Medicines & Healthcare products Regulatory Agency

MHRA

MHRA Register of Written Confirmations For UK Active Substance Manufacturers

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

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T 020 3080 6000 – www.mhra.gov.uk

NOTICES

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

NOTES FOR GUIDANCE

GENERAL

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

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

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

Table of Contents

QUEST INGREDIENTS LIMITED
R MASON CHEMICALS LIMITED
RANSOM NATURALS LIMITED
RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED
RUTLAND BIODYNAMICS LIMITED
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:

20/05/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

NADOLOL
GENERAL FINISHING STEPS
BENZOIC ACID
GENERAL FINISHING STEPS
QUININE SULPHATE
GENERAL FINISHING STEPS
PHENOBARBITAL
GENERAL FINISHING STEPS
CARBIMAZOLE
GENERAL FINISHING STEPS
PARACETAMOL
GENERAL FINISHING STEPS
CHLORAL HYDRATE
GENERAL FINISHING STEPS
MEBEVERINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CLINDAMYCIN PHOSPHATE
GENERAL FINISHING STEPS
ATORVASTATIN
GENERAL FINISHING STEPS
KETOPROFEN
GENERAL FINISHING STEPS
CICLOSPORIN
GENERAL FINISHING STEPS
HYOSCINE BUTYLBROMIDE
GENERAL FINISHING STEPS
ATROPINE SULPHATE
GENERAL FINISHING STEPS
AMITRIPTYLINE HYDROCHLORIDE
GENERAL FINISHING STEPS
PENTOXIFYLLINE
GENERAL FINISHING STEPS
SODIUM VALPROATE
GENERAL FINISHING STEPS
TRANEXAMIC ACID
GENERAL FINISHING STEPS
POTASSIUM CHLORIDE
GENERAL FINISHING STEPS
NEOMYCIN SULPHATE
GENERAL FINISHING STEPS
PHENYTOIN SODIUM
GENERAL FINISHING STEPS
MAGNESIUM SULPHATE HEPTAHYDRATE
GENERAL FINISHING STEPS
LEVOTHYROXINE SODIUM
GENERAL FINISHING STEPS
MAGNESIUM STEARATE
GENERAL FINISHING STEPS

IODINE
GENERAL FINISHING STEPS
FLECAINIDE ACETATE
GENERAL FINISHING STEPS
PHENOL
GENERAL FINISHING STEPS
SODIUM OXYBATE
GENERAL FINISHING STEPS
BORIC ACID
GENERAL FINISHING STEPS
ADRENALINE ACID TARTRATE
GENERAL FINISHING STEPS
ATORVASTATIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GABAPENTIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ACRIFLAVINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM BENZOATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM THIOSULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SULPHACETAMIDE SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FINASTERIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BETAMETHASONE DIPROPIONATE MICRONISED
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CARBIDOPA
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ICHTHAMMOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRIAMCINOLONE ACETONIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FLUOXETINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CLOBETASOL PROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
COAL TAR SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GRISEOFULVIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ISOPROPYL MYRISTATE
GENERAL FINISHING STEPS
METHYLCOBALAMIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METHYL SALICYLATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PHENYLEPHRINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CITRIC ACID ANHYDROUS
GENERAL FINISHING STEPS
CAFFEINE CITRATE
GENERAL FINISHING STEPS

LORAZEPAM
GENERAL FINISHING STEPS
KETAMINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
COAL TAR SOLUTION STRONG
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CLINDAMYCIN PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CHLORPHENIRAMINE MALEATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MESALAZINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENTAMICIN SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MEBEVERINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POTASSIUM CHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM DIHYDROGEN PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MEXILETINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POTASSIUM CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRETINOIN MICRONISED
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM SULPHATE EXSICCATED
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PROFLAVINE HEMISULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRISODIUM CITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
NYSTATIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVODOPA
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FLUDROCORTISONE ACETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FORMALDEHYDE SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM HYDROXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MEDROXYPROGESTERONE ACETATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POTASSIUM BROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVOMEPROMAZINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM DIHYDROGEN PHOSPHATE
GENERAL FINISHING STEPS
CAPTOPRIL
GENERAL FINISHING STEPS
SODIUM CARBONATE
GENERAL FINISHING STEPS
DIPYRIDAMOLE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CAPTOPRIL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
MAGNESIUM OXIDE HEAVY
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DITHRANOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FINASTERIDE
GENERAL FINISHING STEPS
PARACETAMOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ZINC SULPHATE HEPTAHYDRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PYRIDOSTIGMINE BROMIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PILOCARPINE NITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PYRIDOXINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRETINOIN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIAZOXIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BECLOMETHASONE DIPROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PREDNISOLONE SODIUM PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PHENYLEPHRINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CHLORHEXIDINE DIGLUCONATE SOLUTION 20%
GENERAL FINISHING STEPS
SULPHUR
GENERAL FINISHING STEPS
OXYBUTYNIN HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ALIMEMAZINE
GENERAL FINISHING STEPS
DILTIAZEM HYDROCHLORIDE
GENERAL FINISHING STEPS
LORAZEPAM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
BETAMETHASONE VALERATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LIOTHYRONINE SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LANSOPRAZOLE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FORMALDEHYDE SOLUTION
GENERAL FINISHING STEPS
GLYCOPYRRONIUM BROMIDE
GENERAL FINISHING STEPS
COAL TAR
GENERAL FINISHING STEPS
TOPIRAMATE
GENERAL FINISHING STEPS

OXYBUTYNIN HYDROCHLORIDE
GENERAL FINISHING STEPS
PODOPHYLLUM RESIN
GENERAL FINISHING STEPS
AMLODIPINE
GENERAL FINISHING STEPS
TRETINOIN
GENERAL FINISHING STEPS
BETAMETHASONE DIPROPIONATE MICRONISED
GENERAL FINISHING STEPS
METFORMIN HYDROCHLORIDE
GENERAL FINISHING STEPS
GENTAMICIN SULPHATE
GENERAL FINISHING STEPS
COAL TAR SOLUTION
GENERAL FINISHING STEPS
LEVOMEPROMAZINE
GENERAL FINISHING STEPS
BISOPROLOL FUMARATE
GENERAL FINISHING STEPS
TETRACAINE
GENERAL FINISHING STEPS
METHYLCOBALAMIN
GENERAL FINISHING STEPS
MANNITOL
GENERAL FINISHING STEPS
BISACODYL POWDER
GENERAL FINISHING STEPS
PYRIDOSTIGMINE BROMIDE
GENERAL FINISHING STEPS
CAPSICUM TINCTURE
GENERAL FINISHING STEPS
LOSARTAN POTASSIUM
GENERAL FINISHING STEPS
POTASSIUM CITRATE
GENERAL FINISHING STEPS
SODIUM GLYCEROPHOSPHATE HYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PAROXETINE HYDROCHLORIDE
GENERAL FINISHING STEPS
SODIUM BENZOATE
GENERAL FINISHING STEPS
CETRIMIDE
GENERAL FINISHING STEPS
GLUCOSE ANHYDROUS
GENERAL FINISHING STEPS
CLOPIDOGREL BISULFATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
AZELAIC ACID
GENERAL FINISHING STEPS
SILDENAFIL CITRATE
GENERAL FINISHING STEPS
CLOBETASOL PROPIONATE
GENERAL FINISHING STEPS
METFORMIN HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BENZYL BENZOATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BISOPROLOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

POTASSIUM BICARBONATE

GENERAL FINISHING STEPS

DUTASTERIDE

GENERAL FINISHING STEPS

POTASSIUM IODIDE

GENERAL FINISHING STEPS

CHLOROCRESOL

GENERAL FINISHING STEPS

ALUM

GENERAL FINISHING STEPS

ZONISAMIDE

GENERAL FINISHING STEPS

DIAZOXIDE

GENERAL FINISHING STEPS

ENALAPRIL MALEATE

GENERAL FINISHING STEPS

METHOTREXATE

GENERAL FINISHING STEPS

EXEMESTANE

GENERAL FINISHING STEPS

SODIUM THIOSULPHATE

GENERAL FINISHING STEPS

SODIUM CROMOGLICATE

GENERAL FINISHING STEPS

NORADRENALINE TARTRATE

GENERAL FINISHING STEPS

KETAMINE HYDROCHLORIDE

GENERAL FINISHING STEPS

LIOTHYRONINE SODIUM

GENERAL FINISHING STEPS

SODIUM CITRATE

GENERAL FINISHING STEPS

ETHAMBUTOL HYDROCHLORIDE

GENERAL FINISHING STEPS

CALAMINE

GENERAL FINISHING STEPS

BETAMETHASONE DIPROPIONATE

GENERAL FINISHING STEPS

BISOPROLOL

GENERAL FINISHING STEPS

L-ARGININE

GENERAL FINISHING STEPS

PRILOCAINE

GENERAL FINISHING STEPS

ALLOPURINOL

GENERAL FINISHING STEPS

SULPHACETAMIDE SODIUM

GENERAL FINISHING STEPS

BENZALKONIUM CHLORIDE

GENERAL FINISHING STEPS

ACRIFLAVINE

GENERAL FINISHING STEPS

COAL TAR SOLUTION STRONG

GENERAL FINISHING STEPS

ZINC OXIDE

GENERAL FINISHING STEPS

DITHRANOL

GENERAL FINISHING STEPS

TACROLIMUS MONOHYDRATE

GENERAL FINISHING STEPS

CHLORHEXIDINE DIGLUCONATE SOLUTION 20%

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CITRIC ACID ANHYDROUS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DILTIAZEM HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LOPERAMIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

IBUPROFEN

GENERAL FINISHING STEPS

CHLORPHENIRAMINE MALEATE

GENERAL FINISHING STEPS

POTASSIUM BICARBONATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

POVIDONE-IODINE

GENERAL FINISHING STEPS

LEVODOPA

GENERAL FINISHING STEPS

UREA

GENERAL FINISHING STEPS

ZOPICLONE

GENERAL FINISHING STEPS

MINOXIDIL

GENERAL FINISHING STEPS

MAGNESIUM CHLORIDE

GENERAL FINISHING STEPS

SODIUM GLYCEROPHOSPHATE HYDRATE

GENERAL FINISHING STEPS

GRISEOFULVIN

GENERAL FINISHING STEPS

GLICLAZIDE

GENERAL FINISHING STEPS

RANITIDINE HYDROCHLORIDE

GENERAL FINISHING STEPS

LANSOPRAZOLE

GENERAL FINISHING STEPS

OLEIC ACID

GENERAL FINISHING STEPS

HYOSCINE HYDROBROMIDE

GENERAL FINISHING STEPS

RAMIPRIL

GENERAL FINISHING STEPS

GRAMICIDIN

GENERAL FINISHING STEPS

AZELAIC ACID

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LIDOCAINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SULPHASALAZINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CLIOQUINOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MAGNESIUM SULPHATE HEPTAHYDRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

VERAPAMIL HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GLUCOSE MONOHYDRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DEXPANTHENOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

HYDROCORTISONE MICRONISED

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ZINC OXIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LOSARTAN POTASSIUM

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

RANITIDINE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CALCIUM CARBONATE HEAVY

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MINOXIDIL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

QUININE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CETRIMIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MANNITOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CAPSICUM TINCTURE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DUTASTERIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MAGNESIUM CHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ALIMEMAZINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MAGNESIUM HYDROXIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TETRACAINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CARBACHOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GLICLAZIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ADRENALINE ACID TARTRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PODOPHYLLUM RESIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

COAL TAR

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

NORADRENALINE TARTRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PRILOCAINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CAMPHOR RACEMIC

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CLOPIDOGREL BESILATE

GENERAL FINISHING STEPS

METHYL SALICYLATE

GENERAL FINISHING STEPS

VANCOMYCIN HYDROCHLORIDE

GENERAL FINISHING STEPS

ATENOLOL

GENERAL FINISHING STEPS

DEXAMETHASONE SODIUM PHOSPHATE

GENERAL FINISHING STEPS

THEOPHYLLINE

GENERAL FINISHING STEPS

TRETINOIN MICRONISED

GENERAL FINISHING STEPS

ISONIAZID

GENERAL FINISHING STEPS

FLUOXETINE HYDROCHLORIDE

GENERAL FINISHING STEPS

CHLOROQUINE PHOSPHATE

GENERAL FINISHING STEPS

POTASSIUM BROMIDE

GENERAL FINISHING STEPS

OMEPRAZOLE

GENERAL FINISHING STEPS

MESALAZINE

GENERAL FINISHING STEPS

MAGNESIUM HYDROXIDE, LIGHT

GENERAL FINISHING STEPS

DEXPANTHENOL

GENERAL FINISHING STEPS

DAPOXETINE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

HYDROCHLOROTHIAZIDE

GENERAL FINISHING STEPS

GABAPENTIN

GENERAL FINISHING STEPS

POVIDONE-IODINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PROCAINE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CODEINE PHOSPHATE HEMIHYDRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

METHOTREXATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TRISODIUM CITRATE

GENERAL FINISHING STEPS

OXETACAINE

GENERAL FINISHING STEPS

SODIUM CYCLAMATE

GENERAL FINISHING STEPS

ICHTHAMMOL

GENERAL FINISHING STEPS

METRONIDAZOLE

GENERAL FINISHING STEPS

FLUOCINOLONE ACETONIDE

GENERAL FINISHING STEPS

VENLAFAXINE HYDROCHLORIDE

GENERAL FINISHING STEPS

HYDROGEN PEROXIDE SOLUTION 6%

GENERAL FINISHING STEPS

QUININE SULPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

RAMIPRIL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BACLOFEN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BISOPROLOL FUMARATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

NALOXONE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PHENYTOIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

THEOPHYLLINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ACETYLSALICYLIC ACID

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DEXAMETHASONE SODIUM PHOSPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ALLOPURINOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

RESORCINOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

5-AMINOLEVULINIC ACID HYDROCHLORIDE

GENERAL FINISHING STEPS

DISODIUM EDETATE

GENERAL FINISHING STEPS

CLIOQUINOL

GENERAL FINISHING STEPS

SODIUM CHLORIDE

GENERAL FINISHING STEPS

CALCIUM CARBONATE HEAVY

GENERAL FINISHING STEPS

FERROUS SULPHATE HEPTAHYDRATE

GENERAL FINISHING STEPS

BETAMETHASONE VALERATE

GENERAL FINISHING STEPS

MAGNESIUM OXIDE HEAVY

GENERAL FINISHING STEPS

PILOCARPINE NITRATE

GENERAL FINISHING STEPS

SERTRALINE HYDROCHLORIDE

GENERAL FINISHING STEPS

PILOCARPINE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ENALAPRIL MALEATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TRICHLOROACETIC ACID

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

EXEMESTANE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DISODIUM PHOSPHATE ANHYDROUS

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

METRONIDAZOLE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DANTROLENE SODIUM

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SULPHUR

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PHENOL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SALICYLIC ACID

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SODIUM HYDROGEN CARBONATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

POTASSIUM IODIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MAGNESIUM GLYCEROPHOSPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ESTRADIOL VALERATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TEMOZOLOMIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BISACODYL POWDER

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TOPIRAMATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TACROLIMUS MONOHYDRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

POTASSIUM HYDROXIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

NIFEDIPINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

IODINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PHENOBARBITAL

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MIDAZOLAM HYDROCHLORIDE

GENERAL FINISHING STEPS

SILDENAFIL CITRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SODIUM VALPROATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DISODIUM PHOSPHATE ANHYDROUS

GENERAL FINISHING STEPS

PROFLAVINE HEMISULPHATE

GENERAL FINISHING STEPS

HYOSCINE HYDROBROMIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MIDAZOLAM HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

OLEIC ACID

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

IBUPROFEN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MAGNESIUM SULPHATE EXSICCATED

GENERAL FINISHING STEPS

SODIUM CARBONATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TRANEXAMIC ACID

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PHENYTOIN POWDER

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

HYDROCHLOROTHIAZIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

GRAMICIDIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ETHAMBUTOL HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ISONIAZID

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CHLOROQUINE PHOSPHATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CHLORHEXIDINE ACETATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MENTHOL CRYSTALS

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:

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

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 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:

18372677

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

ALMAC SCIENCES (SCOTLAND) LIMITED

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

2. Manufacturer's licence number(s):

API 34369

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

03/06/2021

This written confirmation remains valid until:

03/06/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

839548

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

APTUIT (OXFORD) LIMITED

150 BROOK DRIVE
MILTON PARK
ABINGDON
OX14 4SD

2. Manufacturer's licence number(s):

API 40699

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

06/09/2021

This written confirmation remains valid until:

06/09/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

11/10/2021

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

7634946

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

APTUIT (OXFORD) LIMITED

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

2. Manufacturer's licence number(s):

API 40699

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

06/09/2021

This written confirmation remains valid until:

06/09/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LENALIDOMIDE
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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

16/08/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

22/06/2022

Annex 1:

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

Active substance(s):
Activity(ies):

ICODEXTRIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

22/06/2022

Annex 1:

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

Active substance(s):
Activity(ies):

ICODEXTRIN

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

18235

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

BIO PRODUCTS LABORATORY LIMITED

DAGGER LANE
ELSTREE
BOREHAMWOOD
WD6 3BX

2. Manufacturer's licence number(s):

API 8801

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

29/11/2021

This written confirmation remains valid until:

29/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

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

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

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

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:

28051993

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

BSPG LABORATORIES LIMITED

SPITFIRE HOUSE, HUGIN LANE
DISCOVERY PARK
SANDWICH
CT13 9FG

2. Manufacturer's licence number(s):

API 48727

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

05/12/2022

This written confirmation remains valid until:

05/12/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

03/01/2023

Annex 1:

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

Active substance(s):
Activity(ies):

CANNABIDIOL

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

16389

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

CATALENT MICRON TECHNOLOGIES LIMITED

CROSSWAYS BOULEVARD
CROSSWAYS
DARTFORD
DA2 6QY

2. Manufacturer's licence number(s):

API 5451

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

21/06/2022

This written confirmation remains valid until:

21/06/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

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

18599281

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

CELADON PHARMA LIMITED

13 HOLFORD ESTATE
TAMESIDE DRIVE
BIRMINGHAM
B6 7AY

2. Manufacturer's licence number(s):

API 50530

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

19/10/2022

This written confirmation remains valid until:

19/10/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

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

19230206

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

CONCEPT LIFE SCIENCES INTEGRATED DISCOVERY AND DEVELOPMENT SERVICES LIMITED

DISCOVERY PARK HOUSE
RAMSGATE ROAD
SANDWICH
CT13 9ND

2. Manufacturer's licence number(s):

API 48975

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

22/06/2021

This written confirmation remains valid until:

22/06/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

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

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

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

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

11/12/2023

Annex 1:

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

Active substance(s):
Activity(ies):

CALCIUM PANTOTHENATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ASCORBIC ACID
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SODIUM ASCORBATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
PANTHENOL
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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

08/12/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

119738

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

EUROFINS SELCIA LIMITED

FYFIELD BUSINESS AND RESEARCH PARK
FYFIELD ROAD
ONGAR
CM5 0GS

2. Manufacturer's licence number(s):

API 27830

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

22/11/2021

This written confirmation remains valid until:

22/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

01/07/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

08/01/2021

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

15159

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

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

PRIORY STREET
WARE
SG12 0DJ

2. Manufacturer's licence number(s):

API 4

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

13/09/2021

This written confirmation remains valid until:

13/09/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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

21/09/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

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

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

117769

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

GLAXOSMITHKLINE

COBDEN STREET
MONTROSE
DD10 8EA

2. Manufacturer's licence number(s):

API 4

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

31/08/2022

This written confirmation remains valid until:

31/08/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

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

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

16/03/2021

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

17092

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

INDIVIOR UK LIMITED

DANSOM LANE
HULL
HU8 7DS

2. Manufacturer's licence number(s):

API 36699

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

09/05/2022

This written confirmation remains valid until:

09/05/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

25/08/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

1893

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

MACFARLAN SMITH LIMITED

10 WHEATFIELD ROAD
EDINBURGH
EH11 2QA

2. Manufacturer's licence number(s):

API 1108

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

29/11/2021

This written confirmation remains valid until:

29/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

12/09/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

MORPHINE TARTRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

DIAMORPHINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

NALOXONE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

DIAMORPHINE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

OXYCODONE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

OXYCODONE HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

PHOLCODINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

REMIFENTANIL HYDROCHLORIDE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

SUFENTANIL CITRATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

18248054

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

NEW HOLLAND EXTRACTION LIMITED

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

2. Manufacturer's licence number(s):

API 49277

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

16/03/2021

This written confirmation remains valid until:

16/03/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

24/05/2021

Annex 1:

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

Active substance(s):
Activity(ies):

EVENING PRIMROSE OIL

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

24295773

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

ONYX SCIENTIFIC LIMITED

WAYFARER ROAD
SUNDERLAND
SR5 3XA

2. Manufacturer's licence number(s):

API 21540

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

29/11/2021

This written confirmation remains valid until:

29/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

14/02/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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:

23/03/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

OPICAPONE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

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

DIPIPANONE HYDROCHLORIDE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

FLURBIPROFEN SODIUM DIHYDRATE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

NALOXONE HYDROCHLORIDE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

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

S-(+)-FLURBIPROFEN
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:

330820

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

PHYTOVATION LIMITED

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

2. Manufacturer's licence number(s):

API 30590

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

06/05/2021

This written confirmation remains valid until:

06/05/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

28/05/2021

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

18244

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

PIRAMAL HEALTHCARE UK LIMITED

WHALTON ROAD
MORPETH
NE61 3YA

2. Manufacturer's licence number(s):

API 29595

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

15/06/2021

This written confirmation remains valid until:

15/06/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

16/09/2021

Annex 1:

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

Active substance(s):
Activity(ies):

FERRIC TRIMALTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
CANRENOATE POTASSIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
HALOPERIDOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
MISOPROSTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
FOSTEMSAVIR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
HYDROFLUMETHIAZIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
PARECOXIB SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS
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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COAL TAR SOLUTION
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:

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

ARACHIS OIL
GENERAL FINISHING STEPS
ACETYLSALICYLIC ACID
GENERAL FINISHING STEPS
COMFREY LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
LAVENDER EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WHITE HOREHOUND LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
MYRRH TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ORANGE TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL AQUEOUS SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SENEGA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WHITE PINE COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
IPECACUANHA TINCTURE
GENERAL FINISHING STEPS
CAMPHORATED OPIUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BITTER ORANGE PEEL EXTRACT
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN
GENERAL FINISHING STEPS
COCILLANA EXTRACT
GENERAL FINISHING STEPS
GENTIAN TINCTURE,COMPOUND
GENERAL FINISHING STEPS
CARDAMOM TINCTURE,COMPOUND
GENERAL FINISHING STEPS
MAGNESIUM SULFATE HEPTAHYDRATE
GENERAL FINISHING STEPS
STRONG AMMONIUM ACETATE SOLUTION
GENERAL FINISHING STEPS
WILD LETTUCE AQUEOUS EXTRACT
GENERAL FINISHING STEPS
SENEGA ROOT CONCENTRATED INFUSION
GENERAL FINISHING STEPS
SALICYLIC ACID
GENERAL FINISHING STEPS
LIQUORICE LIQUID EXTRACT
GENERAL FINISHING STEPS

POTASSIUM CHLORIDE
GENERAL FINISHING STEPS
CONCENTRATED PEPPERMINT WATER
GENERAL FINISHING STEPS
COCILLANA LIQUID EXTRACT
GENERAL FINISHING STEPS
SQUILL LIQUID EXTRACT
GENERAL FINISHING STEPS
BENZOIN EXTRACT
GENERAL FINISHING STEPS
VALERIAN TINCTURE
GENERAL FINISHING STEPS
SQUILL TINCTURE
GENERAL FINISHING STEPS
CAMPHORATED OPIUM TINCTURE
GENERAL FINISHING STEPS
ORANGE TINCTURE
GENERAL FINISHING STEPS
BELLADONNA TINCTURE
GENERAL FINISHING STEPS
WHITE HOREHOUND LIQUID EXTRACT
GENERAL FINISHING STEPS
EUPHORBIA LIQUID EXTRACT
GENERAL FINISHING STEPS
WILD CHERRY SYRUP
GENERAL FINISHING STEPS
SQUILL AQUEOUS SOFT EXTRACT
GENERAL FINISHING STEPS
KRAMERIA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BENZOIN TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
IPECACUANHA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BENZOIN EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SENEGA TINCTURE
GENERAL FINISHING STEPS
GINGER TINCTURE,STRONG
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WILD CHERRY EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
EUPHORBIA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ARNICA FLOWER TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BENZOIN TINCTURE
GENERAL FINISHING STEPS
PELARGONIUM SIDOIDES AQUEOUS EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
COMFREY LIQUID EXTRACT
GENERAL FINISHING STEPS

SQUILL ALCOHOLIC SOFT EXTRACT
GENERAL FINISHING STEPS
ARNICA FLOWER TINCTURE
GENERAL FINISHING STEPS
SENEGA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CINCHONA EXTRACT
GENERAL FINISHING STEPS
PERU BALSAM
GENERAL FINISHING STEPS
SQUILL ELIXIR
GENERAL FINISHING STEPS
WHITE PINE COMPOUND
GENERAL FINISHING STEPS
CONCENTRATED PEPPERMINT WATER
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SENEGA ROOT CONCENTRATED INFUSION
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
MYRRH TINCTURE
GENERAL FINISHING STEPS
BENZOIN TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL VINEGAR
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BELLADONNA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BENZOIN EXTRACT COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GINGER EXTRACT
GENERAL FINISHING STEPS
GINGER TINCTURE,STRONG
GENERAL FINISHING STEPS
RHUBARB EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
QUASSIA LIQUID EXTRACT
GENERAL FINISHING STEPS
HEDERA LIQUID EXTRACT
GENERAL FINISHING STEPS
COMPOUND RHUBARB TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
HEDERA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENTIAN TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
QUASSIA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BENZOIN EXTRACT COMPOUND
GENERAL FINISHING STEPS
COMPOUND RHUBARB TINCTURE
GENERAL FINISHING STEPS
RHUBARB EXTRACT
GENERAL FINISHING STEPS
WILD LETTUCE AQUEOUS EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SENEGA LIQUID EXTRACT
GENERAL FINISHING STEPS

PELARGONIUM SIDOIDES AQUEOUS EXTRACT
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
STRONG AMMONIUM ACETATE SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SENEGA EXTRACT
GENERAL FINISHING STEPS
PEPPERMINT OIL
GENERAL FINISHING STEPS
IPECACUANHA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ICHTHAMMOL
GENERAL FINISHING STEPS
UVA URSI AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
CINCHONA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BUCHU DRY EXTRACT
GENERAL FINISHING STEPS
SODIUM BICARBONATE
GENERAL FINISHING STEPS
SLIPPERY ELM BARK EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VALERIAN TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GINGER EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
LAVENDER EXTRACT
GENERAL FINISHING STEPS
SQUILL TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL ALCOHOLIC SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
KRAMERIA TINCTURE
GENERAL FINISHING STEPS
LIQUID PARAFFIN
GENERAL FINISHING STEPS
IPECACUANHA EXTRACT
GENERAL FINISHING STEPS
GENTIAN EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CARDAMOM TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM SOFT EXTRACT
GENERAL FINISHING STEPS
IPECACUANHA LIQUID EXTRACT
GENERAL FINISHING STEPS
BENZOIN TINCTURE,COMPOUND
GENERAL FINISHING STEPS
EUPHORBIA EXTRACT
GENERAL FINISHING STEPS

LETTUCE AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
ZINC OXIDE
GENERAL FINISHING STEPS
SENEGA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VALERIAN AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
SQUILL OXYMEL
GENERAL FINISHING STEPS
GENTIAN EXTRACT
GENERAL FINISHING STEPS
SQUILL VINEGAR
GENERAL FINISHING STEPS
IPECACUANHA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BUCHU LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COCILLANA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
BITTER ORANGE PEEL EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WILD CHERRY SYRUP
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM TINCTURE
GENERAL FINISHING STEPS
COCILLANA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
VALERIAN EXTRACT
GENERAL FINISHING STEPS
PASSIFLORA INCARNATA AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SQUILL OXYMEL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
EUPHORBIA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
WILD CHERRY EXTRACT
GENERAL FINISHING STEPS
BUCHU LIQUID EXTRACT
GENERAL FINISHING STEPS
SLIPPERY ELM BARK EXTRACT
GENERAL FINISHING STEPS
SQUILL ELIXIR
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

119098

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

RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED

NOTTINGHAM SITE
THANE ROAD
NOTTINGHAM
NG90 2DB

2. Manufacturer's licence number(s):

API 12862

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

30/11/2021

This written confirmation remains valid until:

30/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

09/12/2022

Annex 1:

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

Active substance(s):
Activity(ies):

NAPHAZOLINE
GENERAL FINISHING STEPS
FLURBIPROFEN
GENERAL FINISHING STEPS
HAMAMELIS WATER
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
AMYLMETACRESOL
GENERAL FINISHING STEPS
BENZOCAINE
GENERAL FINISHING STEPS
CHLORAMPHENICOL
GENERAL FINISHING STEPS
SALICYLIC ACID
GENERAL FINISHING STEPS
2,4-DICHLOROBENZYL ALCOHOL
GENERAL FINISHING STEPS
HEXYLRESORCINOL
GENERAL FINISHING STEPS
TRIPROLIDINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CAFFEINE ANHYDROUS
GENERAL FINISHING STEPS
MENTHOL
GENERAL FINISHING STEPS
LIDOCAINE HYDROCHLORIDE
GENERAL FINISHING STEPS
CODEINE PHOSPHATE
GENERAL FINISHING STEPS
DIHYDROCODEINE TARTRATE
GENERAL FINISHING STEPS
PSEUDOEPHEDRINE HYDROCHLORIDE
GENERAL FINISHING STEPS
IBUPROFEN DL-LYSINE
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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

MHRA

13/10/2023

Annex 1:

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

Active substance(s):
Activity(ies):

ANISE OIL
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ARCTIUM LAPPA ROOT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
AVENA SATIVA
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BAPTISIA TINCTORIA
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
BELLADONNA TINCTURE
GENERAL FINISHING STEPS
BOSWELLIA SERRATA EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CAMPHORATED OPIUM TINCTURE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CARAPICHEA IPECACUANHA ROOT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CHLOROFORM AND MORPHINE TINCTURE
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
CIMICIFUGA RACEMOSA
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COAL TAR SOLUTION
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COAL TAR SOLUTION STRONG
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COCILLANA EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COCILLANA LIQUID EXTRACT
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
COMMIPHORA MYRRHA RESIN
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
DRIMIA INDICA
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
ECHINACEA

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EPHEDRINE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

FUCUS VESICULOSUS

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

FUMARIA OFFICINALIS HERB

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

GUAREA RUSBYI

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

HYPERICUM PERFORATUM

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

HYSSOPUS OFFICINALIS HERB

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

INULA HELENIUM ROOT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

LIQUIFIED PHENOL

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

LOBELIA INFLATA

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

MARRUBIUM VULGARE HERB

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

MATRICARIA CHAMOMILLA FLOWERS

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

OPIUM TINCTURE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PAEONIA LACTIFLORA UNPEELED ROOT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PASSIFLORA INCARNATA

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

POLYGALA SENEGA ROOT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PREPARED COAL TAR

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

RHEUM PALMATUM
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
SCUTELLARIA LATERIFLORA
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
TOLU BALSAM SOLUTION
GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
TOLU BALSAM SYRUP
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
TOLU FLAVOUR
GENERAL FINISHING STEPS
TOLU-FLAVOUR SOLUTION
GENERAL FINISHING STEPS
VALERIANA OFFICINALIS ROOT
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
VITEX AGNUS-CASTUS FRUIT
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:

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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
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:

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

27/01/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

9727

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

SPECIALTY MINERALS

LIFFORD LANE
KINGS NORTON
BIRMINGHAM
B30 3JW

2. Manufacturer's licence number(s):

API 27886

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

23/06/2022

This written confirmation remains valid until:

23/06/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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

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:

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:

09/06/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

29/06/2021

Annex 1:

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

Active substance(s):
Activity(ies):

ACRIVASTINE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ARFORMOTEROL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CANNABIDIOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CERIUM NITRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
CODEINE PHOSPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIMETHYL FUMARATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
DIROXIMEL FUMARATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
FERRIC MALTOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ILOPERIDONE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVALBUTEROL HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LEVALBUTEROL TARTRATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
LUMACAFTOR
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
METHOXYFLURANE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
OCTENIDINE DIHYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
POLIDOCANOL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
RACTOPAMINE HYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

REBOXETINE METHANESULPHONATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SELAMECTIN
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SESTAMIBI
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
SISAPRONIL
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TAZEMETOSTAT
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TOCERANIB PHOSPHATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
TRIENTINE DIHYDROCHLORIDE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
ZILEUTON
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 LANE
NORTHWICH
CW8 4DT

2. Manufacturer's licence number(s):

API 10762

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

28/09/2021

This written confirmation remains valid until:

28/09/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

21/02/2022

Annex 1:

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

Active substance(s):
Activity(ies):

SODIUM BICARBONATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

1456

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

THOMAS SWAN & COMPANY LIMITED

ROTARY WAY
CONSETT
DH8 7ND

2. Manufacturer's licence number(s):

API 10524

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

02/02/2022

This written confirmation remains valid until:

02/02/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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 Andrew Gray
Group Manager Inspectorate & Process Licensing
and Head of UK GLPMA, MHRA

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):

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