

Medicines and Healthcare products Regulatory Agency

CERTIFICATE NUMBER : UK GMP 25075 Insp GMP/IMP 25075/1992550-0008 [H]

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER(1),(2)

Part 1

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

The competent authority of United Kingdom confirms the following :

The Manufacturer : SOURCE BIOSCIENCE LIMITED

Site address : SOURCE BIOSCIENCE LIMITED, 55 STIRLING ENTERPRISE PARK, STIRLING, FK7 7RP, UNITED KINGDOM

Other :

Is a contract laboratory that has been inspected in accordance with the Medicines Act as amended

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 13/04/2016, 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 valid only when presented with all pages and both Parts 1 and 2. The authenticity of this certificate may be verified in MHRA-GMDP. If it does not appear, please contact the issuing authority.

- (1) *Guidance on the interpretation of this template can be found in the Help menu of MHRA-GMDP database.*
- (2) *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1. MANUFACTURING OPERATIONS

[1.6] Quality control testing

[1.6.1] Microbiological: sterility

[1.6.2] Microbiological: non-sterility

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

Restrictions or Remarks

This certificate cannot be used to support new manufacturing authorisations or marketing authorisations or variations to add the site to manufacturing authorisations or marketing authorisations.

21/11/2016 Name and signature of the authorised person of the Competent Authority of United Kingdom
Confidential
Medicines and Healthcare products Regulatory Agency
Tel : Confidential