



Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with Art. 80(5) of Directive 2001/82/EC.

The competent authority of the United Kingdom confirms the following:

The manufacturer	HOLOGIC LIMITED T/A TEPNEL PHARMA SERVICES
Site address	APPLETON PLACE APPLETON PARKWAY LIVINGSTON EH54 7EZ 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 Art. 111(1) of Directive 2001/83/EC (or Article 80(1) of Directive 2001/82/EC) transposed in the following national legislation: For human medicines 'The Medicines Act 1968 as amended'; for veterinary medicines '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 28/02/2017, it is considered that it complies with the principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.

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.





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

1.6.1 Microbiological: sterility

1.6.2 Microbiological: non-sterility

1.6.3 Chemical/physical

1.6.4 Biological

2. IMPORTATION OF MEDICINAL PRODUCTS

2.1 Quality control testing of imported medicinal products

2.1.1 Microbiological: sterility

2.1.2 Microbiological: non-sterility

2.1.3 Chemical/physical

2.1.4 Biological

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





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**

Lesley Graham
GMP Inspector
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Date: 04/05/2017

