

## 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	GAMMA-DYNACARE MEDICAL LABORATORIES
Site address	115 MIDAIR COURT BRAMPTON ONTARIO CANADA

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 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 13/09/2013, 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.



**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**

**1.6.4 Biological**

**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



**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:**

This site has only been inspected and authorised for the viral testing of plasma pools. Any additional GMP testing will require a full re-inspection.

1. Building(s)/Area(s)

N/A

2. Room(s)

N/A

3. Line(s) Equipment(s)

N/A

4. QC testing

This site has only been inspected and authorised for the viral testing of plasma pools. Any additional GMP testing will require a full re-inspection.

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

N/A

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

*Stephen Grayson*  
*GMP Inspector*  
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*Date: 15/01/2014*

