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: 15/01/2020

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 in the event of no-deal EU Exit.

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

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

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PEPCEUTICALS LIMITED
PHYTOVATION LIMITED
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RANSOM NATURALS LIMITED
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RUTLAND BIODYNAMICS LIMITED
SELCIA LIMITED
SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS
SMITHKLINE BEECHAM LTD T\A SMITHKLINE BEECHAM PHARMACEUTICALS
SOHO FLORDIS UK LIMITED TRADING AS POTTERS
SPECIALITY MINERALS
STERLING PHARMA SOLUTIONS LIMITED
TATA CHEMICALS EUROPE LIMITED
THORNTON & ROSS LIMITED
THORNTON & ROSS 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:

2404

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

A NELSON AND COMPANY LIMITED

UNIT 1, UNIT 5-9 ENDEAVOUR WAY
LONDON
SW19 8UH

2. Manufacturer's licence number(s):

API 1175

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):

21/10/2019

This written confirmation remains valid until:

21/10/2022

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

28/10/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ACIDUM ARSENICOSUM
GENERAL FINISHING STEPS
ACONITUM NAPELLUS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ACONITUM NAPELLUS
GENERAL FINISHING STEPS
ARNICA MONTANA
GENERAL FINISHING STEPS
ARNICA MONTANA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ATROPA BELLADONNA
GENERAL FINISHING STEPS
ATROPA BELLADONNA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CHAMOMILLA RECUTITA
GENERAL FINISHING STEPS
CHAMOMILLA RECUTITA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EUPHRASIA OFFICINALIS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EUPHRASIA OFFICINALIS
GENERAL FINISHING STEPS
GELSEMIUM SEMPERVIRENS
GENERAL FINISHING STEPS
GELSEMIUM SEMPERVIRENS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

NATRUM CHLORATUM
GENERAL FINISHING STEPS
PULSATILLA
GENERAL FINISHING STEPS
PULSATILLA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

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PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

RHUS TOXICODENDRON
GENERAL FINISHING STEPS
SEPIA OFFICINALIS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SEPIA OFFICINALIS

GENERAL FINISHING STEPS

STRYCHNOS IGNATII

GENERAL FINISHING STEPS

STRYCHNOS IGNATII

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

STRYCHNOS NUX-VOMICA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

STRYCHNOS NUX-VOMICA

GENERAL FINISHING STEPS

SULFUR

GENERAL FINISHING STEPS

THUJA OCCIDENTALIS

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

THUJA OCCIDENTALIS

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):

AESICA PHARMACEUTICALS LIMITED

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):

23/05/2018

This written confirmation remains valid until:

23/05/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

CANNABIDIOL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

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

DIPIPANONE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DIPIPANONE HYDROCHLORIDE
GENERAL FINISHING STEPS
FLURBIPROFEN
GENERAL FINISHING STEPS
FLURBIPROFEN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

FLURBIPROFEN SODIUM DIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

FLURBIPROFEN SODIUM DIHYDRATE
GENERAL FINISHING STEPS
FLUTICASONE PROPIONATE
GENERAL FINISHING STEPS
FLUTICASONE PROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

NALTREXONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

NITISINONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

NITISINONE
GENERAL FINISHING STEPS
OPICAPONE
GENERAL FINISHING STEPS
OPICAPONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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OXYCODONE HYDROCHLORIDE
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PAROXETINE HYDROCHLORIDE ANHYDROUS
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PAROXETINE HYDROCHLORIDE ANHYDROUS
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PAROXETINE HYDROCHLORIDE HEMIHYDRATE
GENERAL FINISHING STEPS
PAROXETINE HYDROCHLORIDE HEMIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

S-(+)-FLURBIPROFEN
GENERAL FINISHING STEPS
S-(+)-FLURBIPROFEN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

30433

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

AESICA QUEENBOROUGH LIMITED

NORTH ROAD
QUEENBOROUGH
ME11 5EL

2. Manufacturer's licence number(s):

API 32496

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):

07/05/2019

This written confirmation remains valid until:

07/05/2022

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

07/08/2019

Annex 1:

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

Active substance(s):
Activity(ies):

CISATRACURIUM BESYLATE
GENERAL FINISHING STEPS
CISATRACURIUM BESYLATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

FLURBIPROFEN SODIUM DIHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ISOFLURANE
GENERAL FINISHING STEPS
ISOFLURANE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

NALTREXONE BASE ANHYDROUS
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NALTREXONE BASE ANHYDROUS
GENERAL FINISHING STEPS
NALTREXONE HYDROCHLORIDE
GENERAL FINISHING STEPS
NALTREXONE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

REMIFENTANIL HYDROCHLORIDE
GENERAL FINISHING STEPS
REMIFENTANIL HYDROCHLORIDE
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:

22324

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

AIR PRODUCTS PLC

SALTEND LANE
HEDON
HULL
HU12 8PP

2. Manufacturer's licence number(s):

API 6183

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):

28/11/2018

This written confirmation remains valid until:

28/11/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

OXYGEN

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:

114424

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

ALLIANCE MEDICAL RADIOPHARMACY LIMITED

KEELE UNIVERSITY SCIENCE PARK
KEELE
ST5 5BX

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):

24/07/2019

This written confirmation remains valid until:

24/07/2022

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

16/08/2019

Annex 1:

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

Active substance(s):
Activity(ies):

FLUORODEOXYGLUCOSE (18F)
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

FLUORODEOXYGLUCOSE (18F)
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

926769

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

ALLIANCE MEDICAL RADIOPHARMACY LIMITED

ROYAL MARSDEN HOSPITAL
DOWNS ROAD
SUTTON
SM2 5PT

2. Manufacturer's licence number(s):

API 34938

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

11/12/2017

This written confirmation remains valid until:

11/12/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

FLUORODEOXYGLUCOSE (18F)
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

FLUORODEOXYGLUCOSE (18F)
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):

26/11/2018

This written confirmation remains valid until:

26/11/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ACTIVE SUBSTANCES FOR CLINICAL TRIALS
GENERAL FINISHING STEPS
ACTIVE SUBSTANCES FOR CLINICAL TRIALS
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:

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):

14/11/2018

This written confirmation remains valid until:

14/11/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

FROVATRIPTAN SUCCINATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

LENALIDOMIDE
GENERAL FINISHING STEPS
PLERIXAFOR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PLERIXAFOR
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:

7634946

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

APTUIT (OXFORD) LIMITED

110-111 AND 117 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):

14/11/2018

This written confirmation remains valid until:

14/11/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

FROVATRIPTAN SUCCINATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

LENALIDOMIDE
GENERAL FINISHING STEPS
PLERIXAFOR
GENERAL FINISHING STEPS
PLERIXAFOR
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:

18353863

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

APTUIT (OXFORD) LIMITED

115E-115H INNOVATION DRIVE
MILTON PARK, MILTON
ABINGDON
OX14 4SA

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):

14/11/2018

This written confirmation remains valid until:

14/11/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

FROVATRIPTAN SUCCINATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PLERIXAFOR
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:

14758219

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

ARC TRINOVA LIMITED T\A ARCINOVA

TAYLOR DRIVE
ALNWICK
NE66 2DH

2. Manufacturer's licence number(s):

API 45848

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):

20/06/2019

This written confirmation remains valid until:

20/06/2022

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

29/10/2019

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

RIMIDUCID
GENERAL FINISHING STEPS
RIMIDUCID
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:

10116

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

ASTRAZENECA UK LIMITED

AVLON SITE
SEVERN ROAD, HALLEN
BRISTOL
BS10 7ZE

2. Manufacturer's licence number(s):

API 32467

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):

20/03/2018

This written confirmation remains valid until:

20/03/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

QUETIAPINE FUMARATE
GENERAL FINISHING STEPS
QUETIAPINE FUMARATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ROSUVASTATIN CALCIUM
GENERAL FINISHING STEPS
ROSUVASTATIN CALCIUM
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:

10117

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

ASTRAZENECA UK LIMITED, UK OPERATIONS MACCLESFIELD

SILK ROAD BUSINESS PARK
MACCLESFIELD
SK10 2NA

2. Manufacturer's licence number(s):

API 17901

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):

11/06/2019

This written confirmation remains valid until:

11/06/2022

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

15/08/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ACALABRUTINIB
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ACALABRUTINIB
GENERAL FINISHING STEPS
FULVESTRANT
GENERAL FINISHING STEPS
FULVESTRANT
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
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):

22/03/2018

This written confirmation remains valid until:

22/03/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

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

EICOSAPENTAENOIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

EICOSAPENTAENOIC ACID
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

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):

18/02/2019

This written confirmation remains valid until:

18/02/2022

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

27/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

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

SIMETHICONE EMULSION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SIMETHICONE EMULSION
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):

29/07/2019

This written confirmation remains valid until:

29/07/2022

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

07/10/2019

Annex 1:

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

Active substance(s):
Activity(ies):

B+1 PASTE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

B+1 PASTE
GENERAL FINISHING STEPS
CRYOPRECIPITATE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CRYOPRECIPITATE
GENERAL FINISHING STEPS
FRACTION IV PASTE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

FRACTION IV PASTE
GENERAL FINISHING STEPS
FRACTION V
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

FRACTION V
GENERAL FINISHING STEPS
HUMAN PROTHROMBIN COMPLEX
GENERAL FINISHING STEPS
HUMAN PROTHROMBIN COMPLEX
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:

4473

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

BIORELIANCE LIMITED

TODD CAMPUS
WEST OF SCOTLAND SCIENCE PARK
GLASGOW
G20 0XA

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):

11/10/2017

This written confirmation remains valid until:

11/10/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ADENOVIRUS TYPE 4
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES

ADENOVIRUS TYPE 7
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

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):

09/10/2017

This written confirmation remains valid until:

09/10/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ADENOVIRUS TYPE 4
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES

ADENOVIRUS TYPE 7
MANUFACTURE OF ACTIVE SUBSTANCE USING BIOLOGICAL PROCESSES

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

17652846

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

BSPG LABORATORIES LIMITED

DISCOVERY PARK HOUSE
RAMSGATE ROAD
SANDWICH
CT13 9ND

2. Manufacturer's licence number(s):

API 48727

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

22/01/2019

This written confirmation remains valid until:

22/01/2022

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

28/03/2019

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
CANNABIDIOL
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):

03/05/2017

This written confirmation remains valid until:

03/05/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ACLIDINIUM BROMIDE
GENERAL FINISHING STEPS
ALLOPURINOL
GENERAL FINISHING STEPS
ALPRAZOLAM
GENERAL FINISHING STEPS
APIXABAN
GENERAL FINISHING STEPS
ARIPIPRAZOLE
GENERAL FINISHING STEPS
AXITINIB
GENERAL FINISHING STEPS
CEDIRANIB
GENERAL FINISHING STEPS
CHLORTHALIDONE
GENERAL FINISHING STEPS
CLIOQUINOL
GENERAL FINISHING STEPS
DABRAFENIB MESYLATE
GENERAL FINISHING STEPS
DASATINIB
GENERAL FINISHING STEPS
DIHYDROSTREPTOMYCIN SULPHATE
GENERAL FINISHING STEPS
DISODIUM TETRABORATE DECAHYDRATE
GENERAL FINISHING STEPS
DOLUTEGRAVIR SODIUM
GENERAL FINISHING STEPS
EFAVIRENZ
GENERAL FINISHING STEPS
ESOMEPRAZOLE
GENERAL FINISHING STEPS
ESTRADIOL HEMIHYDRATE
GENERAL FINISHING STEPS
FOLIC ACID
GENERAL FINISHING STEPS
GLIBENCLAMIDE
GENERAL FINISHING STEPS
GLIPIZIDE
GENERAL FINISHING STEPS
ILOPERIDONE
GENERAL FINISHING STEPS
ISOTRETINOIN
GENERAL FINISHING STEPS
IVERMECTIN
GENERAL FINISHING STEPS
LACTOSE
GENERAL FINISHING STEPS

LENALIDOMIDE
GENERAL FINISHING STEPS
LOPERAMIDE HYDROCHLORIDE
GENERAL FINISHING STEPS
MIFEPRISTONE
GENERAL FINISHING STEPS
NITISINONE
GENERAL FINISHING STEPS
OXYTETRACYCLINE DIHYDRATE
GENERAL FINISHING STEPS
PAZOPANIB HYDROCHLORIDE
GENERAL FINISHING STEPS
PHENYLBUTAZONE
GENERAL FINISHING STEPS
SALBUTAMOL SULPHATE
GENERAL FINISHING STEPS
TETRACAINE HYDROCHLORIDE
GENERAL FINISHING STEPS
TRETINOIN
GENERAL FINISHING STEPS
TRIAZOLAM
GENERAL FINISHING STEPS
TRILOSTANE
GENERAL FINISHING STEPS
VANDETANIB
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):

29/08/2018

This written confirmation remains valid until:

29/08/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

CAFFEINE AND SODIUM BENZOATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CAFFEINE AND SODIUM BENZOATE
GENERAL FINISHING STEPS
CAFFEINE CITRATE
GENERAL FINISHING STEPS
CAFFEINE CITRATE
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:

7560

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

COVANCE LABORATORIES LIMITED

TAYLOR DRIVE
ALNWICK
NE66 2DH

2. Manufacturer's licence number(s):

API 15967

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):

13/02/2017

This written confirmation remains valid until:

20/02/2020

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

11/03/2019

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

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:

16026

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

CRODA EUROPE LIMITED

FOUNDRY LANE
DITTON
WIDNES
WA8 8UB

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):

24/09/2019

This written confirmation remains valid until:

24/09/2022

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

24/10/2019

Annex 1:

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

Active substance(s):
Activity(ies):

TITANIUM DIOXIDE
GENERAL FINISHING STEPS
TITANIUM DIOXIDE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ZINC OXIDE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ZINC OXIDE
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:

646098

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

DR REDDY'S LABORATORIES (EU) LIMITED

STEANARD LANE
MIRFIELD
WF14 8HZ

2. Manufacturer's licence number(s):

API 8931

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):

22/10/2019

This written confirmation remains valid until:

22/10/2022

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

08/11/2019

Annex 1:

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

Active substance(s):
Activity(ies):

LUBIPROSTONE
GENERAL FINISHING STEPS
LUBIPROSTONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PERMETHRIN MEDICAL GRADE CIS/TRANS ISOMERS 25/75
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PERMETHRIN MEDICAL GRADE CIS/TRANS ISOMERS 25/75
GENERAL FINISHING STEPS
PERMETHRIN MEDICAL GRADE VETERINARY CIS:TRANS 25:75
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PERMETHRIN MEDICAL GRADE VETERINARY CIS:TRANS 25:75
GENERAL FINISHING STEPS
PERMETHRIN MEDICAL GRADE VETERINARY CIS:TRANS 40:60
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PERMETHRIN MEDICAL GRADE VETERINARY CIS:TRANS 40:60
GENERAL FINISHING STEPS
TRAVOPROST
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TRAVOPROST
GENERAL FINISHING STEPS
TREPROSTINIL
GENERAL FINISHING STEPS
TREPROSTINIL
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):

29/10/2018

This written confirmation remains valid until:

29/10/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ASCORBIC ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ASCORBIC ACID
GENERAL FINISHING STEPS
CALCIUM PANTOTHENATE
GENERAL FINISHING STEPS
CALCIUM PANTOTHENATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

PANTHENOL
GENERAL FINISHING STEPS
PANTHENOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SODIUM ASCORBATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SODIUM ASCORBATE
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:

3399

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

F D COPELAND AND SONS LIMITED

COLANOL HOUSE
5 WESTFIELD STREET
LONDON
SE18 5TL

2. Manufacturer's licence number(s):

API 12822

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):

10/09/2019

This written confirmation remains valid until:

10/09/2022

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

29/10/2019

Annex 1:

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

Active substance(s):
Activity(ies):

CAJEPUT OIL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAJEPUT OIL
GENERAL FINISHING STEPS
CLOVE OIL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CLOVE OIL
GENERAL FINISHING STEPS
DEMENTHOLISED MINT OIL
GENERAL FINISHING STEPS
DEMENTHOLISED MINT OIL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EUCALYPTUS OIL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EUCALYPTUS OIL
GENERAL FINISHING STEPS
JUNIPER BERRY OIL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

JUNIPER BERRY OIL
GENERAL FINISHING STEPS
PEPPERMINT OIL
GENERAL FINISHING STEPS
PEPPERMINT OIL
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:

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):

26/09/2017

This written confirmation remains valid until:

26/09/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

KETAMINE HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

KETAMINE HYDROCHLORIDE
GENERAL FINISHING STEPS
LIQUIFIED PHENOL
GENERAL FINISHING STEPS
LIQUIFIED PHENOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

METARAMINOL BITARTRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

STRONG AMMONIA SOLUTION
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:

14432

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

GE HEALTHCARE LIMITED

THE GROVE CENTRE
WHITE LION ROAD
AMERSHAM
HP7 9LL

2. Manufacturer's licence number(s):

API 221

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):

01/06/2018

This written confirmation remains valid until:

01/06/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

CHROMIUM EDETATE (51CR)
GENERAL FINISHING STEPS
CHROMIUM EDETATE (51CR)
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

CHROMIUM EDETATE (51CR)
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SODIUM CHROMATE (51CR)
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SODIUM CHROMATE (51CR)
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

SODIUM CHROMATE (51CR)
GENERAL FINISHING STEPS
STRONTIUM-89 DICHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

STRONTIUM-89 DICHLORIDE
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

STRONTIUM-89 DICHLORIDE
GENERAL FINISHING STEPS
TAUROSELCHOLIC ACID (75SE)
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TAUROSELCHOLIC ACID (75SE)
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:

18052

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

GENZYME 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):

22/07/2019

This written confirmation remains valid until:

22/07/2022

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

07/10/2019

Annex 1:

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

Active substance(s):
Activity(ies):

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

SEVELAMER HYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SEVELAMER 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:

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):

21/01/2019

This written confirmation remains valid until:

21/01/2022

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

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

22/05/2017

This written confirmation remains valid until:

22/05/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

AVIBACTAM SODIUM
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

AVIBACTAM SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

AVIBACTAM SODIUM
GENERAL FINISHING STEPS
CEFTAZIDIME PENTAHYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CEFTAZIDIME PENTAHYDRATE
GENERAL FINISHING STEPS
CEFTAZIDIME PENTAHYDRATE
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

CEFUROXIME AXETIL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CEFUROXIME AXETIL
GENERAL FINISHING STEPS
CEFUROXIME SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CEFUROXIME SODIUM
GENERAL FINISHING STEPS
CEFUROXIME SODIUM
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

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):

22/05/2019

This written confirmation remains valid until:

22/05/2022

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

22/05/2019

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
ABACAVIR SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ALUMINIUM PHOSPHATE
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

ALUMINIUM PHOSPHATE
GENERAL FINISHING STEPS
ALUMINIUM PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BETAMETHASONE ALCOHOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BETAMETHASONE ALCOHOL
GENERAL FINISHING STEPS
BETAMETHASONE VALERATE
GENERAL FINISHING STEPS
BETAMETHASONE VALERATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CLOBETASOL PROPIONATE
GENERAL FINISHING STEPS
CLOBETASOL PROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CLOBETASONE BUTYRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CLOBETASONE BUTYRATE
GENERAL FINISHING STEPS
DUTASTERIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DUTASTERIDE
GENERAL FINISHING STEPS
FLUTICASONE FUROATE
GENERAL FINISHING STEPS
FLUTICASONE FUROATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

FLUTICASONE PROPIONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

FLUTICASONE PROPIONATE
GENERAL FINISHING STEPS

LACIDIPINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LACIDIPINE
GENERAL FINISHING STEPS

SALBUTAMOL SULPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SALBUTAMOL SULPHATE
GENERAL FINISHING STEPS

ZANAMIVIR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ZANAMIVIR
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):

12/09/2017

This written confirmation remains valid until:

12/09/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

BUPRENORPHINE HYDROCHLORIDE
GENERAL FINISHING STEPS
BUPRENORPHINE HYDROCHLORIDE
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:

17726

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

KLINGE CHEMICALS LIMITED

5-7 ALBION WAY
KELVIN INDUSTRIAL ESTATE, EAST KILBRIDE
GLASGOW
G75 0YN

2. Manufacturer's licence number(s):

API 8170

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):

12/03/2019

This written confirmation remains valid until:

12/03/2022

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

12/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

POTASSIUM CHLORIDE
GENERAL FINISHING STEPS
POTASSIUM CHLORIDE
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:

17762203

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

MACFARLAN SMITH LIMITED

THREE TREES ROAD
NEWBIE
ANNAN
DG12 5QH

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):

29/01/2019

This written confirmation remains valid until:

29/01/2022

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

15/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

BUPRENORPHINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

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

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

OXYCODONE HYDROCHLORIDE
GENERAL FINISHING STEPS
OXYCODONE HYDROCHLORIDE
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:

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):

13/06/2018

This written confirmation remains valid until:

13/06/2021

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

11/03/2019

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

EVENING PRIMROSE OIL
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:

1722

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

NICOBRAND LIMITED

189 CASTLEROE ROAD
COLERAINE
BT51 3RP

2. Manufacturer's licence number(s):

API 10866

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):

31/12/2018

This written confirmation remains valid until:

31/12/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

NICOTINE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

NICOTINE
GENERAL FINISHING STEPS
NICOTINE POLACRILEX
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

NICOTINE POLACRILEX
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

1769489

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

NOVARTIS GRIMSBY LIMITED

PYEWIPE
GRIMSBY
DN31 2SR

2. Manufacturer's licence number(s):

API 15856

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

18/03/2019

This written confirmation remains valid until:

18/03/2022

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

12/09/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ALISKIREN HEMIFUMARATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ALISKIREN HEMIFUMARATE
GENERAL FINISHING STEPS
BENZONATATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

BENZONATATE
GENERAL FINISHING STEPS
DICLOFENAC DIETHYLAMINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DICLOFENAC DIETHYLAMINE
GENERAL FINISHING STEPS
DICLOFENAC FREE ACID
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DICLOFENAC FREE ACID
GENERAL FINISHING STEPS
DICLOFENAC POTASSIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DICLOFENAC POTASSIUM
GENERAL FINISHING STEPS
DICLOFENAC SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

DICLOFENAC SODIUM
GENERAL FINISHING STEPS
FAMCICLOVIR
GENERAL FINISHING STEPS
FAMCICLOVIR
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

LUMIRACOXIB
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

METHYLPHENIDATE HYDROCHLORIDE
GENERAL FINISHING STEPS
OXCARBAZEPINE
GENERAL FINISHING STEPS
OXCARBAZEPINE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

RIBOCICLIB SUCCINATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

RIBOCICLIB SUCCINATE
GENERAL FINISHING STEPS
SACUBITRIL VALSARTAN SODIUM HYDRATE
GENERAL FINISHING STEPS
SACUBITRIL VALSARTAN SODIUM HYDRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TELBIVUDINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TELBIVUDINE
GENERAL FINISHING STEPS
TERBINAFINE BASE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

TERBINAFINE BASE
GENERAL FINISHING STEPS
TRIBENOSIDE
GENERAL FINISHING STEPS
TRIBENOSIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

VALSARTAN
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

VALSARTAN
GENERAL FINISHING STEPS
VILDAGLIPTIN
GENERAL FINISHING STEPS
VILDAGLIPTIN
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:

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):

26/09/2017

This written confirmation remains valid until:

26/09/2020

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

11/03/2019

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

ACTIVE SUBSTANCES FOR CLINICAL TRIALS
GENERAL FINISHING STEPS
ACTIVE SUBSTANCES FOR CLINICAL TRIALS
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:

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):

12/12/2017

This written confirmation remains valid until:

12/12/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ALMOND OIL
GENERAL FINISHING STEPS
ANHYDROUS LANOLIN
GENERAL FINISHING STEPS
CANTHARIDES
GENERAL FINISHING STEPS
EMULSIFYING WAX ANIONIC
GENERAL FINISHING STEPS
EMULSIFYING WAX NON-IONIC
GENERAL FINISHING STEPS
EUCALYPTUS OIL
GENERAL FINISHING STEPS
GINGER TINCTURE,STRONG
GENERAL FINISHING STEPS
GLYCERIN
GENERAL FINISHING STEPS
ICHTHAMMOL
GENERAL FINISHING STEPS
IPECACUANHA TINCTURE
GENERAL FINISHING STEPS
KRAMERIA TINCTURE
GENERAL FINISHING STEPS
LAVENDER OIL
GENERAL FINISHING STEPS
MENTHOL
GENERAL FINISHING STEPS
PARAFFIN SOFT YELLOW
GENERAL FINISHING STEPS
PEPPERMINT OIL
GENERAL FINISHING STEPS
SENNA PODS, POWDERED, STANDARDISED
GENERAL FINISHING STEPS
SENNA PODS, POWDERED, STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL TINCTURE
GENERAL FINISHING STEPS
WOOL ALCOHOLS
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):

17/09/2018

This written confirmation remains valid until:

17/09/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

CANRENOATE POTASSIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CANRENOATE POTASSIUM
GENERAL FINISHING STEPS
FERRIC TRIMALTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

FERRIC TRIMALTOL
GENERAL FINISHING STEPS
HALOPERIDOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

HALOPERIDOL
GENERAL FINISHING STEPS
HYDROFLUMETHIAZIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

HYDROFLUMETHIAZIDE
GENERAL FINISHING STEPS
MISOPROSTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MISOPROSTOL
GENERAL FINISHING STEPS
MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MISOPROSTOL:HYPROMELLOSE 1:100 DISPERSION
GENERAL FINISHING STEPS
PARECOXIB SODIUM
GENERAL FINISHING STEPS
PARECOXIB SODIUM
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SPIRONOLACTONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SPIRONOLACTONE
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

345063

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

RANSOM NATURALS LIMITED

51-55 BURY MEAD ROAD
HITCHIN
SG5 1RT

2. Manufacturer's licence number(s):

API 39937

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

10/12/2019

This written confirmation remains valid until:

10/12/2022

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

10/12/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ACETYLSALICYLIC ACID
GENERAL FINISHING STEPS
ARACHIS OIL
GENERAL FINISHING STEPS
ARNICA FLOWER TINCTURE
GENERAL FINISHING STEPS
ARNICA FLOWER TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BELLADONNA TINCTURE
GENERAL FINISHING STEPS
BELLADONNA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN EXTRACT
GENERAL FINISHING STEPS
BENZOIN EXTRACT COMPOUND
GENERAL FINISHING STEPS
BENZOIN EXTRACT COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN TINCTURE
GENERAL FINISHING STEPS
BENZOIN TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZOIN TINCTURE,COMPOUND
GENERAL FINISHING STEPS
BENZOIN TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BITTER ORANGE PEEL EXTRACT
GENERAL FINISHING STEPS
BITTER ORANGE PEEL EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BUCHU DRY EXTRACT
GENERAL FINISHING STEPS
BUCHU LIQUID EXTRACT
GENERAL FINISHING STEPS
BUCHU LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAMPHORATED OPIUM TINCTURE
GENERAL FINISHING STEPS

CAMPHORATED OPIUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN 12.6%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 2.0%, REFINED AND STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED
GENERAL FINISHING STEPS
CAPSICUM OLEORESIN 8.4%, REFINED AND STANDARDISED
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAPSICUM TINCTURE
GENERAL FINISHING STEPS
CAPSICUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CARDAMOM TINCTURE,COMPOUND
GENERAL FINISHING STEPS
CARDAMOM TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CINCHONA EXTRACT
GENERAL FINISHING STEPS
CINCHONA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COCILLANA EXTRACT
GENERAL FINISHING STEPS
COCILLANA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COCILLANA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COCILLANA LIQUID EXTRACT
GENERAL FINISHING STEPS
COMFREY LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COMFREY LIQUID EXTRACT
GENERAL FINISHING STEPS
COMPOUND RHUBARB TINCTURE
GENERAL FINISHING STEPS
COMPOUND RHUBARB TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CONCENTRATED PEPPERMINT WATER
GENERAL FINISHING STEPS
CONCENTRATED PEPPERMINT WATER
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EUPHORBIA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

EUPHORBIA EXTRACT
GENERAL FINISHING STEPS
EUPHORBIA LIQUID EXTRACT
GENERAL FINISHING STEPS
EUPHORBIA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GENTIAN EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GENTIAN EXTRACT
GENERAL FINISHING STEPS
GENTIAN TINCTURE,COMPOUND
GENERAL FINISHING STEPS
GENTIAN TINCTURE,COMPOUND
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GINGER EXTRACT
GENERAL FINISHING STEPS
GINGER EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GINGER TINCTURE,STRONG
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GINGER TINCTURE,STRONG
GENERAL FINISHING STEPS
HEDERA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

HEDERA LIQUID EXTRACT
GENERAL FINISHING STEPS
ICHTHAMMOL
GENERAL FINISHING STEPS
IPECACUANHA EXTRACT
GENERAL FINISHING STEPS
IPECACUANHA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

IPECACUANHA LIQUID EXTRACT
GENERAL FINISHING STEPS
IPECACUANHA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

IPECACUANHA TINCTURE
GENERAL FINISHING STEPS

IPECACUANHA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

KRAMERIA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

KRAMERIA TINCTURE
GENERAL FINISHING STEPS
LAVENDER EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

LAVENDER EXTRACT
GENERAL FINISHING STEPS
LETTUCE AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
LIQUID PARAFFIN
GENERAL FINISHING STEPS
LIQUORICE LIQUID EXTRACT
GENERAL FINISHING STEPS
MAGNESIUM SULFATE HEPTAHYDRATE
GENERAL FINISHING STEPS
MYRRH TINCTURE
GENERAL FINISHING STEPS
MYRRH TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ORANGE TINCTURE
GENERAL FINISHING STEPS
ORANGE TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PASSIFLORA INCARNATA AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
PELARGONIUM SIDOIDES AQUEOUS EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PELARGONIUM SIDOIDES AQUEOUS EXTRACT
GENERAL FINISHING STEPS
PEPPERMINT OIL
GENERAL FINISHING STEPS
PERU BALSAM
GENERAL FINISHING STEPS
POTASSIUM CHLORIDE
GENERAL FINISHING STEPS
QUASSIA LIQUID EXTRACT
GENERAL FINISHING STEPS
QUASSIA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

RHUBARB EXTRACT
GENERAL FINISHING STEPS
RHUBARB EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SALICYLIC ACID
GENERAL FINISHING STEPS

SENEGA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SENEGA EXTRACT
GENERAL FINISHING STEPS
SENEGA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SENEGA LIQUID EXTRACT
GENERAL FINISHING STEPS
SENEGA ROOT CONCENTRATED INFUSION
GENERAL FINISHING STEPS
SENEGA ROOT CONCENTRATED INFUSION
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SENEGA TINCTURE
GENERAL FINISHING STEPS
SENEGA TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SLIPPERY ELM BARK EXTRACT
GENERAL FINISHING STEPS
SLIPPERY ELM BARK EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SODIUM BICARBONATE
GENERAL FINISHING STEPS
SQUILL ALCOHOLIC SOFT EXTRACT
GENERAL FINISHING STEPS
SQUILL ALCOHOLIC SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL AQUEOUS SOFT EXTRACT
GENERAL FINISHING STEPS
SQUILL AQUEOUS SOFT EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL ELIXIR
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL ELIXIR
GENERAL FINISHING STEPS
SQUILL LIQUID EXTRACT
GENERAL FINISHING STEPS
SQUILL LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL OXYMEL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL OXYMEL
GENERAL FINISHING STEPS
SQUILL TINCTURE
GENERAL FINISHING STEPS
SQUILL TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SQUILL VINEGAR
GENERAL FINISHING STEPS
SQUILL VINEGAR
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

STRONG AMMONIUM ACETATE SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

STRONG AMMONIUM ACETATE SOLUTION
GENERAL FINISHING STEPS
UVA URSI AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
VALERIAN AQUEOUS POWDERED EXTRACT
GENERAL FINISHING STEPS
VALERIAN EXTRACT
GENERAL FINISHING STEPS
VALERIAN TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

VALERIAN TINCTURE
GENERAL FINISHING STEPS

Medicines & Healthcare products Regulatory Agency

MHRA

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

Written Confirmation number:

17092

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

RECKITT BENCKISER HEALTHCARE (UK) LIMITED

DANSOM LANE
HULL
HU8 7DS

2. Manufacturer's licence number(s):

API 63

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

The Issuing Regulatory Authority Hereby Confirms That:

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

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

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

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

12/09/2017

This written confirmation remains valid until:

12/09/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ACETYLSALICYLIC ACID
GENERAL FINISHING STEPS
AMBROXOL HYDROCHLORIDE
GENERAL FINISHING STEPS
ANHYDROUS LANOLIN
GENERAL FINISHING STEPS
ASCORBIC ACID
GENERAL FINISHING STEPS
ASCORBIC ACID
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BENZALKONIUM CHLORIDE
GENERAL FINISHING STEPS
BENZYL ALCOHOL
GENERAL FINISHING STEPS
CAFFEINE ANHYDROUS
GENERAL FINISHING STEPS
CALCIUM CARBONATE
GENERAL FINISHING STEPS
CHLOROXYLENOL
GENERAL FINISHING STEPS
CODEINE PHOSPHATE
GENERAL FINISHING STEPS
DILL SEED OIL TERPENELESS
GENERAL FINISHING STEPS
DIPHENHYDRAMINE
GENERAL FINISHING STEPS
DISODIUM EDETATE
GENERAL FINISHING STEPS
GLYCEROL
GENERAL FINISHING STEPS
GLYCEROL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

HYDROCORTISONE ACETATE
GENERAL FINISHING STEPS
LEMON OIL-TERPENELESS
GENERAL FINISHING STEPS
LIDOCAINE HYDROCHLORIDE
GENERAL FINISHING STEPS
LIGHT LIQUID PARAFFIN
GENERAL FINISHING STEPS
MAGNESIUM ALGINATE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

MAGNESIUM ALGINATE
GENERAL FINISHING STEPS
NALOXONE HYDROCHLORIDE

GENERAL FINISHING STEPS

POTASSIUM BICARBONATE

GENERAL FINISHING STEPS

POTASSIUM BICARBONATE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PSEUDOEPHEDRINE HYDROCHLORIDE

GENERAL FINISHING STEPS

SODIUM ALGINATE

GENERAL FINISHING STEPS

SODIUM ALGINATE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SODIUM BICARBONATE

GENERAL FINISHING STEPS

UREA

GENERAL FINISHING STEPS

WHITE SOFT PARAFFIN

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):

29/10/2019

This written confirmation remains valid until:

29/10/2022

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

06/12/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ANISE OIL
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ANISE OIL
GENERAL FINISHING STEPS
ARCTIUM LAPPA ROOT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ARCTIUM LAPPA ROOT
GENERAL FINISHING STEPS
AVENA SATIVA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

AVENA SATIVA
GENERAL FINISHING STEPS
BAPTISIA TINCTORIA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

BAPTISIA TINCTORIA
GENERAL FINISHING STEPS
BOSWELLIA SERRATA EXTRACT
GENERAL FINISHING STEPS
BOSWELLIA SERRATA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CAMPHORATED OPIUM TINCTURE
GENERAL FINISHING STEPS
CAMPHORATED OPIUM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CARAPICHEA IPECACUANHA ROOT
GENERAL FINISHING STEPS
CARAPICHEA IPECACUANHA ROOT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CHLOROFORM AND MORPHINE TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

CHLOROFORM AND MORPHINE TINCTURE
GENERAL FINISHING STEPS
CIMICIFUGA RACEMOSA
GENERAL FINISHING STEPS
CIMICIFUGA RACEMOSA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COAL TAR SOLUTION
GENERAL FINISHING STEPS
COAL TAR SOLUTION

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

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

COCILLANA EXTRACT
GENERAL FINISHING STEPS
COCILLANA EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COCILLANA LIQUID EXTRACT
GENERAL FINISHING STEPS
COCILLANA LIQUID EXTRACT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COMMIPHORA MYRRHA RESIN
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

COMMIPHORA MYRRHA RESIN
GENERAL FINISHING STEPS
DRIMIA INDICA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

DRIMIA INDICA
GENERAL FINISHING STEPS
ECHINACEA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

ECHINACEA
GENERAL FINISHING STEPS
FUCUS VESICULOSUS
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

FUCUS VESICULOSUS
GENERAL FINISHING STEPS
FUMARIA OFFICINALIS HERB
GENERAL FINISHING STEPS
FUMARIA OFFICINALIS HERB
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GLYCYRRHIZA GLABRA ROOT
GENERAL FINISHING STEPS
GLYCYRRHIZA GLABRA ROOT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

GUAREA RUSBYI
GENERAL FINISHING STEPS
GUAREA RUSBYI
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

HYPERICUM PERFORATUM
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

HYPERICUM PERFORATUM

GENERAL FINISHING STEPS

HYSSOPUS OFFICINALIS HERB

GENERAL FINISHING STEPS

HYSSOPUS OFFICINALIS HERB

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

INULA HELENIUM ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

INULA HELENIUM ROOT

GENERAL FINISHING STEPS

LOBELIA INFLATA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

LOBELIA INFLATA

GENERAL FINISHING STEPS

MARRUBIUM VULGARE HERB

GENERAL FINISHING STEPS

MARRUBIUM VULGARE HERB

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

MATRICARIA CHAMOMILLA FLOWERS

GENERAL FINISHING STEPS

MATRICARIA CHAMOMILLA FLOWERS

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

GENERAL FINISHING STEPS

MELISSA OFFICINALIS QUANTIFIED DRY EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

OPIUM TINCTURE

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

OPIUM TINCTURE

GENERAL FINISHING STEPS

PAEONIA LACTIFLORA UNPEELED ROOT

GENERAL FINISHING STEPS

PAEONIA LACTIFLORA UNPEELED ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PASSIFLORA INCARNATA

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PASSIFLORA INCARNATA

GENERAL FINISHING STEPS

POLYGALA SENEGA ROOT

GENERAL FINISHING STEPS

POLYGALA SENEGA ROOT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PREPARED COAL TAR

GENERAL FINISHING STEPS

PREPARED COAL TAR

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

RHEUM PALMATUM
GENERAL FINISHING STEPS
RHEUM PALMATUM
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

SCUTELLARIA LATERIFLORA
GENERAL FINISHING STEPS
SCUTELLARIA LATERIFLORA
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

THYMUS SERPYLLUM HERB
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

THYMUS SERPYLLUM HERB
GENERAL FINISHING STEPS
TOLU BALSAM SOLUTION
GENERAL FINISHING STEPS
TOLU BALSAM SOLUTION
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

TOLU BALSAM SYRUP
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

TOLU BALSAM SYRUP
GENERAL FINISHING STEPS
TOLU BALSAM TINCTURE
GENERAL FINISHING STEPS
TOLU BALSAM TINCTURE
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

TOLU FLAVOUR
GENERAL FINISHING STEPS
TOLU-FLAVOUR SOLUTION
GENERAL FINISHING STEPS
VALERIANA OFFICINALIS ROOT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

VALERIANA OFFICINALIS ROOT
GENERAL FINISHING STEPS
VERBENA OFFICINALIS HERB
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

VERBENA OFFICINALIS HERB
GENERAL FINISHING STEPS
VITEX AGNUS-CASTUS FRUIT
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

VITEX AGNUS-CASTUS FRUIT
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:

119738

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

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):

28/09/2017

This written confirmation remains valid until:

28/09/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

ACTIVE SUBSTANCES FOR CLINICAL TRIALS
GENERAL FINISHING STEPS
ACTIVE SUBSTANCES FOR CLINICAL TRIALS
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):

28/02/2019

This written confirmation remains valid until:

28/02/2022

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

17/09/2019

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

POTASSIUM CLAVULANATE DILUTED
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):

08/04/2019

This written confirmation remains valid until:

08/04/2022

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

23/05/2019

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
POTASSIUM CLAVULANATE
MANUFACTURE OF STERILE ACTIVE SUBSTANCE

POTASSIUM CLAVULANATE
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):

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):

27/02/2018

This written confirmation remains valid until:

27/02/2021

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

BURDOCK ROOT LIQUID EXTRACT 1:1
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

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

HYSSOP LIQUID EXTRACT 1:1
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:

9727

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

SPECIALITY 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):

21/11/2019

This written confirmation remains valid until:

21/11/2022

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

02/01/2020

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
CALCIUM CARBONATE
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):

22/10/2019

This written confirmation remains valid until:

22/10/2022

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

23/10/2019

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
ACRIVASTINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

AZIMILIDE DIHYDROCHLORIDE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

AZIMILIDE DIHYDROCHLORIDE
GENERAL FINISHING STEPS
BUPRENORPHINE
GENERAL FINISHING STEPS
BUPRENORPHINE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CANNABIDIOL
GENERAL FINISHING STEPS
CANNABIDIOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CERIUM NITRATE
GENERAL FINISHING STEPS
CERIUM NITRATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

CODEINE PHOSPHATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

DIMETHYL FUMARATE
GENERAL FINISHING STEPS
FERRIC MALTOL
GENERAL FINISHING STEPS
FERRIC MALTOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

IBUPROFEN LYSINATE
GENERAL FINISHING STEPS
IBUPROFEN LYSINATE

MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

ILOPERIDONE
GENERAL FINISHING STEPS
ILOPERIDONE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

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

METHOXYFLURANE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

POLIDOCANOL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

POLIDOCANOL
GENERAL FINISHING STEPS
REBOXETINE METHANESULPHONATE
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

REBOXETINE METHANESULPHONATE
GENERAL FINISHING STEPS
SESTAMIBI
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SESTAMIBI
GENERAL FINISHING STEPS
TAZEMETOSTAT
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

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

ZILEUTON
GENERAL FINISHING STEPS
ZILEUTON
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):

20/09/2019

This written confirmation remains valid until:

20/09/2022

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

30/09/2019

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

SODIUM BICARBONATE
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:

14497

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

THORNTON & ROSS LIMITED

MANCHESTER ROAD
LINTHWAITE
HUDDERSFIELD
HD7 5QH

2. Manufacturer's licence number(s):

API 240

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):

16/11/2017

This written confirmation remains valid until:

16/11/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

DIETHYLAMINE SALICYLATE SOLUTION
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

MAGNESIUM HYDROXIDE PASTE CONCENTRATED
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:

14497

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

THORNTON & ROSS LIMITED

MANCHESTER ROAD
LINTHWAITE
HUDDERSFIELD
HD7 5QH

2. Manufacturer's licence number(s):

API 12965

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):

16/11/2017

This written confirmation remains valid until:

16/11/2020

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

11/03/2019

Annex 1:

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

Active substance(s):
Activity(ies):

SQUILL OXYMEL
MANUFACTURE OF ACTIVE SUBSTANCE BY CHEMICAL SYNTHESIS

SQUILL OXYMEL
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):

01/11/2017

This written confirmation remains valid until:

01/11/2020

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

11/03/2019

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):

27/02/2018

This written confirmation remains valid until:

27/02/2021

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

11/03/2019

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

BLUE FLAG DRY EXTRACT 3:1 CONCENTRATE
GENERAL FINISHING STEPS
BONESET LIQUID EXTRACT 1:1
PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

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

BURDOCK ROOT LIQUID EXTRACT 1:1
GENERAL FINISHING STEPS
BURDOCK ROOT LIQUID EXTRACT 1:1
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ECHINACEA ANGUSTIFOLIA
GENERAL FINISHING STEPS
ECHINACEA ANGUSTIFOLIA
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HOREHOUND EXTRACT
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HYSSOP LIQUID EXTRACT 1:1
GENERAL FINISHING STEPS
HYSSOP LIQUID EXTRACT 1:1

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PASSION FLOWER DRY EXTRACT 5:1

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

PASSION FLOWER DRY EXTRACT 5:1

GENERAL FINISHING STEPS

VERVAIN EXTRACT

PROCESSING ACTIVITIES OF ACTIVE SUBSTANCE FROM NATURAL SOURCES

VERVAIN EXTRACT

GENERAL FINISHING STEPS
