROCORTISONE ACETATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DUTASTERIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MESALAZINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM GLYCEROPHOSPHATE HYDRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BISOPROLOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CETRIMIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PILOCARPINE NITRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CHLORAL HYDRATE
GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BORIC ACID

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SALICYLIC ACID

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PRILOCAINE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MEDROXYPROGESTERONE ACETATE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CHOLESTEROL

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CARBIMAZOLE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

THEOPHYLLINE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MINOXIDIL

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DANTROLENE SODIUM

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DEXPANTHENOL

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

OXYBUTYNIN HYDROCHLORIDE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MAGNESIUM CHLORIDE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

VANCOMYCIN HYDROCHLORIDE

GENERAL FINISHING STEPS

BUPIVACAINE HYDROCHLORIDE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BENZOCAINE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ALUM

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ATORVASTATIN

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CODEINE PHOSPHATE HEMIHYDRATE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GRISEOFULVIN

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

POTASSIUM CHLORIDE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CLIOQUINOL

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LOSARTAN POTASSIUM

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

CLOBETASOL PROPIONATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

BENZYL BENZOATE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ZINC SULPHATE HEPTAHYDRATE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ACRIFLAVINE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ICHTHAMMOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

MELATONIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

PYRIDOXINE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

PILOCARPINE HYDROCHLORIDE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PARACETAMOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

GRAMICIDIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

CHLORAMPHENICOL

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TRISODIUM CITRATE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

L-ARGININE

GENERAL FINISHING STEPS

METHYL SALICYLATE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LOPERAMIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

CHLOROQUINE PHOSPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GENERAL FINISHING STEPS

SULPHASALAZINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

COAL TAR

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

AMLODIPINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

SPIRONOLACTONE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

METHADONE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

COAL TAR SOLUTION STRONG

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

SODIUM DIHYDROGEN PHOSPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MAGNESIUM HYDROXIDE, LIGHT

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

TOCOPHERYL ACETATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

DISODIUM EDETATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

LORAZEPAM

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

FLUOCINOLONE ACETONIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

PODOPHYLLUM RESIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

ZINC OXIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

VERAPAMIL HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

TRIAMCINOLONE ACETONIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

SODIUM CYCLAMATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

FINASTERIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

FLECAINIDE ACETATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

QUININE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

SODIUM THIOSULPHATE

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DEXAMETHASONE SODIUM PHOSPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

HYOSCINE HYDROBROMIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

METHYLCOBALAMIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

HYDROCORTISONE MICRONISED

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

FERROUS SULPHATE HEPTAHYDRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MAGNESIUM GLYCEROPHOSPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

GLUCOSE ANHYDROUS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

ISONIAZID

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

IODINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

PROPANTHELINE BROMIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

DITHRANOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MANNITOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MIDAZOLAM HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

BETAMETHASONE VALERATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

CHLORPHENIRAMINE MALEATE

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BENZALKONIUM CHLORIDE

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

METRONIDAZOLE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
HYOSCINE BUTYLBROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
5-AMINOLEVULINIC ACID HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BECLOMETHASONE DIPROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CALCIUM CARBONATE HEAVY
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NYSTATIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
AMITRIPTYLINE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
AMIODARONE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVOTHYROXINE SODIUM
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NEOMYCIN SULPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CICLOSPORIN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM CARBONATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GLACIAL ACETIC ACID
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM OXIDE HEAVY
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POTASSIUM IODIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ALIMEMAZINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ESTRADIOL VALERATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BISOPROLOL FUMARATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SIROLIMUS
GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM SULPHATE EXSICCATED
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
KETAMINE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYDROQUINONE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CAPSICUM TINCTURE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TERBUTALINE SULPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CLOPIDOGREL BESILATE
GENERAL FINISHING STEPS
PHENYLEPHRINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CITRIC ACID MONOHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
POTASSIUM HYDROXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PREDNISOLONE SODIUM PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
POVIDONE-IODINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CAPTOPRIL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CHLORHEXIDINE DIGLUCONATE SOLUTION 20%
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CHLOROTHIAZIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ATENOLOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
COAL TAR SOLUTION
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DILTIAZEM HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LIDOCAINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM BICARBONATE
GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SILDENAFIL CITRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CHLORHEXIDINE DIACETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SULPHACETAMIDE SODIUM
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
IBUPROFEN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PHENOBARBITAL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM HYDROXIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ALLOPURINOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MERCAPTOPURINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENTAMICIN SULPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
RANITIDINE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ETHAMBUTOL HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM SULPHATE HEPTAHYDRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CARBIDOPA
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
RAMIPRIL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CLOPIDOGREL BISULFATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRICHLOROACETIC ACID
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CITRIC ACID ANHYDROUS
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM BENZOATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SERTRALINE HYDROCHLORIDE

GENERAL FINISHING STEPS
ISOPROPYL MYRISTATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MEBEVERINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CHLOROCRESOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
OMEPRAZOLE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FLUDROCORTISONE ACETATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRETINOIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
BETAMETHASONE DIPROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PREGABALIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
POTASSIUM BICARBONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
THIAMINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
EXEMESTANE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DIAZOXIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ADRENALINE ACID TARTRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM HYDROXIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CAMPHOR RACEMIC
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
OLEIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
UREA
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DAPOXETINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DISODIUM PHOSPHATE ANHYDROUS

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
QUININE SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
POTASSIUM CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TACROLIMUS MONOHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PROFLAVINE HEMISULPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NADOLOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FORMALDEHYDE SOLUTION
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ATROPINE SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
L-CITRULLINE
GENERAL FINISHING STEPS
ALUMINIUM OXIDE HYDRATED
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NORADRENALINE TARTRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM STEARATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GLYCOPYRRONIUM BROMIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM CARBONATE LIGHT
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TEMOZOLOMIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
VENLAFAXINE HYDROCHLORIDE
GENERAL FINISHING STEPS
GLUCOSE MONOHYDRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PHENYTOIN SODIUM
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
RESORCINOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
AZELAIC ACID
GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NIFEDIPINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PHENYTOIN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PENTOXIFYLLINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CARBACHOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GLICLAZIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
OXETACAINE
GENERAL FINISHING STEPS
LIDOCAINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LIOTHYRONINE SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TOPIRAMATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TRANEXAMIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
HYDROCHLOROTHIAZIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CHLORHEXIDINE ACETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SODIUM HYDROGEN CARBONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TRETINOIN MICRONISED
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PHENYTOIN POWDER
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
HYDROGEN PEROXIDE SOLUTION 6%
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CAFFEINE CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
ACETYLSALICYLIC ACID
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SUCRALFATE
GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METFORMIN HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ESOMEPRAZOLE MAGNESIUM TRIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LEVODOPA
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM OXYBATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TETRACAINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PAROXETINE HYDROCHLORIDE
GENERAL FINISHING STEPS
PYRIDOSTIGMINE BROMIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METHOTREXATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PYRAZINAMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
ZONISAMIDE
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:

761454

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

ALBUMEDIX LIMITED

MABEL STREET
THE MEADOWS
NOTTINGHAM
NG2 3ED

2. Manufacturer's licence number(s):

API 32930

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):

10/01/2020

This written confirmation remains valid until:

31/12/2024

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

30/01/2020

Annex 1:

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

Active substance(s):
Activity(ies):

RECOMBUMIN ELITE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES
MANUFACTURE OF STERILE ACTIVE SUBSTANCE
RECOMBUMIN PRIME
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES
GENERAL FINISHING STEPS
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:

926769

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

ALLIANCE MEDICAL RADIOPHARMACY LIMITED

ROYAL MARSDEN HOSPITAL
DOWNS ROAD
SUTTON
SM2 5PT

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):

09/08/2023

This written confirmation remains valid until:

09/08/2026

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

15/04/2024

Annex 1:

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

Active substance(s):
Activity(ies):

FLUORODEOXYGLUCOSE (18F)
MANUFACTURE OF STERILE ACTIVE SUBSTANCE
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:

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:

31/12/2024

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

21/12/2020

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:

31/12/2024

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:

31/12/2024

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):

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

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:

31/12/2024

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):

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

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):

DOCOSAHEXAENOIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
EICOSAPENTAENOIC 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
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIMETHICONE
GENERAL FINISHING STEPS
SIMETHICONE EMULSION
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:

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

12/04/2024

Annex 1:

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

Active substance(s):
Activity(ies):

ICODEXTRIN

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:

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

12/04/2024

Annex 1:

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

Active substance(s):
Activity(ies):

ICODEXTRIN

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:

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):

B+1 PASTE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
HUMAN PROTHROMBIN COMPLEX
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
FRACTION IV PASTE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CRYOPRECIPITATE
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 7
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES
ADENOVIRUS TYPE 4
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:

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):

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

31/12/2024

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

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:

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
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:

336305

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

CRODA EUROPE LIMITED

BARNFIELD ROAD
LEEK
ST13 5QJ

2. Manufacturer's licence number(s):

API 30812

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):

11/02/2020

This written confirmation remains valid until:

31/12/2024

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

MHRA

27/03/2020

Annex 1:

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

Active substance(s):
Activity(ies):

OMEGA-3-ACID ETHYL ESTERS 90
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
OMEGA-3-ACID TRIGLYCERIDES
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:

29211

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

DSM NUTRITIONAL PRODUCTS (UK) LIMITED

DRAKEMYRE
DALRY
KA24 5JJ

2. Manufacturer's licence number(s):

API 19108

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):

15/11/2023

This written confirmation remains valid until:

15/11/2026

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

11/12/2023

Annex 1:

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

Active substance(s):
Activity(ies):

ASCORBIC ACID
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM ASCORBATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PANTHENOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CALCIUM PANTOTHENATE
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
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
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):

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:

31/12/2024

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

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

31/12/2024

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):

VILANTEROL TRIFENATATE
GENERAL FINISHING STEPS
FLUTICASONE PROPIONATE
GENERAL FINISHING STEPS
FLUTICASONE FUROATE
GENERAL FINISHING STEPS
SALMETEROL XINAFOATE
GENERAL FINISHING STEPS
CABOTEGRAVIR SODIUM
GENERAL FINISHING STEPS
UMECLIDINIUM BROMIDE
GENERAL FINISHING STEPS
DOLUTEGRAVIR SODIUM
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:

15697

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

GLAXO OPERATIONS UK LTD TRADING AS GLAXO WELLCOME OPERATIONS

NORTH LONSDALE ROAD
ULVERSTON
LA12 9DR

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):

21/09/2021

This written confirmation remains valid until:

31/12/2024

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

16/03/2022

Annex 1:

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

Active substance(s):
Activity(ies):

CEFUROXIME AXETIL

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:

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):

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

31/12/2024

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

16/03/2021

Annex 1:

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

Active substance(s):
Activity(ies):

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

31/12/2024

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

16/03/2021

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):

26/02/2024

This written confirmation remains valid until:

26/02/2027

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

25/03/2024

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
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:

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):

BUPRENORPHINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
MORPHINE SULFATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CODEINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
REMIFENTANIL HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ALFENTANIL HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BUPRENORPHINE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NALOXONE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
OXYCODONE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIAMORPHINE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
COCAINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
HYDROMORPHONE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FENTANYL CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DIHYDROCODEINE HYDROGEN TARTRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CODEINE PHOSPHATE HEMIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SUFENTANIL CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
METHYLPHENIDATE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

MORPHINE
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

OXYCODONE HYDROCHLORIDE
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MORPHINE HYDROCHLORIDE
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

PHOLCODINE
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
- GENERAL FINISHING STEPS

MORPHINE TARTRATE
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

CODEINE SULFATE
- 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:

31/12/2024

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

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:

14798

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

NORGINE LIMITED

NEW ROAD
TIR-Y-BERTH
HENGOED
CF82 8SJ

2. Manufacturer's licence number(s):

API 322

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):

15/03/2021

This written confirmation remains valid until:

31/12/2024

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

11/06/2021

Annex 1:

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

Active substance(s):
Activity(ies):

MACROGOL 3350
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:

1769489

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

NOVARTIS GRIMSBY LIMITED

PYEWIPE
GRIMSBY
DN31 2SR

2. Manufacturer's licence number(s):

API 15856

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):

09/03/2020

This written confirmation remains valid until:

31/12/2024

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

02/04/2020

Annex 1:

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

Active substance(s):
Activity(ies):

PAZOPANIB HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DICLOFENAC SODIUM
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DICLOFENAC POTASSIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SACUBITRIL VALSARTAN SODIUM HYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
RIBOCICLIB SUCCINATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TELBIVUDINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DICLOFENAC DIETHYLAMINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRIBENOSIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FAMCICLOVIR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
BENZONATATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ALISKIREN HEMIFUMARATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
OXCARBAZEPINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LUMIRACOXIB
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DICLOFENAC FREE ACID
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METHYLPHENIDATE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
VILDAGLIPTIN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TERBINAFINE BASE

GENERAL FINISHING STEPS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

VALSARTAN

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:

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
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:

714421

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

PCCA LIMITED

UNITS 1, 2 AND 3 REGENTS DRIVE
LOW PRUDHOE INDUSTRIAL ESTATE
PRUDHOE
NE42 6PX

2. Manufacturer's licence number(s):

API 17661

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):

15/05/2023

This written confirmation remains valid until:

15/05/2026

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

15/09/2023

Annex 1:

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

Active substance(s):
Activity(ies):

THYROID
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:

31/12/2024

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

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:

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

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:

31/12/2024

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:

31/12/2024

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):

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

20306

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

QUEST INGREDIENTS LIMITED

GOOSES FOOT INDUSTRIAL ESTATE
KINGSTONE
HEREFORD
HR2 9HY

2. Manufacturer's licence number(s):

API 18667

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):

30/04/2020

This written confirmation remains valid until:

31/12/2024

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

16/06/2021

Annex 1:

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

Active substance(s):
Activity(ies):

SQUILL OXYMEL
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL TINCTURE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
COAL TAR SOLUTION
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:

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

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:

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:

31/12/2024

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

26/10/2020

Annex 1:

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

Active substance(s):
Activity(ies):

LAVENDER EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
EUPHORBIA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
IPECACUANHA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
COMFREY LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
SQUILL VINEGAR
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
SENEGA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WHITE HOREHOUND LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
SENEGA ROOT CONCENTRATED INFUSION
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
PERU BALSAM
GENERAL FINISHING STEPS
CONCENTRATED PEPPERMINT WATER
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BELLADONNA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BENZOIN TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BENZOIN TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BENZOIN EXTRACT COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
WILD CHERRY EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

GENTIAN EXTRACT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

EUPHORBIA EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

KRAMERIA TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

SQUILL OXYMEL

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

SQUILL ELIXIR

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

WILD CHERRY SYRUP

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

BUCHU LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

COCILLANA LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

CARDAMOM TINCTURE,COMPOUND

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

COCILLANA EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

IPECACUANHA TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

BENZOIN EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

MYRRH TINCTURE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

LETTUCE AQUEOUS POWDERED EXTRACT

GENERAL FINISHING STEPS

VALERIAN AQUEOUS POWDERED EXTRACT

GENERAL FINISHING STEPS

ZINC OXIDE

GENERAL FINISHING STEPS

SENEGA TINCTURE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GENTIAN TINCTURE,COMPOUND

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

POTASSIUM CHLORIDE
GENERAL FINISHING STEPS
MAGNESIUM SULFATE HEPTAHYDRATE
GENERAL FINISHING STEPS
SLIPPERY ELM BARK EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL AQUEOUS SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ORANGE TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CAPSICUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
WHITE PINE COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
SQUILL ALCOHOLIC SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
ARNICA FLOWER TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
PELARGONIUM SIDOIDES AQUEOUS EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BITTER ORANGE PEEL EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
STRONG AMMONIUM ACETATE SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CAMPHORATED OPIUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
WILD LETTUCE AQUEOUS EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL TINCTURE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VALERIAN TINCTURE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL LIQUID EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
LIQUORICE LIQUID EXTRACT
GENERAL FINISHING STEPS
CAPSICUM SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GENERAL FINISHING STEPS

SALICYLIC ACID

GENERAL FINISHING STEPS

PEPPERMINT OIL

GENERAL FINISHING STEPS

ICHTHAMMOL

GENERAL FINISHING STEPS

VALERIAN EXTRACT

GENERAL FINISHING STEPS

QUASSIA LIQUID EXTRACT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GINGER EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

IPECACUANHA LIQUID EXTRACT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

RHUBARB EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

ARACHIS OIL

GENERAL FINISHING STEPS

LIQUID PARAFFIN

GENERAL FINISHING STEPS

SENEGA EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

PASSIFLORA INCARNATA AQUEOUS POWDERED EXTRACT

GENERAL FINISHING STEPS

SODIUM BICARBONATE

GENERAL FINISHING STEPS

ACETYLSALICYLIC ACID

GENERAL FINISHING STEPS

HEDERA LIQUID EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

COMPOUND RHUBARB TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

CINCHONA EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

GINGER TINCTURE,STRONG

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

UVA URSI AQUEOUS POWDERED EXTRACT

GENERAL FINISHING STEPS

BUCHU DRY EXTRACT

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):

RECKITT BENCKISER HEALTHCARE (UK) LIMITED

DANSOM LANE
HULL
HU8 7DS

2. Manufacturer's licence number(s):

API 63

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):

26/02/2024

This written confirmation remains valid until:

26/02/2027

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

25/03/2024

Annex 1:

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

Active substance(s):
Activity(ies):

ASCORBIC ACID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
SODIUM ALGINATE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CHLOROXYLENOL
GENERAL FINISHING STEPS
POTASSIUM BICARBONATE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
BENZALKONIUM CHLORIDE
GENERAL FINISHING STEPS
AMBROXOL HYDROCHLORIDE
GENERAL FINISHING STEPS
WHITE SOFT PARAFFIN
GENERAL FINISHING STEPS
DIPHENHYDRAMINE
GENERAL FINISHING STEPS
MAGNESIUM ALGINATE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
LIGHT LIQUID PARAFFIN
GENERAL FINISHING STEPS
GLYCEROL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
NALOXONE HYDROCHLORIDE
GENERAL FINISHING STEPS
ACETYLSALICYLIC ACID
GENERAL FINISHING STEPS
CAFFEINE ANHYDROUS
GENERAL FINISHING STEPS
LIDOCAINE HYDROCHLORIDE
GENERAL FINISHING STEPS
HYDROCORTISONE ACETATE
GENERAL FINISHING STEPS
ANHYDROUS LANOLIN
GENERAL FINISHING STEPS
DISODIUM EDETATE
GENERAL FINISHING STEPS
LEMON OIL-TERPENELESS
GENERAL FINISHING STEPS
DILL SEED OIL TERPENELESS
GENERAL FINISHING STEPS
CALCIUM CARBONATE
GENERAL FINISHING STEPS
SODIUM BICARBONATE

GENERAL FINISHING STEPS

BENZYL ALCOHOL

GENERAL FINISHING STEPS

CODEINE PHOSPHATE

GENERAL FINISHING STEPS

PSEUDOEPHEDRINE HYDROCHLORIDE

GENERAL FINISHING STEPS

UREA

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:

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):

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

123039

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

RUTLAND BIODYNAMICS LIMITED

TOWN PARK FARM
OAKHAM ROAD, BROOKE
OAKHAM
LE15 8DG

2. Manufacturer's licence number(s):

API 28255

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):

31/08/2023

This written confirmation remains valid until:

31/08/2026

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

13/10/2023

Annex 1:

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

Active substance(s):
Activity(ies):

PAEONIA LACTIFLORA UNPEELED ROOT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COCILLANA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
CIMICIFUGA RACEMOSA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
RHEUM PALMATUM
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
EPHEDRINE
GENERAL FINISHING STEPS
HYSSOPUS OFFICINALIS HERB
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
COAL TAR SOLUTION STRONG
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
LOBELIA INFLATA
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GLYCYRRHIZA GLABRA ROOT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
THYMUS SERPYLLUM HERB
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VITEX AGNUS-CASTUS FRUIT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BOSWELLIA SERRATA EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GUAREA RUSBYI
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
TOLU BALSAM TINCTURE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VERBENA OFFICINALIS HERB
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
PASSIFLORA INCARNATA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS
FUMARIA OFFICINALIS HERB

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ANISE OIL

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

PREPARED COAL TAR

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

OPIUM TINCTURE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

POLYGALA SENEGA ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

BAPTISIA TINCTORIA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

MARRUBIUM VULGARE HERB

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

SCUTELLARIA LATERIFLORA

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

FUCUS VESICULOSUS

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

ARCTIUM LAPPA ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

HYPERICUM PERFORATUM

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

BELLADONNA TINCTURE

GENERAL FINISHING STEPS

TOLU BALSAM SOLUTION

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COMMIPHORA MYRRHA RESIN

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

COCILLANA LIQUID EXTRACT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COAL TAR SOLUTION

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

ECHINACEA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

TOLU BALSAM SYRUP

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

MATRICARIA CHAMOMILLA FLOWERS

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

AVENA SATIVA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

CARAPICHEA IPECACUANHA ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

TOLU FLAVOUR

GENERAL FINISHING STEPS

DRIMIA INDICA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

INULA HELENIUM ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

TOLU-FLAVOUR SOLUTION

GENERAL FINISHING STEPS

CHLOROFORM AND MORPHINE TINCTURE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

LIQUIFIED PHENOL

GENERAL FINISHING STEPS

VALERIANA OFFICINALIS ROOT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAMPHORATED OPIUM TINCTURE

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

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:

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:

31/12/2024

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

16/02/2021

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:

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):

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

292119

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

STERLING PHARMA SOLUTIONS LIMITED

DUDLEY LANE
DUDLEY
CRAMLINGTON
NE23 7QG

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:

31/12/2024

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

MHRA

29/06/2021

Annex 1:

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

Active substance(s):
Activity(ies):

FERRIC MALTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CERIUM NITRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METHOXYFLURANE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SESTAMIBI
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIROXIMEL FUMARATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
DIMETHYL FUMARATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
ILOPERIDONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
POLIDOCANOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ACRIVASTINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TOCERANIB PHOSPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CANNABIDIOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
LEVALBUTEROL TARTRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
TAZEMETOSTAT
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
REBOXETINE METHANESULPHONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
SELAMECTIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CODEINE PHOSPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LUMACAFTOR
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ARFORMOTEROL
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

RACTOPAMINE HYDROCHLORIDE
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
- GENERAL FINISHING STEPS

ZILEUTON
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SISAPRONIL
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
- GENERAL FINISHING STEPS

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

OCTENIDINE DIHYDROCHLORIDE
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TRIENTINE DIHYDROCHLORIDE
- GENERAL FINISHING STEPS
- MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LEVALBUTEROL 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:

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:

31/12/2024

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
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:

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

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):

20/06/2023

This written confirmation remains valid until:

20/06/2026

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

15/09/2023

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):

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