Medicines & Healthcare products Regulatory Agency

MHRA

MHRA Register of Written Confirmations For UK Active Substance Manufacturers

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

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

Date of Publication: 09 Aug 2024

T 020 3080 6000 – www.mhra.gov.uk

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

119098

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

RECKITT BENCKISER HEALTHCARE INTERNATIONAL LIMITED

NOTTINGHAM SITE
THANE ROAD
NOTTINGHAM
NG90 2DB

2. Manufacturer's licence number(s):

API 12862

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

30/11/2021

This written confirmation remains valid until:

30/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

09/12/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

123039

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

RUTLAND BIODYNAMICS LIMITED

TOWN PARK FARM
OAKHAM ROAD, BROOKE
OAKHAM
LE15 8DG

2. Manufacturer's licence number(s):

API 28255

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

31/08/2023

This written confirmation remains valid until:

31/08/2026

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

13/10/2023

Annex 1:

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

Active substance(s):
Activity(ies):

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

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ANISE OIL

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

PREPARED COAL TAR

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

OPIUM TINCTURE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

POLYGALA SENEGA ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

BAPTISIA TINCTORIA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

MARRUBIUM VULGARE HERB

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

SCUTELLARIA LATERIFLORA

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

FUCUS VESICULOSUS

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

ARCTIUM LAPPA ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

HYPERICUM PERFORATUM

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

BELLADONNA TINCTURE

GENERAL FINISHING STEPS

TOLU BALSAM SOLUTION

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COMMIPHORA MYRRHA RESIN

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

COCILLANA LIQUID EXTRACT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COAL TAR SOLUTION

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

ECHINACEA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

TOLU BALSAM SYRUP

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

MATRICARIA CHAMOMILLA FLOWERS

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

AVENA SATIVA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

CARAPICHEA IPECACUANHA ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

TOLU FLAVOUR

GENERAL FINISHING STEPS

DRIMIA INDICA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

INULA HELENIUM ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

TOLU-FLAVOUR SOLUTION

GENERAL FINISHING STEPS

CHLOROFORM AND MORPHINE TINCTURE

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

LIQUIFIED PHENOL

GENERAL FINISHING STEPS

VALERIANA OFFICINALIS ROOT

GENERAL FINISHING STEPS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAMPHORATED OPIUM TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

3922

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

SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS

CLARENDON ROAD
WORTHING
BN14 8QH

2. Manufacturer's licence number(s):

API 10592

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

13/07/2022

This written confirmation remains valid until:

13/07/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

16/08/2022

Annex 1:

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

Active substance(s):
Activity(ies):

POTASSIUM CLAVULANATE

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

1524

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

SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS

SHEWALTON ROAD
IRVINE
KA11 5AP

2. Manufacturer's licence number(s):

API 10592

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

14/12/2020

This written confirmation remains valid until:

31/12/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

16/02/2021

Annex 1:

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

Active substance(s):
Activity(ies):

POTASSIUM CLAVULANATE DILUTED

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

296341

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

SOHO FLORDIS UK LIMITED TRADING AS POTTERS

1 BOTANIC COURT
MARTLAND PARK
WIGAN
WN5 0JZ

2. Manufacturer's licence number(s):

API 44893

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

15/11/2021

This written confirmation remains valid until:

15/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

27/01/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

9727

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

SPECIALTY MINERALS

LIFFORD LANE
KINGS NORTON
BIRMINGHAM
B30 3JW

2. Manufacturer's licence number(s):

API 27886

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

23/06/2022

This written confirmation remains valid until:

23/06/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

14/09/2022

Annex 1:

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

Active substance(s):
Activity(ies):

CALCIUM CARBONATE

GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

6523

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

STERLING PHARMA SOLUTIONS LIMITED

CRAMLINGTON ROAD
DUDLEY
NE23 7QG

2. Manufacturer's licence number(s):

API 29350

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

09/06/2021

This written confirmation remains valid until:

31/12/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

29/06/2021

Annex 1:

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

Active substance(s):
Activity(ies):

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

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

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

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

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

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

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

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

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

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

1649

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

TATA CHEMICALS EUROPE LIMITED

MOND HOUSE
WINNINGTON
NORTHWICH
CW8 4DT

2. Manufacturer's licence number(s):

API 10762

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

28/09/2021

This written confirmation remains valid until:

31/12/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

21/02/2022

Annex 1:

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

Active substance(s):
Activity(ies):

SODIUM BICARBONATE
GENERAL FINISHING STEPS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

1456

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

THOMAS SWAN & COMPANY LIMITED

ROTARY WAY
CONSETT
DH8 7ND

2. Manufacturer's licence number(s):

API 10524

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

02/02/2022

This written confirmation remains valid until:

02/02/2025

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

15/03/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

817429

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

VENATOR PIGMENTS UK LIMITED

BIRTLEY
CHESTER LE STREET
DH3 1QX

2. Manufacturer's licence number(s):

API 34855

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

20/06/2023

This written confirmation remains valid until:

20/06/2026

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

15/09/2023

Annex 1:

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

Active substance(s):
Activity(ies):

CALAMINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

296341

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

VIFOR PHARMA UK LIMITED - POTTERS DIVISION

1 BOTANIC COURT
MARTLAND PARK
WIGAN
WN5 0JZ

2. Manufacturer's licence number(s):

API 33656

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

15/11/2021

This written confirmation remains valid until:

15/11/2024

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

Address of the issuing regulatory authority:

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

Name and function of responsible person:

Mr James Pound
Deputy Director Standards & Compliance

E-mail and Telephone no.:

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

Signature Stamp of the authority and date

27/01/2022

Annex 1:

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

Active substance(s):
Activity(ies):

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