MHRA
Regulating Medicines and Medical Devices

MHRA
151 Buckingham Palace Road
London SW1W 9SZ
United Kingdom

mhra.gov.uk

RESTRICTED – COMMERCIAL
Mr Mark Hitchen
AIR PRODUCTS PLC
SHARP STREET
WALKDEN
WORSLEY
MANCHESTER
M28 5WA
UNITED KINGDOM

Certificate No: UK MIA 6183 Insp GMP/GDP 6183/17005-0007

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Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	AIR PRODUCTS PLC
Site address	SHARP STREET WALKDEN WORSLEY MANCHESTER M28 5WA UNITED KINGDOM

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. MIA 6183 in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 27/08/2014, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

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 EudraGMDP. If it does not appear please contact the issuing authority.

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Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

1.1 Sterile products

Not Authorised

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)

1.2.1.7 Medicinal gases

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

1.6.3 Chemical/physical

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

Not Authorised

2.2 Batch certification of imported medicinal products

Not Authorised

2.3 Other importation activities

Not Authorised

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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

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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

Graeme McKilligan
GMP Inspector
graeme.mckilligan@mhra.gsi.gov.uk

Date: 06/10/2014

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Mr Mark Hitchen
AIR PRODUCTS PLC
SHARP STREET
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Certificate No: UK WDA(H) 6183 Insp GMP/GDP 6183/17005-0007

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CERTIFICATE OF GDP COMPLIANCE OF A WHOLESALE DISTRIBUTOR

Issued following an inspection in accordance with Article 111 of Directive 2001/83/EC as amended.

The competent Authority of the United Kingdom confirms the following:

The Wholesale Distributor: AIR PRODUCTS PLC

Site Address in the United Kingdom:

SHARP STREET
WALKDEN
WORSLEY
MANCHESTER
M28 5WA
UNITED KINGDOM

Has been inspected under the national inspection programme in connection with the authorisation required in accordance with Article 77 (1) of Directive 2001/83/EC transposed in the following national legislation: The Human Medicines Regulations 2012 (SI 2012/1916).

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 27/08/2014, it is considered that it complies with the principles of good distribution practice requirements referred to in Article 84 of Directive 2001/83/EC as amended.

This certificate reflects the status of the inspected site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than five years have elapsed since the date of inspection. However this period of validity may be reduced 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.

The authenticity of this certificate may be verified in the EUDRAGMDP database.

The authorisation of this wholesale distributor may be verified with the issuing authority.

Medicines and Healthcare
Products Regulatory Agency

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Regulating Medicines and Medical Devices

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

N/A

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

Graeme McKilligan
GDP Inspector
graeme.mckilligan@mhra.gsi.gov.uk

Date: 06/10/2014