Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 22775 Insp GMP/IMP 22775/35426248-0001

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Regulation 331A of The Human Medicines Regulation 2012 (SI 2012/1916)

The competent authority of the United Kingdom confirms the following:

The manufacturer	ASSOCIATES OF CAPE COD INTERNATIONAL INCORPORATED
Site address	UNIT 1 F/G/H ACADEMY BUSINESS PARK LEES ROAD KNOWSLEY INDUSTRIAL PARK LIVERPOOL L33 7SA UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with for human medicines Regulation 327 of 'The Human Medicines Regulations 2012 (SI 2012/1916)'; for veterinary medicines Regulation 5 of 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21/11/2023, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Regulation B17 of the Human Medicines Regulations 2012 (as amended).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

This certificate is only valid when presented with all pages and both parts 1 and 2.

The authenticity of this certificate may be verified in MHRA-GMDP database. If it does not appear please contact the issuing authority.

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 22775 Insp GMP/IMP 22775/35426248-0001

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

1.6.2 Microbiological: non-sterility

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.2 Microbiological: non-sterility

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 22775 Insp GMP/IMP 22775/35426248-0001

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Christine E. Gray
Head of Compliance Team 2 (GMP and GDP)
inspectionplanning@mhra.gov.uk

Date: 16/01/2024

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 22775 Insp GMP/IMP 22775/35426248-0001

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Regulation 5 of the current Veterinary Medicines Regulations

The competent authority of the United Kingdom confirms the following:

The manufacturer	ASSOCIATES OF CAPE COD INTERNATIONAL INCORPORATED
Site address	UNIT 1 F/G/H ACADEMY BUSINESS PARK LEES ROAD KNOWSLEY INDUSTRIAL PARK LIVERPOOL L33 7SA UNITED KINGDOM

Has been inspected in connection with Manufacturing and/or Marketing Authorisation(s) listing the company as a site of QC testing, in accordance with for human medicines Regulation 327 of 'The Human Medicines Regulations 2012 (SI 2012/1916)'; for veterinary medicines Regulation 5 of 'The current Veterinary Medicines Regulations'; for investigational medicinal products 'The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031)'.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 21/11/2023, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Regulation 5 of the current Veterinary Medicines Regulations.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field.

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Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 22775 Insp GMP/IMP 22775/35426248-0001

Part 2

Veterinary Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

Not Authorised

1.3 Biological medicinal products

Not Authorised

1.4 Other products or manufacturing activity

Not Authorised

1.5 Packaging

Not Authorised

1.6 Quality control testing

1.6.2 Microbiological: non-sterility

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.2 Microbiological: non-sterility

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

3. MANUFACTURING OPERATIONS

3.1 Manufacture of Active Substance by Chemical Synthesis
Not Authorised

3.2 Processing Activities of Active Substance from Natural Sources
Not Authorised

3.3 Manufacture of Active Substance using Biological Processes
Not Authorised

3.4 Manufacture of sterile active substance
Not Authorised

3.5 General Finishing Steps
Not Authorised

3.6 Quality Control Testing
Not Authorised

4 Other Activities
Not Authorised

Medicines & Healthcare products Regulatory Agency

MHRA

Certificate No: UK GMP 22775 Insp GMP/IMP 22775/35426248-0001

Any restrictions or clarifying remarks related to the scope of this certificate:

N/A

1. Building(s)/Area(s)

   N/A

2. Room(s)

   N/A

3. Line(s) Equipment(s)

   N/A

4. QC testing

   N/A

5. Medicinal Product(s)/IMP(s)

   N/A

Name of the authorised person of the Competent Authority of the United Kingdom

Christine E. Gray
Head of Compliance Team 2 (GMP and GDP)
inspectionplanning@mhra.gov.uk

Date: 16/01/2024