



Certificate No: UK GMP 29716 Insp GMP/IMP 29716/388368-0008

## 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 | GEN-PROBE LIFE SCIENCES                                                                        |
| Site address     | APPLETON PLACE<br>APPLETON PARKWAY<br>LIVINGSTON<br>WEST LOTHIAN<br>EH54 7EZ<br>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 11/11/2009, 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, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.



## Part 2

Human Medicinal Products

**1. MANUFACTURING OPERATIONS****1.1 Sterile products**

|         |                                                     |                |
|---------|-----------------------------------------------------|----------------|
| 1.1.1   | <i>Aseptically prepared (list of dosage forms)</i>  |                |
| 1.1.1.1 | Large volume liquids                                | Not Authorised |
| 1.1.1.2 | Lyophilisates                                       | Not Authorised |
| 1.1.1.3 | Semi-solids                                         | Not Authorised |
| 1.1.1.4 | Small volume liquids                                | Not Authorised |
| 1.1.1.5 | Solids and implants                                 | Not Authorised |
| 1.1.1.6 | Other aseptically prepared products                 | Not Authorised |
|         | <i>Not Authorised</i>                               |                |
| 1.1.2   | <i>Terminally sterilised (list of dosage forms)</i> |                |
| 1.1.2.1 | Large volume liquids                                | Not Authorised |
| 1.1.2.2 | Semi-solids                                         | Not Authorised |
| 1.1.2.3 | Small volume liquids                                | Not Authorised |
| 1.1.2.4 | Solids and implants                                 | Not Authorised |
| 1.1.2.5 | Other terminally sterilised prepared products       | Not Authorised |
|         | <i>Not Authorised</i>                               |                |
| 1.1.3   | Batch certification only                            | Not Authorised |





| 1.2 Non-sterile products          |                                                       |
|-----------------------------------|-------------------------------------------------------|
| 1.2.1                             | <i>Non-sterile products (list of dosage forms)</i>    |
| 1.2.1.1                           | Capsules, hard shell<br>Not Authorised                |
| 1.2.1.2                           | Capsules, soft shell<br>Not Authorised                |
| 1.2.1.3                           | Chewing gums<br>Not Authorised                        |
| 1.2.1.4                           | Impregnated matrices<br>Not Authorised                |
| 1.2.1.5                           | Liquids for external use<br>Not Authorised            |
| 1.2.1.6                           | Liquids for internal use<br>Not Authorised            |
| 1.2.1.7                           | Medicinal gases<br>Not Authorised                     |
| 1.2.1.8                           | Other solid dosage forms<br>Not Authorised            |
| 1.2.1.9                           | Pressurised preparations<br>Not Authorised            |
| 1.2.1.10                          | Radionuclide generators<br>Not Authorised             |
| 1.2.1.11                          | Semi-solids<br>Not Authorised                         |
| 1.2.1.12                          | Suppositories<br>Not Authorised                       |
| 1.2.1.13                          | Tablets<br>Not Authorised                             |
| 1.2.1.14                          | Transdermal patches<br>Not Authorised                 |
| 1.2.1.15                          | Intraruminal devices<br>Not Authorised                |
| 1.2.1.16                          | Veterinary premixes<br>Not Authorised                 |
| 1.2.1.17                          | Other non-sterile medicinal product<br>Not Authorised |
| 1.2.2                             | <i>Batch certification only</i><br>Not Authorised     |
| 1.3 Biological medicinal products |                                                       |
| 1.3.1                             | <i>Biological medicinal products</i>                  |
| 1.3.1.1                           | Blood products<br>Not Authorised                      |
| 1.3.1.2                           | Immunological products<br>Not Authorised              |
| 1.3.1.3                           | Cell therapy products<br>Not Authorised               |
| 1.3.1.4                           | Gene therapy products<br>Not Authorised               |
| 1.3.1.5                           | Biotechnology products<br>Not Authorised              |
| 1.3.1.6                           | Human or animal extracted products<br>Not Authorised  |
| 1.3.1.7                           | Other biological medicinal products<br>Not Authorised |





|     |                                                 |                                                                        |                |
|-----|-------------------------------------------------|------------------------------------------------------------------------|----------------|
|     | 1.3.2                                           | <i>Batch certification only (list of product types)</i>                |                |
|     |                                                 | 1.3.2.1 Blood products                                                 | Not Authorised |
|     |                                                 | 1.3.2.2 Immunological products                                         | Not Authorised |
|     |                                                 | 1.3.2.3 Cell therapy products                                          | Not Authorised |
|     |                                                 | 1.3.2.4 Gene therapy products                                          | Not Authorised |
|     |                                                 | 1.3.2.5 Biotechnology products                                         | Not Authorised |
|     |                                                 | 1.3.2.6 Human or animal extracted products                             | Not Authorised |
|     |                                                 | 1.3.2.7 Other biological medicinal products                            | Not Authorised |
|     |                                                 | <i>Not Authorised</i>                                                  |                |
| 1.4 | <b>Other products or manufacturing activity</b> |                                                                        |                |
|     | 1.4.1                                           | <i>Manufacture of:</i>                                                 |                |
|     |                                                 | 1.4.1.1 Herbal products                                                | Not Authorised |
|     |                                                 | 1.4.1.2 Homoeopathic products                                          | Not Authorised |
|     |                                                 | 1.4.1.3 Biological active starting materials                           | Not Authorised |
|     |                                                 | 1.4.1.4 Other                                                          | Not Authorised |
|     |                                                 | <i>Not Authorised</i>                                                  |                |
|     | 1.4.2                                           | <i>Sterilisation of active substances/excipients/finished product:</i> |                |
|     |                                                 | 1.4.2.1 Filtration                                                     | Not Authorised |
|     |                                                 | 1.4.2.2 Dry heat                                                       | Not Authorised |
|     |                                                 | 1.4.2.3 Moist heat                                                     | Not Authorised |
|     |                                                 | 1.4.2.4 Chemical                                                       | Not Authorised |
|     |                                                 | 1.4.2.5 Gamma irradiation                                              | Not Authorised |
|     |                                                 | 1.4.2.6 Electron beam                                                  | Not Authorised |
|     | 1.4.3                                           | Other                                                                  | Not Authorised |
|     |                                                 | <i>Not Authorised</i>                                                  |                |





| 1.5 |          | Packaging only                       |                |
|-----|----------|--------------------------------------|----------------|
|     | 1.5.1    | <i>Primary packaging</i>             |                |
|     | 1.5.1.1  | Capsules, hard shell                 | Not Authorised |
|     | 1.5.1.2  | Capsules, soft shell                 | Not Authorised |
|     | 1.5.1.3  | Chewing gums                         | Not Authorised |
|     | 1.5.1.4  | Impregnated matrices                 | Not Authorised |
|     | 1.5.1.5  | Liquids for external use             | Not Authorised |
|     | 1.5.1.6  | Liquids for internal use             | Not Authorised |
|     | 1.5.1.7  | Medicinal gases                      | Not Authorised |
|     | 1.5.1.8  | Other solid dosage forms             | Not Authorised |
|     | 1.5.1.9  | Pressurised preparations             | Not Authorised |
|     | 1.5.1.10 | Radionuclide generators              | Not Authorised |
|     | 1.5.1.11 | Semi-solids                          | Not Authorised |
|     | 1.5.1.12 | Suppositories                        | Not Authorised |
|     | 1.5.1.13 | Tablets                              | Not Authorised |
|     | 1.5.1.14 | Transdermal patches                  | Not Authorised |
|     | 1.5.1.15 | Intraruminal devices                 | Not Authorised |
|     | 1.5.1.16 | Veterinary premixes                  | Not Authorised |
|     | 1.5.1.17 | Other non-sterile medicinal products | Not Authorised |
|     |          | <i>Not Authorised</i>                |                |
|     | 1.5.2    | Secondary packaging                  | Not Authorised |
| 1.6 |          | Quality control testing              |                |
|     | 1.6.1    | Microbiological: sterility           | Authorised     |
|     | 1.6.2    | Microbiological: non-sterility       | Authorised     |
|     | 1.6.3    | Chemical/Physical                    | Authorised     |
|     | 1.6.4    | Biological                           | Not Authorised |



| 2. IMPORTATION OF MEDICINAL PRODUCTS |                                                               |                |
|--------------------------------------|---------------------------------------------------------------|----------------|
| <b>2.1</b>                           | <b>Quality control testing of imported medicinal products</b> |                |
| 2.1.1                                | Microbiological: sterility                                    | Authorised     |
| 2.1.2                                | Microbiological: non-sterility                                | Authorised     |
| 2.1.3                                | Chemical/Physical                                             | Authorised     |
| 2.1.4                                | Biological                                                    | Not Authorised |
| <b>2.2</b>                           | <b>Batch certification of imported medicinal products</b>     |                |
| 2.2.1                                | <i>Sterile Products</i>                                       |                |
|                                      | 2.2.1.1 Aseptically prepared                                  | Not Authorised |
|                                      | 2.2.1.2 Terminally sterilised                                 | Not Authorised |
| 2.2.2                                | Non-sterile Products                                          | Not Authorised |
| 2.2.3                                | <i>Biological medicinal products</i>                          |                |
|                                      | 2.2.3.1 Blood products                                        | Not Authorised |
|                                      | 2.2.3.2 Immunological product                                 | Not Authorised |
|                                      | 2.2.3.3 Cell therapy products                                 | Not Authorised |
|                                      | 2.2.3.4 Gene therapy products                                 | Not Authorised |
|                                      | 2.2.3.5 Biotechnology products                                | Not Authorised |
|                                      | 2.2.3.6 Human or animal extracted products                    | Not Authorised |
|                                      | 2.2.3.7 Other biological medicinal products                   | Not Authorised |
|                                      | <i>Not Authorised</i>                                         |                |
| 2.2.4                                | <i>Other importation activities</i>                           |                |
|                                      | 2.2.4.1 Radiopharmaceuticals/Radionuclide generators          | Not Authorised |
|                                      | 2.2.4.2 Medicinal gases                                       | Not Authorised |
|                                      | 2.2.4.3 Herbal products                                       | Not Authorised |
|                                      | 2.2.4.4 Homoeopathic products                                 | Not Authorised |
|                                      | 2.2.4.5 Biological active starting materials                  | Not Authorised |
|                                      | 2.2.4.6 Other                                                 | Not Authorised |
|                                      | <i>Not Authorised</i>                                         |                |





**Manufacture of active substance. Names of substances subject to inspection:**

| ACTIVE NAME |
|-------------|
| N/A         |

| EXCIPIENT NAME |
|----------------|
| N/A            |



**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: 18/12/2009***

